Healthcare: Reform or ration

April 2013

WITH SUPPORT FROM:

committee for economic development of australia

Australian Unity

Healthcare:
Reform or ration

April 2013

committee for economic development of australia

About this publication
Healthcare: Reform or ration

ISBN: 0 85801 286 3

Design: Robyn Zwar Graphic Design

Photography:
Chapter 1: A person holding a Medicare card in their hand, Fairfax Syndication/Peter Braig.
All other images: iStock Photo Library.

About CEDA
CEDA – the Committee for Economic Development of Australia – is a national, independent, member-based organisation providing thought leadership and policy perspectives on the economic and social issues affecting Australia.

We achieve this through a rigorous and evidence-based research agenda, and forums and events that deliver lively debate and critical perspectives.

CEDA's expanding membership includes more than 800 of Australia's leading businesses and organisations, and leaders from a wide cross-section of industries and academia. It allows us to reach major decision makers across the private and public sectors.

CEDA is an independent not-for-profit organisation, founded in 1960 by leading Australian economist Sir Douglas Copland. Our funding comes from membership fees, events and sponsorship.

CEDA – the Committee for Economic Development of Australia

Level 13, 440 Collins Street
Melbourne 3000 Australia
Telephone: +61 3 9662 3544
Fax: +61 3 9663 7271
Email: info@ceda.com.au
Web: ceda.com.au

committee for economic development of australia

Contents

Foreword 4

Executive summary 6

CEDA overview – Nathan Taylor 10

Chapter 1 19
Sustaining universal healthcare in Australia: Introducing dynamic efficiency
Professor Johannes Stoelwinder

Chapter 2 31
Healthcare reform in an ageing Australia
Dr Vince FitzGerald

Chapter 3 41
The price is wrong: Pharmaceutical expenditure in Australia over the last decade and options for reform
Professor Philip Clarke

Chapter 4 55
Ensuring Australia's comparative advantage in biotechnology
Dr Anna Lavelle

Chapter 5 67
Traversing the valley of death
Dr Julian Clark

Chapter 6 81
Why STEM skills are important for innovation
Professor Ian Chubb AC

Foreword

Australia's universal healthcare system won't be sustainable in its current form if the current rate of increasing utilisation, and therefore the cost to taxpayers, continues.

Spiralling healthcare costs have the potential to jeopardise our universal healthcare system and result in rationing of services, such as through longer waiting times for surgery. They will also be a significant burden on future generations and reduce government funding available for other key areas from education to infrastructure.

Meaningful reform is the only option and this policy perspective sets out key options for how that reform can be undertaken.

Recommendations in this report include introducing pre-funding for healthcare costs by quarantining three per cent of superannuation (either by increasing the current rate or using a portion of that already paid).

It also recommends hypothecating a portion of tax revenue directly to healthcare spending to improve transparency of the cost of healthcare and provide a cap on spending. This would mean that the community would get what it is willing to pay for and if additional spending was required there would be a direct link to the amount of tax collected and healthcare premiums paid.

It also provides recommendations for improving the pricing of generic drugs in Australia, potentially saving billions in healthcare spending by Government.

Finally, this policy perspective examines how to build on Australia's comparative advantage in the biomedicine industry. To grow this industry it is vital that there is significantly stronger recognition and funding support for commercialisation of new drugs through the National Health and Medical Research Council primary research funding.

In addition, there needs to be better engagement between science, technology, engineering and mathematics (STEM) students with industry through, for example, internships and improved industry engagement with degree accreditation schemes to ensure that courses reflect skill demand.

I would like to thank the CEDA Advisory Group that oversaw the development of this project and the six contributing authors. The calibre of these authors and their contributions is outstanding.

I would also like to particularly thank Australian Unity for embracing this research. Support such as this from our members makes it possible for CEDA to drive debate and discussion on significant issues such as those in this report.

Professor the Hon. Stephen Martin
Chief Executive
CEDA

committee for economic development of australia

Health is a foundation stone of the nation's wellbeing and prosperity. Good health drives workforce participation and productivity, in turn delivering financial resilience and quality of life. It frees people up for the social and civic engagement that is so critical to functioning communities. And it eases pressure on the healthcare system.

Australia's health system has much to commend it – indeed on some measures it has been world-leading. Over the last 30 years life expectancy has greatly increased and preventable deaths have reduced. But while more Australians are living longer, they are often living unwell. The rate of chronic disease is mounting, and fast. Overlay a demographic component – the ageing of the population as the Baby Boomer generation moves into retirement – and the pressure on the nation's health system inexorably builds.

Without significant reform in the medium term, the demand for health resources threatens to exceed supply, overwhelming the system, swamping state and federal budgets and reducing quality of life for all.

In this context, the time is ripe for a robust national discussion on healthcare. We can be doing more to make our health system work smarter. A key change, in my view, is to broaden the remit of healthcare from its traditional role of providing acute services to sick patients towards giving the public greater support to maintaining good health and managing illness effectively. In other words, patient-centred care.

Healthcare is such an important policy arena that it demands policy makers lift themselves above today's "strife of interests" and focus on reforms that will yield a sustainable sector, decades into the future.

CEDA's independent research and thought-leadership can play a crucial role in the public policy debate on healthcare, and Australian Unity is proud to support this contribution.

Rohan Mead
Group Managing Director, Australian Unity.

Australian Unity

Executive summary

Advances in medicine over the past 100 years have transformed human life expectancy and the management of illness. Here in Australia we enjoy one of the longest life expectancies in the world. This is largely due to the reasonably equitable and relatively efficient healthcare system the nation operates. Australia has also developed a comparative advantage in biotechnology that has resulted in it becoming one of the nation's largest export earning sectors.

However, Australia's healthcare funding arrangements can at best be described as suboptimal and current policy settings involve a level of rationing of access to medical service, typically through waiting lists for elective surgery or restricting access to medical treatments.

As medical technology advances, it becomes more desirable to intervene earlier and more intensively than in the past. This increases the level of utilisation of healthcare services at all ages. It is this increasing utilisation of medical services that will have a larger influence over the financial sustainability of the healthcare sector than the ageing of the population.

The combined impact of greater utilisation and an ageing and growing population means that the system must adapt and for that to happen, we need health reform that ensures every dollar spent will buy more and better quality health services.

In light of these escalating health pressures, it will be important to ensure that the health system provides value for money. This requires a health system that responds well to innovation, funding cost-effective improvements to healthcare while being able to adjust spending levels in areas where better value for money could be obtained.

Recommendations

The recommendations in this policy perspective represent a significant change to the way healthcare is funded. However, the reforms are necessary if Australia is to maintain universal access to the best possible healthcare in the future.

This policy perspective also puts forward important recommendations so that Australia can continue to take advantage of its comparative advantage in biotechnology and sustain it in the future.

Reforming the healthcare sector

To introduce dynamic efficiency into the healthcare sector and to reduce the level of intergenerational equity transfer, major reforms are needed to the way healthcare costs are funded and services delivered. Improvements to incentives could be achieved by:

- Aggregating all health funding at the level of the individual;
- Having financial risk reside with competing health funds through insurance arrangements, introducing managed competition, eliminating fragmented responsibility and cost shifting;
- Linking public healthcare budgets and community expectations of healthcare services to economic capacity to pay, via a fully hypothecated Medicare levy that funds healthcare expenditure; and
- Introducing pre-funding for healthcare costs by quarantining a portion of the Superannuation Guarantee rate, or increasing the Levy, so that approximately three per cent is set aside to cover healthcare costs.

Improving the Pharmaceutical Benefits Scheme pricing

Australia is currently paying substantially more for key generic drugs than comparable countries. These high costs account for a substantial portion of the Pharmaceutical Benefits Scheme's (PBS) financial impost. To improve the pricing of generic drugs the PBS should:

- Adopt a public consultation process in setting the next pricing agreement, due next year, that engages all stakeholders and not just those with a vested financial interest; and
- Explicitly attempt to capitalise on the expiry of pharmaceutical patents by adopting price cuts that reflect the price of manufacturing generic drugs. A tendering system similar to New Zealand or the Netherlands should be considered.

Enhancing our comparative advantage: Translating ideas into action

To improve the research culture and to allow greater interaction between academia and industry:

- The National Health and Medical Research Council (NHMRC) research funding criteria should be changed to acknowledge work on commercialisation.

To help develop commercialisation critical mass in our universities and research centres:

- The small and disaggregated commercialisation units should be integrated to achieve greater levels of commercialisation expertise.

To help traverse the innovation "valley of death" in biotechnology:

- A portion of the $780 million a year allocated through the NHMRC for primary research should explicitly support translation efforts. These funds should be allocated via a passive ownership model, such as a program that converts to equity if successful or to a grant if not.

To encourage greater mobility between academia and industry, and to improve the work ready skills of science, technology, engineering and mathematics (STEM) students, the Government should:

- Ensure that students starting STEM are engaged in collaborative efforts with industry, for example internships. The Australian CRC program could act as an environment to foster industry-relevant skills; and
- Industry should be engaged with degree accreditation schemes to ensure that the curricula reflects skill demands.

Contributions and acknowledgements

This report includes a series of contributions from a range of experts providing significant reform recommendations for the healthcare sector and on how Australia can capitalise on biotechnology developments to enhance our knowledge intensive and high value export sector.

In *Sustaining universal healthcare in Australia: Introducing dynamic efficiency*, Professor Johannes (Just) Stoelwinder describes how the financial unsustainability of Australia's healthcare system is a consequence of the growing utilisation of medical services, not just the ageing of the population. He argues that politicians are not well positioned to manage community expectations and achieve efficiency improvements on an ongoing basis. To address these problems, Professor Stoelwinder recommends a model that puts the patient at the centre of healthcare funding arrangements and creates incentives that can promote efficiency improvements.

In *Healthcare reform in an ageing Australia*, Dr Vince FitzGerald elaborates on the patient centred funding model, highlighting the importance of healthcare security in retirement and how healthcare costs are concentrated in old age. He describes how the reforms recommended by Professor Stoelwinder could be funded more equitably, between generations, and more sustainably, with a component of pre-funding (funds contributed and accumulating before retirement). This would reduce the burden on future taxpayers. This could be administered using the existing superannuation system. Dr FitzGerald notes that the proposals would create stronger incentives for innovation and productivity improvement and better balance the benefits and costs of healthcare choices.

In *The price is wrong: Pharmaceutical expenditure in Australia over the last decade and options for reform*, Professor Philip Clarke details how Australia has failed to capitalise on the expiry of many pharmaceutical patents. As a consequence, a substantial portion of the Pharmaceutical Benefits Scheme (PBS) is spent paying internationally high prices for generic drugs. Professor Clarke details how comparable countries have reduced the costs of generic drugs significantly.

In *Ensuring Australia's comparative advantage in biotechnology*, Dr Anna Lavelle describes how Australia's world class science and medical research, strong capacity for international partnerships, cost effectiveness and transparent and effective regulatory system, have contributed to the nation's comparative advantage in biotechnology. Dr Lavelle also outlines a series of actions that could enhance this comparative advantage.

The technological developments that are facilitating medical advances are also making it more challenging to take a potential drug from concept to commercial reality. In *Traversing the valley of death*, Dr Julian Clark elaborates on these technical difficulties, and the institutional and cultural challenges that make Australia's translation record particularly poor when compared internationally. Dr Clark also makes recommendations to facilitate more translation research.

In *Why STEM skills are important for innovation*, Professor Ian Chubb describes the trends in science, technology, engineering and mathematics education. Professor Chubb also outlines the challenges Australia will face in sustaining a competitive advantage in innovative industries based on current education trends.

CEDA wishes to acknowledge the input and expert advice from the Advisory Group in the development of this policy perspective. The CEDA Advisory Group consisted of:

- Professor David Penington AC, Professor Emeritus, Melbourne University; Chairman of Bionic Vision Australia; and former Chairman, Bio21 Australia;
- Dr Meera Verma, Proprietor at Headland Vision; and Non-Executive Director at Biosenssis and AusBiotech; and
- Ian Ferres, Chairman of the Australian Healthcare Investment Company; Director of Australian Unity; and a Consultant for Tresscox Lawyers.

These healthcare experts provided guidance at the start of the project and input on the final recommendations. However, the final report is entirely the responsibility of the individual authors.

CEDA overview: Reform or ration

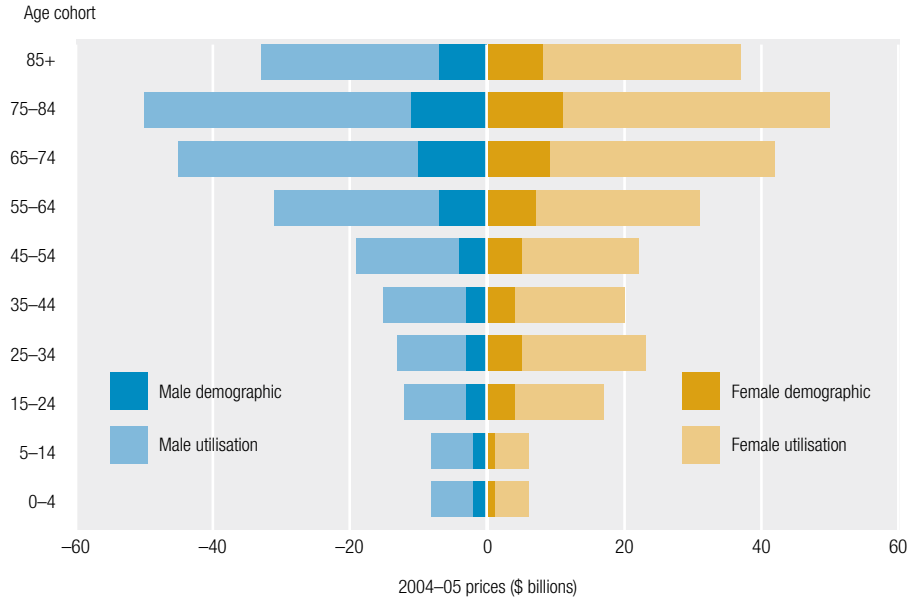
Nathan Taylor

CEDA Chief Economist

Australia's healthcare funding arrangements can at best be described as suboptimal. Universal healthcare access is funded by a number of sources, Commonwealth, state governments, and private contributions, and is focused on processes and institutions rather than patient outcomes. Not only is there a lack of clarity about financial responsibility for services, which encourages elaborate cost shifting behaviour between the tiers of government and service providers, the incentives of the funding arrangements are flawed. The result is poorer, and relatively more expensive, outcomes for patients and few incentives to achieve ongoing innovation in the healthcare sector.

Australia's Medical Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) are open ended commitments trying to achieve an appropriate trade-off between cost and benefits for services. The MBS pays doctors for medical services on the basis of open-ended, fee for service arrangements. This approach has many benefits, such as responsiveness to patient needs. However, a major disadvantage is that it is very difficult to manage expenditure and has been

FIGURE 1
HEALTHCARE EXPENDITURE IN 2050–51



Source: AIHW, Health system expenditure 2004-05 and Intergenerational Report 2012

described as "a blank cheque to providers, who can induce demand for their own services if they so wish".[1] This publication outlines how successive governments have failed to capitalise on potential cost savings in the PBS.[2]

Medical advances have the potential to drive efficiencies but only with the right incentive structures to encourage best clinical practice. Currently there is a tendency for medical advances to be additive rather than replacing obsolete practices. Coronary artery angioplasty represents a good example. This medical intervention is a much less invasive and less costly alternative to coronary artery bypass grafting (CABG). However, over the first years of its introduction the number of CABG procedures did not change, while angioplasties were able to be used in older patients who were not eligible for the CABG.[3] The result was an overall increase in healthcare expenditure and the continuation of a less efficient treatment. The model proposed in this publication would create incentives for the most efficacious treatment to be used.

The overall level of waste and adverse events has been estimated at between 20 and 30 per cent of healthcare expenditure in the United States.[4] While the figure is likely to be equivalently significant in Australia, the Strategic Review of Health and Medical Research in Australia (the McKeon Review) consultation paper states that the exact amount is not currently known. The McKeon Review recommended establishing integrated health research centres to facilitate best-practice translation of research directly into healthcare delivery improvements.[5]

It is important to create a stronger link between a patient's use of medical services and the benefits they receive from them. The funding model used to support healthcare needs to be individual focused rather than institution or process focused. This is particularly important given how the increasing level of

use of medical services will undermine the financial sustainability of the healthcare system. A business as usual projection of healthcare expenditure to 2050-51 shows that the costs associated with the ageing of the population are dwarfed by those associated with increasing use of healthcare services (See Figure 1).[6]

Politicians are not well positioned to link community expectations for access to healthcare services with the associated financial costs, or to introduce administrative reforms.[7] There is a need to address the institutional arrangements and place the patient's interests at the centre of the healthcare system. The proposal set out in this publication may not resolve all financial problems with the healthcare system but it would add a level of accountability and efficiency incentives that do not currently exist. Continuing with the existing system of allocating healthcare resources will result in greater levels of rationing of access to healthcare services in the future than occur now.

Issues posed by the funding of future health costs are similar to those for the funding future retirement income.[8] The beneficiaries of future healthcare spending will be disproportionately the older groups in the population, comprising a larger proportion of the population in the future than they do now. These individuals are generally in the working population at this point in time. Introducing an element of pre-funding for future health costs will both be more sustainable and efficient and be more equitable between successive generations.

To introduce dynamic efficiency into the healthcare sector and to reduce the level of intergenerational equity transfer, major reforms are needed to the way healthcare costs are funded and services delivered. Improvements to incentives could be achieved by:

- Aggregating all health funding at the level of the individual;
- Having financial risk reside with competing health funds through insurance arrangements, introducing managed competition, eliminating fragmented responsibility and cost shifting;
- Linking public healthcare budgets and community expectations of healthcare services to economic capacity to pay, via a fully hypothecated Medicare Levy that funds healthcare expenditure; and
- Introducing pre-funding for healthcare costs by quarantining a portion of the Superannuation Guarantee rate, or increasing the Levy, so that approximately three per cent is set aside to cover healthcare costs.

Pricing generic drugs

The current price adjustment mechanism for drugs exiting patent protection is very weak in Australia. The eight generic drugs that receive the largest subsidies from the PBS were between two to almost 30 times higher in Australia relative to comparable healthcare regimes.[9] If Australia had paid prices for these generic drugs equivalent to the UK then the financial savings would be more than a billion dollars. Australia should seek to have generic drugs priced closer to their marginal

cost of production. Not only would this reduce the financial impost of the PBS, but it could improve the health of the population as the prescription of many generic medications could be expanded.[10]

The memorandum of understanding (MOU) that sets the price for generic drugs is set to expire in July 2014. This represents an opportunity to more appropriately priced generic drugs. Yet the Government has only indicated that it would set a new price agreement with representatives from the Pharmaceutical Industry and the Consumers Health Forum, the same bodies that established the current MOU.

Since the mid-2000s a large number of widely used pharmaceuticals have expired and many more are set to expire. Governments in other countries have taken advantage of this to significantly lower the prices of generic drugs which constitute a large portion of the financial impost of the PBS. To improve the pricing of generic drugs in the PBS, Australia should:

- Adopt a public consultation process in setting the next pricing agreement, one that engages all stakeholders and not just those with a vested financial interest; and
- Explicitly attempt to capitalise on the expiry of pharmaceutical patents by adopting price cuts that reflect the price of manufacturing generic drugs. A tendering system similar to New Zealand or the Netherlands should be considered.

These reforms would enhance the financial and potentially the physical health of all Australians, but particularly those with chronic illnesses.

Economic opportunities in medical advances

There have been many promising breakthroughs that have occurred in biomedicine in recent years. Coupled with increasing demand from an ageing world growing in wealth, there is a substantial global market for medical advances. Australia has managed to leverage its educated workforce and strong institutions to create a commercial comparative advantage in biotechnology. As a consequence, Australia has a biotechnology sector that is capitalised at twice the OECD average as a portion of the stock market. While growing rapidly, the sector also represents one of the largest high value adding export earning industries for the country.

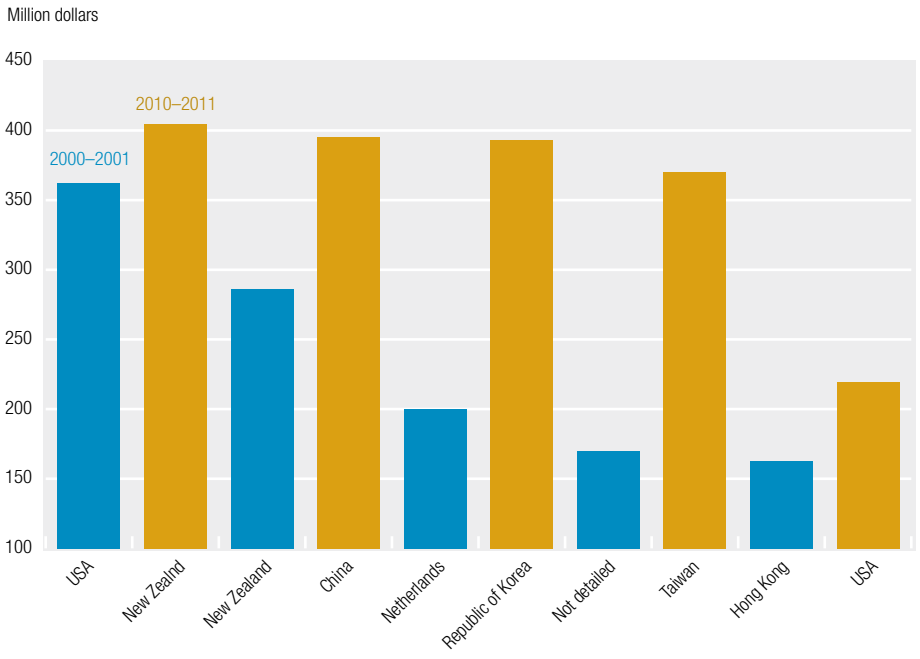
Australia's success in the biotechnology industry is indicative of the role the nation can play in high skilled, high value adding industries that are global in nature. As a consequence, the policy framework that underpins the continued development of biomedicine is important for all innovative industries. Australia needs to be able to effectively encourage innovation if it seeks to enjoy continued advances in national prosperity when the terms of trade normalise and commodities do not buttress national income growth.

Translating ideas into action

Australia has consistently developed a disproportionate amount of the world's medical advances, producing three per cent of the world's patents while having only one per cent of the global population. Australia's biotechnology industry has seized on the opportunities presented by medical advances to transform itself from a domestically focused sector into one intimately linked with global innovation. As a consequence, medicinal and pharmaceutical exports have risen from $455 million in 1991–92 to over four billion in 2011–12.[11] Biotechnology represents one of the most successful, high-skilled export earning industries in Australia, significantly outstripping exports from the automobile sector.

Australia's biotechnology industry successfully built on the nation's strong primary research coupled with robust international connections. The economic growth of India and China, among other developing countries, has opened up substantial export opportunities for Australia, with exports to China representing over 10 per cent of total exports during the financial year 2010–11.[12] As the level of income rises in developing economies, the demand for medical products will only increase.

FIGURE 2
TOP FIVE PHARMACEUTICAL EXPORT DESTINATIONS



Source: ABS International Merchandise Trade, Exports by ANZSIC class

Despite the positive environment for biotechnology, the global industry faces increasing challenges in commercialising research due to the increasing risk and complexity involved in the process. Breakthroughs such as molecular biomarkers for certain diseases generate many new potential therapies to be investigated, each of which requires large amounts of research at a cost of hundreds of millions of dollars and with a substantial probability of failure. Despite a near doubling

of aggregate research and development budgets in the pharmaceutical industry, from $68 billion in 2002 to $127 billion in 2010, there has not been a marked increase in the number of new drugs approved.[13] Past commercialisation success does not guarantee continued growth in Australia's biotechnology sector.

Australia has a poor track record of turning primary research into commercial reality. Australia ranks highly in terms of global innovation input, but rates 107th out of 141 countries assessed in terms of innovation efficiency.[14] A key reason for this research inefficiency is an academic culture that is seemingly divorced from the commercialisation process. The important National Health and Medical Research Council (NHMRC) project grants and fellowships are provided for health and medical research but not medical commercialisation. The metrics to measure applicants focus on academic criteria. Time spent in the translation process results in fewer academic publications and so reduces the likelihood of a successful funding application. The current NHMRC criteria indirectly punish those who spend time on commercialisation activity.

Poor academic incentives in Australia may help explain why Sweden and Switzerland have a patenting rate between four and five times higher, along with a long history of academic engagement in transferring technological innovations into commercial products. To improve the research culture and to allow greater interaction between academia and industry:

- Rather than indirectly penalising translation efforts, the NHMRC research funding criteria should be changed to acknowledge work on commercialisation activity.

The growing complexity of biomedicine requires more highly skilled practitioners throughout the translation chain, including all aspects of commercialisation. Most universities and research institutes have commercialisation units associated with them but they often lack the expertise to successfully navigate the increasingly complex translation process.

The situation can radically change when critical mass is achieved, as demonstrated by UniQuest, the commercialisation arm of the University of Queensland.[15] UniQuest has generated over $320 million in revenue from initial funding of $10 million.[16] To help develop commercialisation critical mass in our universities and research centres:

- The small and disaggregated commercialisation units should be integrated to achieve greater levels of commercialisation resources and expertise.

The growing complexity of the process involved in translating an idea into a commercial product has put significant strains on traditional sources of funding of pharmaceutical research and development. This is particularly pronounced in Australia which lacks the economies of scale associated with highly successful venture capital areas. The level of risk involved in the translation process diminishes dramatically as the concept moves through the three "valleys of death."[17] While research and experimentation received more than $8 billion in annual support, only approximately 1.5 per cent is spent on commercialisation, and half of these funds were directed towards the automotive sector.[18]

To help traverse the innovation "valley of death" in biomedicine:

- A portion of the $780 million a year allocated through the NHMRC for primary research should explicitly support translation efforts. These funds should be allocated via a passive ownership model, such as a program that converts to equity if successful or to a grant if not.

Maintaining comparative advantage

While Australia has contributed a disproportionate amount to global knowledge in healthcare, this has been assisted by it being an advanced economy and having a highly educated workforce. As the productivity differential between workers in the OECD and the rest of the world diminishes, Australia's comparative advantage in healthcare could prove transitory rather than a source of sustained competitive advantage. This is a challenge for all innovative sectors operating in Australia.

In common with many developed economies, the historical comparative advantage that Australia has enjoyed because of its highly educated workforce is diminishing. This is partially due to the quality of the developing world's educational systems having improved. It is also due to a declining number of Australian students undertaking the science, technology, engineering and mathematics (STEM) studies that underpin an innovative economy.

In contrast, many developing countries have started from a low educational base but have been investing heavily in improving the productivity of their workforces. For instance, when South Korea developed its modern educational system:

> *"The very vocabulary to talk about modern science and mathematics hardly existed in the Korean language and had to be invented before textbooks could even be written."* [19]

Concerted efforts to improve scientific and technical education underpinned South Korea's emergence into a modern developed economy. A similar transformation is underway in China and India. In 2002, the total number of STEM field[20] first university degrees awarded in Asia was just over one million, with almost half a million in China alone and a further 176,036 in India. By 2010 the total STEM degrees awarded in China had risen to 2.6 million, with the figure anticipated to rise to 3.5 million by 2015.[21] China alone will produce more STEM degrees in 2015 than all of Asia did as first degrees in 2002. India is experiencing similar growth trajectories.

While Australia's advantage of having a relatively highly educated workforce is eroding, the nation is still placed above average in the Program for International Student Assessment (PISA) results. However, this relative success is rapidly declining as illustrated in the table below.

Countries outperforming Australia in PISA testing

2000	2003	2006	2009
Korea	Finland	Finland	Shanghai-China
Japan	Japan	HK	Finland
	Korea	Canada	Hong Kong – China
			Singapore
			Japan
			Korea
Australia	Australia	Australia	Australia

Not only does the relative decline in student performance need to be addressed, but a concerted effort needs to be made to improve the quality and quantity of all STEM students. In the US it has been recognised that there needs to be a shift away from:

> *"University degree programs aimed almost exclusively at preparing people for academic research positions to include diverse training in entrepreneurship, project management, and research translation."* [22]

To encourage greater mobility between academia and industry, and to improve the work ready skills of STEM students, the Government should:

- Ensure that students starting STEM are engaged in collaborative efforts with industry, for instance internships. The Australian CRC program could act as an environment to foster industry-relevant skills; and
- Have industry engaged with degree accreditation schemes to ensure that the curricula reflects skill demands.

Endnotes

1 Rochaiz, L., *Performance-tied payment systems for physicians*, in R B Saltman, J Figueras and C Sakellarides (eds), *Critical Challenges for Health Care Reform in Europe*, Open University Press, Buckingham, 1998, page 1999.

2 Clarke, P., The price is wrong: Pharmaceutical expenditure in Australia over the last decade and options for reform, CEDA, Healthcare: Reform or ration, page 48.

3 Quoted in Department of Health and Aged Care, *Technology, Health and Health Care*, Occasional Papers: Health Financing Series, pages 13–14.

4 Strategic Review of Health and Medical Research in Australia, *Consultation paper summary: Issues and proposed recommendations*, 3 October 2012, page 9.

5 Strategic Review of Health and Medical Research in Australia, *Consultation paper issues and proposed recommendations*, 3 October 2012, Page 14.

6 This chart is based on health expenditure by age and sex, Australia 2004–05 published by the Australian Institute of Health and Welfare in *Health system expenditure on disease and injury in Australia*, *2004–05*, April 2010. This information is extended to 2050–51 at the real historical growth rates for Australian government health spending from 1984–85 to 2007–08 as identified by the 2010 Intergenerational Report *Australia to 2050: Future challenges*, page 48. The population figures for each age cohort are taken from series B of the ABS catalogue number 3222.0.

7 Stoelwinder, J., Sustaining universal health care in Australia: Introducing dynamic efficiency, CEDA, Healthcare: Reform or ration, page 21.

8 FitzGerald, V., Health care reform in an ageing Australia, CEDA, Healthcare: Reform or ration, page 32.

9 Clarke, P., *The price is wrong: Pharmaceutical expenditure in Australia over the last decade and options for reform*, CEDA, Healthcare: Reform or ration, page 48.

10 Clarke, P., *The price is wrong: Pharmaceutical expenditure in Australia over the last decade and options for reform*, CEDA, Healthcare: Reform or ration, page 50.

11 Australian Bureau of Statistics, Catalogue number 5368.0 International Trade in Goods and Services, Australia, Table 12a.

12 IBIS World, *Bitter pill: Industry players must adapt as some drugs lose patent protection*, IBIS World Industry Report C2543 Pharmaceutical Product Manufacturing in Australia, December 2012, page 15.

13 Sourced from Fernandez, J., Stein, R. M., and Lo, A. W., *Commercializing biomedical research through securitization techniques*, Nature biotechnology, 2012 from Anonymous, World Preview 2016 (Evaluate Pharma, 2010).

14 Sourced from Lavelle, A., *Ensuring Australia's comparative advantage in biotechnology, Healthcare: Reform or ration*, CEDA policy perspective, citing INSEAD, 2012, Global Innovation Index, http://www.globalinnovationindex.org/gii/main/2012rankings.html

15 Lavelle, A., *Ensuring Australia's comparative advantage in biotechnology, Healthcare: Reform or ration*, CEDA policy perspective, page 63.

16 Lavelle, A., Ensuring Australia's comparative advantage in biotechnology, Healthcare: Reform or ration, CEDA policy perspective, page 63.

17 Clark, J., Traversing the valley of death, CEDA, Healthcare: Reform or ration, page 68.

18 Lavelle, A., *Ensuring Australia's comparative advantage in biotechnology, Healthcare: Reform or ration*, CEDA policy perspective, page 58.

19 Sorensen, C. W., *Success and Education in South Korea*. Comparative Education Review, Vol 38: 10–35, 1994.

20 National Science Foundation, Science and Engineering Indicators, 2006, Volume 1, Arlington, VA, NSB 06–01, January 2006, Table 2–37, cited in the Office of the Chief Scientist report *Mathematics, Engineering and Science in the national interest*.

21 Craig, E., Thomas, R. J., Hou, C., and Mathur, S, 2011, *No Shortage of Talent*, Accenture Institute for High Performance, page 6. This figure includes Masters and PhDs awarded in STEM subjects.

22 US National Institutes of Health Advisory Committee to the Director, 2012. *Biomedical Research Workforce Working Group Report*, page 8.

1. Sustaining universal healthcare in Australia: Introducing dynamic efficiency

Professor Johannes Stoelwinder

This chapter examines why the present healthcare system is unsustainable and in need of further reform and options for addressing the root causes of its unsustainability.

Professor Johannes (Just) Stoelwinder holds the Chair of Health Services Management in the School of Public Health and Preventive Medicine, Monash University and is also Chair of Ambulance Victoria. He has been a provider, payer, regulator and academic in the health system ranging from specialist physician, public hospital CEO, private hospital director, Member of the Private Health Insurance Administration Council and a Director of Medibank Private Limited.

Introduction

Despite five years of reform effort, Australia's universal healthcare system remains unsustainable in the long term. It is not population nor demographic changes that are the main drivers of healthcare's inexorable cost increases, but the vulnerability to pressure from vested interest groups on the political process of allocation of resources in a tax funded system.

Maintaining universal access to a tax-based system is appropriate as it provides an equitable cross-subsidy to support those in the community with high cost healthcare needs. However, a superior model of funding is needed that links total expenditure to the capacity of the economy to pay; that makes the cost of providing universal healthcare transparent to all; that accommodates choice and competition at the level of the healthcare plan to create the conditions for what economists refer to as dynamic efficiency.

Australia has the building blocks necessary and the Netherlands reforms of 2006 provide guidelines to design a system that meets these conditions. This paper aims to demonstrate the need and explores how such a fundamental reform could be designed.

Background

After five years of effort to reform Australia's healthcare system what have we achieved? The main structural characteristics of financing and stewardship remain largely unchanged, with dysfunctional fragmentation between the Commonwealth, state governments and private insurers. The main constraint seems to be that imposed by the nature of the Australian federation. This has allowed state governments and their health bureaucrats to blunt the main reform effort by the Commonwealth to progressively take-over responsibility for public

hospitals so as to create a single health system, having instead to settle for linking marginal increased contribution for hospital funding to the states to devolution of hospital funding and governance, centralised "efficient" pricing and greater clarity and transparency in performance measurement and accountability – reforms that were already at play. The "blame game" remains alive and well.[1]

In the areas in which the Commonwealth has a free hand, such as primary care, reform has centred on the implementation of Medicare Locals as geographic coordinators of primary care. These will likely develop as conduits for funding specific initiatives, such as after-hours access, but they have not been given the levers to influence the dominant component, that of General Practice. Whatever its potential, this reform is vulnerable if there is a change in government at the next election, as the Opposition has pledged to abolish them.[2] The Government's reform commitment to prevention, through the Australian Preventive Health Agency, has already suffered a significant budget cut.[2] While the eHealth strategy of developing the personally controlled electronic health record (PCEHR) met its scheduled implementation date of July 2012, enrolment to date has been limited, although it is too early to judge its success.[4]

On the one hand we should not be too disappointed with the reform outcome, for as the Canadian political scientist Carolyn Hughes Tuohy long ago warned us: "Major policy initiatives altering the fundamental institutional mix and structural balance in healthcare….are episodic and rare. (They) have required an extraordinary mobilisation of political authority and will and…have depended on factors largely external to (health)."[5]

On the other hand we continue to face serious long term challenges to the sustainability of one of our important policy achievements – universal healthcare in the form of Medicare.

Is Medicare sustainable?

The Commonwealth Treasury Intergenerational Reports give the clearest indication of the challenge of sustainability of Medicare. The Commonwealth contributes around 50 per cent of total funding for healthcare through the Medical Benefits Scheme, the Pharmaceutical Benefits Scheme and its contribution to the states for public hospitals. Already in its 2002–03 Intergenerational Report Treasury forecast, the Commonwealth's contribution to healthcare would increase from the then four per cent of GDP to eight per cent of GDP by 2041–42.[6] It further noted that real growth in spending was mainly driven by increased utilisation of services (i.e. non-demographic growth) at 3.2 per cent per annum since 1989–90, compared to that due to population growth at 1.2 per cent per annum, and ageing of the population contributing 0.5 per cent growth per annum. The 2010 Intergenerational Report updates the forecast suggesting that Commonwealth spending on health will increase to a lower 7.1 per cent of GDP by 2050 with ageing and population growth continuing to contribute around 40 per cent and increased utilisation of services accounting for 60 per cent.[7] As for the states,

their financial vulnerability to escalating healthcare spending and, in particular, spending on public hospitals is even greater, with health expenditure being the largest component of their budget, typically around 27 per cent.

These facts highlight two key challenges to financial sustainability. The first is the capacity and desire of the Commonwealth and state governments to continue to fund this level of growth in spending. Economic circumstances and political priorities will influence their response, but the states in particular will remain constrained by their limited capacity to raise revenue. For the Commonwealth this ongoing trend in health spending will be the major contributor to the forecast escalation of its fiscal gap, commencing at around 2030. The second is that increased utilisation (more services per person per year) is the main driver of this increase in cost, not the commonly held concerns about ageing of the population. Utilisation growth is important as policy decisions and management can influence it, but there is little that can be done to alter demographic changes.

It is clear from the above that Australia's capacity to sustain a universal health scheme will depend on a political willingness to continue to fund the predicted growth in health spending by either re-allocation within the budget, increased taxes and/or greater co-payments. Alternatively, or in addition, the growth in cost needs scaling back by restraining utilisation and improving healthcare productivity. Improving labour productivity will be important because of the labour intensity of healthcare, but it has actually been declining. In the United States over the period 1990 to 2010 the healthcare and social assistance industry sector experienced employment growth of 2.9 per cent (compound annual growth rate), but labor productivity growth was minus 0.6 per cent (compared to positive 1.7 per cent for the overall US economy).[8] Similar concerns have been expressed about poor labour productivity in Australian healthcare.[9]

"Tax funding sets up moral hazard – neither the consumer nor their agent, typically their doctor, wears significant financial cost as a consequence of the decisions they make to consume healthcare resources, therefore encouraging consumption, even if only potentially beneficial."

Given we have a predominantly government controlled, tax-funded healthcare system the allocation of governments' budgets, changes to healthcare utilisation and improving healthcare labour productivity all become political exercises, pitting political decision makers against the power of health professions, health organisations and other vested interests. In a tax-funded model providers have no option but to engage in the politics of the budget allocation process. Their revenue/income results not from the accumulation of decisions made by consumers exercising choice, but the result of their success in political lobbying during the budget process.

Tax funding sets up moral hazard – neither the consumer nor their agent, typically their doctor, wears significant financial cost as a consequence of the decisions they make to consume healthcare resources, therefore encouraging consumption, even if only potentially beneficial. This is further complicated by the incentives of a predominantly fee-for-service payment arrangement for doctors and other health practitioners. Together these features facilitate the observed increase in healthcare utilisation.

The prospect of governments managing the politics involved in controlling the growth of utilisation in these circumstances seem problematic and have rarely been successfully achieved. Finally, government-controlled health professional regulation maintains occupational silos in healthcare delivery. This protects health professionals from competition and is actively resisted when challenged, for example the introduction of independent nurse practitioners in primary care or the tension between obstetricians and independent midwives. Improving health workforce productivity will surely require a more flexible and coordinated workforce.

The difficulty politicians face in seeking to respond to these challenges was best articulated in a speech by the then Dutch Health Minister, Hans Hoogervorst, in explaining the Dutch 2006 health reforms. He identified three crucial problems:

> *"Firstly, there is the sharp rise in costs caused by technological advances and ageing…*
>
> *Secondly, most Dutch citizens – like their counterparts in most other European countries – have grown up with the idea that healthcare is free…*
>
> *Thirdly, we need to change because when it comes to controlling costs, the government always stands alone. The result was increasingly spasmodic efforts to keep a grip on prices. True, you can hold down costs by having maximum prices, fixed tariffs and budgetary ceilings. But it also obstructs any kind of creativity. The government is always the bad guy, while the established powers in the healthcare sector – and they are very strong ones – make every change difficult."* [10]

This analysis begs the question – can we mitigate the influence of health politics on the reform of the health system? The Dutch have sought to do so in their 2006 reforms.[11] While it is not possible to transpose one country's health system onto another because of the different paths they have travelled in their history, it is possible to distil the design features of one and test how they could be applied in another. In the following section the key features of the Dutch reform as they could apply to supporting sustainability of Medicare in Australia are explored. This is not to argue that the Dutch reforms have yet achieved a sustainable healthcare system, but that its design features provide insights into an alternative design that may address the key incentive issues that will make Australia's system sustainable.[12]

Funding a universal health scheme

A universal health scheme requires mandatory participation in which access to benefits is not constrained by an individual's capacity to pay. Therefore, some form of cross-subsidy has to be constructed in funding care. Most commonly this is done through taxation by which richer members of the community cross-subsidise poorer. This may be via general taxation (e.g. Australia and Canada) or a hypothecated tax (usually payroll e.g. Medicare for those aged over 65 in the USA, or part of the new Dutch scheme). An alternative is from compulsory insurance (usually referred to as social insurance), used in Western European countries

with “Bismarckian” systems (e.g. Germany and Switzerland). An alternative form of cross-subsidy is that based on risk – in which participants with lower than average risk cross-subsidise those of higher risk. This is mostly used in voluntary health insurance where solidarity is achieved through regulated community-rating (i.e. the premium cost of a health policy is not rated according to the individual’s risk but the pooled risk of those with that policy). This model is used, for example, in voluntary health insurance in Australia and South Africa.

Deciding how much to spend on healthcare in the case of tax funding from general revenue is a political process involving both decisions about budget allocation and the scope of the benefit package to be covered. As argued above, these are subject to the influence of vested interests that politicians seem to struggle to withstand. Other than the general resistance to increased taxes and the pressure from competing budget recipients, politicians have little support in controlling spending on healthcare. The Dutch have sought to deal with this by explicitly linking, through their insurance law, 50 per cent of the total spending on health to the funds raised by a hypothecated payroll tax[13] – thus creating a spending cap linked to economic growth. More can be spent on health but this would need an explicit political decision to raise the level of the payroll tax. Australia could introduce similar dynamics by hypothecating the Medicare levy and restricting it as the full funding source for Medicare. The current Medicare levy of 1.5 per cent, which is not hypothecated, raises less than 20 per cent of the Commonwealth’s contribution to spending on health. Based on the National Health and Hospitals Reform Commission’s estimate a hypothecated Medicare levy required to fully fund Medicare would have to be increased to around 14 per cent of personal income tax.[14] A concomitant reduction in personal income tax would then be neutral in terms of total personal tax paid and total tax received by the Government, but would place an automatic cap on healthcare spending linked to the economy.

“The Dutch have sought to deal with this by explicitly linking, through their insurance law, 50 per cent of the total spending on health to the funds raised by a hypothecated payroll tax – thus creating a spending cap linked to economic growth. More can be spent on health but this would need an explicit political decision to raise the level of the payroll tax.”

In the Netherlands the Government pays for children up to the age of 18 from general taxation and this accounts for approximately five per cent of the funding pool. The remaining 45 per cent of the pool is raised by community-rated premium payments by individual adults to competing insurance funds for the basic benefit package – the nominal premium. (The basic package provides for services equivalent to those covered by Medicare in Australia). A typical premium in 2012 is around €1250 per year per adult. This level of payment is designed to provide an incentive to all consumers to shop between product features and funds. It makes the cost of healthcare more directly transparent to the community. To make this payment equitable the Government provides an income related subsidy sourced from general taxation; a healthcare allowance (*zorgtoeslag*) of up to €750 – paid through the tax system. Such a funding arrangement could be implemented in Australia, but consideration would need to be given as to whether the gains in transparency, consumer engagement and the potential political counter-balance would warrant the extra complexity.

Moral hazard will remain a feature in any tax funded or insurance model. Co-payments are used in most systems to mitigate against it, but because of their regressive nature and impact on the sickest, there is usually a safety net, such as the Medicare Safety Net, or a limit to co-payments. In the Netherlands a compulsory maximal deductible for some services of the first €220 is applied (increasing to €350 in 2013) together with an additional voluntary deductible of up to €500, which can be chosen in return for a discount of around €250 per annum on the premium.[15,16]

Defining the benefit package in a universal system will always remain a political decision, but at least the above arrangements would provide a different dynamic to the politics of funding healthcare in Australia, with a more explicit engagement of the community in deciding on the growth of healthcare spending. Enhancing the package would require a linked and transparent increase in funding through both the level of the hypothecated tax and the nominal premium paid by individuals. The community's desire for access to new and expensive treatments would then need to be matched with its willingness to pay for it.

Using choice and competition to drive innovation

The Dutch reform of competing health funds with associated consumer choice, is designed to drive innovation and efficiency and is modeled on the concept promoted by the American health economist, Alain Enthoven.[17] Such "managed competition" has also been canvassed from time to time in Australia.[18] It also underpinned the longer term reform proposed by the National Health and Hospitals Reform Commission under the title of Medicare Select.[19]

The Dutch were able to implement a competitive health fund model because they already had in their former Bismarckian health insurance model an independent "meso-level" layer of (traditionally non-for-profit) health funds with the role of fund poolers and service payers, operating between the funder and providers.[20] The presence of competing private health insurance funds in Australia also provides the structural basis for a managed competition model. This is not to say new entrants, such as significant provider organisations, could not join the market by vertically integrating into the insurance space.

Competition between health funds, based on a mandated basic benefits package (e.g. current Medicare benefits), is intended to drive innovation in insurance product design, in purchasing strategies with providers and in the coordination of comprehensive care of those members with chronic diseases. Funds can compete on price and or the quality and quantity of the benefits provided beyond the basic package. By aggregating all health funding for an individual (public and private) the health fund is the single point at financial risk for the cost of a member's healthcare, noting that benefit outlays represent some 90 per cent of the expenses of a health fund. The fund therefore has the incentive to become an active purchaser of care for its members (not just to be a passive payer), to negotiate prices and payment models for health services providers. It has the

incentive to ensure the coordination of care and innovate in care delivery models for those with chronic diseases, so that costs are reduced over multiple years, rather than simply to seek to cost shift to another payer, as happens extensively in the current Australian fragmented funding system. The drive to reduce provider costs, for example through preferred provider contracts, will be counter-balanced by the extent to which members will want to pay for an insurance product with greater provider choice. Consumer choice around the trade-off between premium costs, deductibles, additional benefits and provider restrictions can be expected to vary in the community. A managed competition model allows this variation in consumer preferences to play out in the market place, all the time preserving the basic benefit package. The alternative is a one-size-fits-all solution imposed by government from above with all the political ramifications discussed earlier.

"A managed competition model allows this variation in consumer preferences to play out in the market place, all the time preserving the basic benefit package. The alternative is a one-size-fits-all solution imposed by government from above with all the political ramifications discussed earlier."

Competition for consumers is played out at the level of the fund. Consumers are not required to engage in the market place at the time of needing healthcare services. They have choice of fund and choice of insurance product features, which, in the case of the Dutch system, is exercised, during one time window each year. This enables the calculation of the risk equalisation scheme, which will be explained in the next section. Consumers need reliable information to compare prices and insurance options when they are exercising this choice. The Dutch government assists them with this with a comparator website – http://www.kiesbeter.nl/algemeen (translation: choose better). Apart from comparative information on health insurance this portal also provides a provider location finder and specific information on quality (even a black list), waiting times and general health information. As with many such sites much information on quality metrics is still in development.

Controlling inappropriate competition

Competing health funds placed at increased financial exposure to the healthcare costs of their members, required by regulation to provide community rated policies, have a significant incentive to compete with each other through risk selection, or "cherry-picking" the lowest risk consumers. With a lower than average risk pool for an equivalent policy an insurer can offer a lower premium and thus attract more lower cost entrants to the market or those interested in switching. As a result other funds are left with a progressively higher than average risk pool and then have to increase premiums further, resulting in a so-called death spiral. This is exacerbated if insurers can, as in Australia, incorporate benefit exclusions in their policies. For example, a policy that excludes cardiac procedures is likely to attract low claiming younger members who will not see the need for such procedures. As a result the community rated premium for such a

policy will be comparatively low. However, the exclusion will not be attractive to an older member as they are likely to need such coverage. They will stay or enrol in a policy with broader benefits, which will then have an increasing risk pool and increasing premiums. There are, of course, many other ways funds can risk select including advertising strategies, only being accessible via the Internet, closed funds being available only to employees in certain companies or industries, and linking risk-rated ancillary or life insurance to community rated health insurance being just some of the creative approaches available.

The Dutch deal with this inappropriate competition in part by defining a standard benefit package that all insurers must cover – that is no exclusions – but most importantly by a sophisticated risk equalisation scheme.

Risk equalisation

Risk equalisation involves the transfer of funds from insurers with lower than average risk pools to funds with higher than average pools, so as to maintain affordability for those with higher healthcare needs, by reversing the financial effects of risk selection and preserving the principles of cross subsidy from those of low healthcare needs to those with higher needs. It is not a requirement of risk equalisation to adjust for all variation in healthcare need or cost, mitigating that is the role of an insurance pool. However, it should adjust for predictable variation in risk between consumers that can be identified and used by insurers to risk select. These include variables such as age (healthcare cost at the level of the population varies predictably by age); gender, chronic disease, and socio-economic factors.

"Its other key feature is that it is mainly prospective. In other words, while the insurers compete for members on price of the community rated products they offer the actual funding they receive from the total funding pool for a member depends on their risk profile."

The design and calculation of risk equalisation is a complex actuarial exercise that we have described in detail elsewhere.[21] The Dutch, over 20 years have progressively developed the most sophisticated risk equalisation scheme incorporating all of the above variables. Its other key feature is that it is mainly prospective. In other words, while the insurers compete for members on price of the community rated products they offer, the actual funding they receive from the total funding pool for a member depends on their risk profile. So an elderly member with a chronic disease will earn the insurer a significantly larger payment from the fund pool than a healthy young man, even though both contributed the same health insurance payroll tax and nominal premium into the funding pool. This incentivises the fund to seek to manage the cost of a person with large predicted cost through innovation in care coordination and disease management strategies.

Managing a sophisticated risk equalisation regime requires appropriate regulatory frameworks and structures and data. Australia operates a primitive risk equalisation arrangement in private health insurance, managed by the Private Health

Insurance Administration Council that provides the foundations for implementing the more sophisticated regulatory arrangement that would be required by a competing health plan model.

Conclusion

Australia has a healthcare system to be proud of. Its funding model provides universal access and the technical quality of care is of top standard. To achieve that we currently spend over $5500 per person – all up over $130 billion – per year. Healthcare spending grew at an average of 5.3 per cent per year in real terms in the decade from 2000–01 to 2010–11. During this time real GDP growth averaged 3.1 per cent per year, so health spending is increasing 70 per cent faster than GDP.[22] Most of this increase is due to per person growth in utilisation of services rather than due to demographic changes. Clearly this is not sustainable in the long term. For the Commonwealth Government, the major source of funding for healthcare, increased healthcare spending is the main cause of its projected fiscal imbalance and thus debt, starting around 2030 and escalating beyond.

The longish timeframe before government healthcare funding becomes unsustainable is part of the reform challenge. Because of the political nature of decision making about healthcare spending, the political strength of its vested interests and the emotive nature of the topic it is very difficult to make significant reform decisions today to achieve policy outcomes in the (relatively distant) future. However, Australia has achieved reform with foresight in the past in other domains with such long term challenges. For example, the introduction of compulsory superannuation as part of the 1985 Prices and Incomes Accord to address the affordability of future state pensions[23] and the introduction of the GST in 2000 to adjust the future tax base to the changing structure of the economy. The later also reminds us that such reforms can be a long time in the making, with a broad based consumption tax first mooted by the Labor Party in 1985.[24] The Dutch healthcare reform of managed competition was 20 years in the making.

"Long term sustainability of our universal health scheme will not be achieved by incremental changes to the current governance and stewardship arrangement. A step change will be required at some point."

Long term sustainability of our universal health scheme will not be achieved by incremental changes to the current governance and stewardship arrangement. A step change will be required at some point. In this commentary it is argued that such a step will need to facilitate dynamic efficiency through the following design features:

- Aggregation of all healthcare funding at the level of the individual, but with financial risk residing in organisations at the meso level (such as competing health funds) through insurance arrangements. This will get rid of fragmentation and cost shifting and sets up the capacity for consumer choice and managed competition.

- Links public macro budgets through a formula to the economy's capacity to pay. This will maintain financial sustainability, enhance transparency and enable politicians to counteract pressure from vested interests.
- Engages the whole adult community in responsibility for health funding through transparent funding and consumer choice. The level of spending and constraints then reflect the aggregate result of consumer choice rather than vested interest politics.
- Competing health plans engaging providers in bottom-up innovation in regard to service utilisation and workforce productivity – replacing centralised top-down efforts at control.

The 2006 reforms in the Netherlands provide the guidelines for how such a step change could be designed. The current structure of the Australian healthcare system has the necessary components that could enable a consumer choice or managed competition model to be designed. The question remains, at what point will political and economic circumstances be such that governments will bite the bullet and truly reform Medicare to make it sustainable in the long term?

Endnotes

1 Elective Surgery waiting lists blow out. *ABC News*, 16 October 2012. http://www.abc.net.au/news/2012–10–16/elective-surgery-waiting-lists-blow-out/4316302 accessed 26 November 2012.

2 Medicare Locals will go, pledges Opposition. *Australian Doctor*, 25 May 2012. http://www.australiandoctor.com.au/news/latest-news/medicare-locals-will-go-pledges-opposition accessed 26 November 2012

3 Dismay over anti-obesity program cuts. *The Age*, 4 November 2012. http://www.theage.com.au/national/dismay-over-antiobesity-program-cuts-20121103-28r1f.html?skin=text-only accessed 26 November 2012.

4 Kate Newton. Patient sign-up to PCEHR steady. *Australian Doctor*, 17 October 2012. http://www.australiandoctor.com.au/news/latest-news/sign-up-steady-as-e-health-plan-is-put-into-practi accessed 26 November 2012.

5 Carolyn Hughes Tuohy, *Accidental logics: The dynamics of change in the health care arena in the United States, Britain, and Canada*. New York: Oxford, 1999, p11.

6 Commonwealth of Australia. *2002-03 Budget Paper No. 5. Intergenerational Report 2002–03*. Canberra. p34.

7 Commonwealth of *Australia. Australia to 2050: future challenges*. Canberra, 2010. p49

8 Kocher R, Sahni NR. Rethinking health care labor. *N Engl J Med* 365;15:1370–1372.

9 Novak J, Judah A. *Towards a healthy productivity reform agenda for Australia*. Melbourne: Australian Centre for Health Research, 2011.

10 Hoogervorst H. Healthcare reforms in the Netherlands: a model for Germany? Speech 18 May 2006 http://www.minvws.nl/en/speeches/staf/2006/healthcare-reforms-in-the-netherlands-a-model-for-germany.asp accessed August 2008.

11 Stoelwinder J. *Medicare Choice? Insights from Netherlands health insurance reforms*. Melbourne: Australian Centre for Health Research, 2008. http://www.achr.com.au/pdfs/MedicareChoice.pdf accessed 26 November 2012

12 The economic downturn in Europe has placed significant pressure on all social systems and to date the Dutch have experienced levels of spending in health care growth of four to six per cent per annum since the reform. See: Westert GP, van den Berg MJ, Zwakhals SLN, et al. *Dutch Health Care Performance Report 2010: Executive Summary*. National Institute for Public Health and the Environment. p11. http://www.gezondheidszorgbalans.nl/object_binary/o9931_Dutch_Health_Care_Performance_Report_2010_ES.pdf accessed 26 November 2012.

13 The level of the hypothecated payroll tax varies with the type of income. In 2012 employee wages were taxed at 7.1% and most other income at 5%. Source: http://www.belastingdienst.nl/wps/wcm/connect/bldcontentnl/belastingdienst/prive/werk_en_inkomen/zorgverzekeringswet/bijdrage_zorgverzekeringswet/hoe_wordt_de_bijdrage_zvw_berekend/percentages_bijdrage_zvw_en_mogelijke_vergoeding accessed 26 November 2012.

14 National Health and Hospitals Reform Commission. *A healthier future for all Australians – Interim report December 2008*, Canberra: Commonwealth of Australia, 2008. p296. http://www.health.gov.au/internet/nhhrc/publishing.nsf/Content/BA7D3EF4EC7A1F2BCA25755B001817EC/$File/NHHRC.pdf accessed 26 November 2012.

15 Insurance costs and deductibles based on quoted prices for ZilverenKruis ACHME for 2012. See: http://www.zilverenkruis.nl/English/insurances/national-healthcare-insurance/Pages/obligatory-deductable-excess.aspx accessed 26 November 2012.

16 Health care services in the Netherlands typically are fully insured and involve no co-payment. This may reflect their history of price setting as a key regulatory mechanism in the past.

17 Enthoven AC. Consumer-choice health plan. *N Engl J Med* 1978;298:650–8, 709–20.

18 Productivity Commission. *Managed competition in health care*. Canberra: The Commission, 2002.

19 Stoelwinder JU. Final report of the National Health and Hospitals Reform Commission: will we get the health care governance we need? *MJA* 2009; 191: 1–2.

20 For details on the "meso-level" in health care see Foley M, Bennett C, Stoelwinder J. *Making Medicare Select Real: A roadmap for reform to put people at the centre of health care*. Sydney:PricewaterhouseCoopers, 2009. http://www.pwc.com.au/industry/healthcare/publications/making-medicare-select-real.htm accessed 26 November 2012.

21 Paolucci F. Stoelwinder J. Risk-equalization in health insurance markets: Models and international experience. Melbourne: Australian Centre for Health Research, 2011. http://www.achr.com.au/pdfs/Risk%20Equalisation%20-%20Stowelwinder%20and%20Paolucci%20-%20Final%20paper.pdf accessed 26 November 2012.

22 Australian Institute of Health and Welfare. *Health expenditure Australia 2010–11*. Health and welfare expenditure series no. 47. Cat. no. HWE 56. Canberra: AIHW, 2012.

23 Gruen D. *Compulsory Superannuation and National Saving*. Speech to Economic and Social Outlook Conference. Melbourne, 2011. http://www.treasury.gov.au/PublicationsAndMedia/Speeches/2011/Compulsory-superannuation-and-national-saving accessed 26 November 2012.

24 Deloitte. *GST ten years on. Reinventing the wheel?* http://www.deloitte.com/assets/Dcom-Australia/Local%20Assets/Documents/Services/Tax%20services/Deloitte%20GST%20Adviser%20Survey%202010%20FINAL%20(2).pdf accessed 26 November 2012.

2. Healthcare reform in an ageing Australia

Dr Vince FitzGerald

This chapter examines options for reform to ensure future healthcare costs can be met more equitably and efficiently, including through pre-funding similar to compulsory superannuation.

Dr Vince FitzGerald is a Principal with ACIL Allen Consulting and a former Chairman and Director of the Allen Consulting Group. He has written extensively on superannuation and saving, public finance and policy and healthcare reform. He is a CEDA Senior Research Fellow and member of its Council on Economic Policy, and a member of the Industry Advisory Committee of the Australian Centre for Financial Studies. He is a National Fellow of the Institute of Public Administration Australia.

He is also a Director of ETF Securities, The Conversation Media Group and the Goulburn-Murray indigenous community's Kaiela Institute, President of the Victorian State Council of the AICD and a member of its National Board, an ANU Council member and a Trustee of the Finkel and Tuckwell Foundations.

Introduction

In this paper I set out some ideas prompted by Professor Stoelwinder's excellent paper, *Sustaining universal healthcare in Australia: Introducing dynamic efficiency*,[1] and by some earlier work of my own[2] which examined how future healthcare costs might be provided for within a framework similar to that already in place to provide for future retirement income. I focus on the question of how to fund a reform model along Professor Stoelwinder's lines in a way that is equitable between successive generations, and efficient in dealing with costs that are rising over time, without implying increasing tax rates and their attendant disincentive effects and consequent drag on economic growth.

I bring to the topic a "retirement policy" perspective, noting that healthcare needs, like retirement income needs, are heavily concentrated in old age. In Australia, as in many other countries, the ageing of the population implies large future rises in health costs, a large proportion of which is and will be publicly funded out of contemporaneously raised taxes. This poses, *inter alia*, intergenerational equity issues, potentially implying a significantly heavier tax burden on the next generation for the support of the present one – who will be the aged in the future and the recipients of a disproportionate share of healthcare services.

How can these rising future costs be met more equitably and efficiently? The answer to that, it seems to me, is to bring in a component of pre-funding, just as we now have for retirement income in the Superannuation Guarantee system. Through that system people accumulate savings while they are of working age, which are invested – ultimately in physical capital or other earning assets. These and other private savings will, in combination with the age pension, which will be taxpayer-funded in the future, pay for a significantly higher standard of living in retirement than would be feasible otherwise, while keeping the burdens on future, mainly young, taxpayers moderate. Can something similar be done to help pay for future healthcare needs?

The need for reform

Professor Stoelwinder has set out a strong case that our present healthcare system is unsustainable and in need of reform to address the root causes of its unsustainability:

- Over the previous decade, healthcare spending in Australia grew at about 1.7 times the rate of growth of GDP (5.3 per cent vs 3.1 per cent p.a. in real terms);
- Proximate drivers include demography (population growth and ageing – the latter more a factor for the future than it has been in the past) and increasingly expensive medical technology (including pharmaceuticals)[3], but above all, increased per capita utilisation of healthcare services. Over the 1990s growth in utilisation contributed 3.2 per cent p.a. to the growth of healthcare costs (in real terms) vs population growth 1.2 per cent and ageing 0.5 per cent; and
- In future, demographic factors will be somewhat more important, ageing in particular, but with the present system continuing, increases in utilisation per capita are expected still to dominate (accounting for 60 per cent of growth in costs). Commonwealth spending on healthcare, about four per cent of GDP at the beginning of the 2000s, is projected to rise to over seven per cent of GDP by mid-century.

"…increases in utilisation per capita are expected still to dominate (accounting for 60 per cent of growth in costs). Commonwealth spending on healthcare, about four per cent of GDP at the beginning of the 2000s, is projected to rise to over seven per cent of GDP by mid-century."

While healthcare services are what economists term a "superior good" – one whose share in consumption will tend to rise somewhat in any event, as incomes rise – the consequences for public spending of proceeding with the status quo are concerning. They imply crowding out of other worthwhile public spending and rising burdens on future taxpayers (if they accept that), and the latter will in turn be a disincentive factor inhibiting economic participation and economic growth. It is for these reasons that one must conclude that the present system is not sustainable over the medium and longer term.

Underlying factors identified by Professor Stoelwinder in the increasing cost of healthcare – and in particular in utilisation (which is in principle controllable, but not being very effectively controlled) include:

- Inhibitors to efficiency that are inherent in how the healthcare system is organised, such as rigid patterns of reservation of tasks to particular professional and occupational groups; this (and the factors cited below) contribute to low or negative productivity improvement rates in healthcare;
- A lack of sufficiently effective price signals, and in large parts of the healthcare system, weak or absent countervailing influence of purchasers or funders over providers. Consequently moral hazard is endemic;[4]
- Responsibility for funding healthcare is divided between the Commonwealth and the states, for public or publicly funded provision; and overall, between them and (regulated) private health insurers, who largely fund private hospital and some other provisions. Individuals make some payments, e.g. as health insurance premiums and as co-payments for doctor visits and drugs; and
- At root, as identified by Professor Stoelwinder, is the powerful influence on government of interest groups – particularly provider groups, but also healthcare recipients, both individuals and organised groups.

The last factor above, and the second last to an extent, are undoubtedly the ones that have most bedevilled attempts to achieve reform of the system. Nevertheless, as Professor Stoelwinder's analysis makes clear, there *must* be reform if we are to maintain universal healthcare into the future in Australia on a sustainable basis.

Proposed reform model

Professor Stoelwinder sets out a description and commentary on reforms implemented in the Netherlands from 2006, which were designed to tackle issues similar to those Australia faces. Drawing on that model, having regard to features of the Australian system, Professor Stoelwinder proposes a model of reform – or more precisely, a set of design principles for a reformed system. In essence they are:

1. Aggregation of all healthcare funding at the level of the individual;
2. Financial risk to reside at a macro level above, in competing health funds through insurance arrangements;
3. Elimination of fragmentation (of responsibility) and cost shifting;
4. Development of a capacity for consumer choice and managed competition;
5. Linkage of public healthcare budgets to economic capacity to pay – thereby introducing fiscal discipline and helping resist pressure from interest groups;
6. Everyone facing some responsibility (for balancing healthcare choices against their cost) through transparency of costs and of who pays those costs, and consumer choice; and

7. Competing health funds engaging public providers to stimulate them to pursue "bottom up" innovation, addressing productivity and control of utilisation.

Observations on the proposed reform model

My observations on that reform model focus particularly on how it might be funded into the future. At the outset I note that if increasing utilisation continues to be a major driver of increasing cost, even if somewhat better controlled, then that in combination with demographic factors – increasingly ageing (noting that health-care needs are strongly concentrated late in life) – implies continuing significantly increasing costs to public budgets, diversion of resources from other public spending and increasing burdens on future taxpayers, as well as increasing private costs – if healthcare costs are funded contemporaneously in the future.

"…the present Medicare levy is really just an element of general taxation – it is not hypothecated – and it meets only a small fraction of the Commonwealth's cost for healthcare."

The Dutch reform model's link of funding to economic capacity to pay is via a levy (a payroll tax) that is set to meet 50 per cent of the total costs of healthcare and is hypothecated to that purpose. General taxation meets five per cent (to pay for young people's healthcare) and premiums to health funds plus some mandatory co-payments meet 45 per cent.

In Australia, Professor Stoelwinder points out, the present Medicare levy is really just an element of general taxation – it is not hypothecated – and it meets only a small fraction of the Commonwealth's cost for healthcare. He quotes calculations that the levy would need to rise to 14 per cent to cover all those costs, or to seven per cent to cover half – and if that were done, there could be an offsetting reduction in other personal income tax to accommodate the increase in the levy. It would be hypothecated and adjusted as costs rose to rise in line with those.

There would also be premiums to health funds (which could be public or private), and co-payments, as in the Dutch model.

However, such a system still implies fully contemporaneous funding. The levy rate would need to rise steadily over time in any scenario, albeit after the effects of other elements of reform in restraining costs somewhat. While a hypothecated levy linked to cost increases would bring more fiscal discipline to bear, it would still act as a rising tax burden on individuals, and imply increasing marginal disincentives to economic participation.

Elements in the proposed reform model which would help restrain cost increases are:

- The aggregation of costs transparently at the level of the individual (but with risk pooling on a community rated basis,[5] avoiding "cherry picking" by funds); and
- A framework allowing consumer choice among funds which in turn exercise purchaser influence over providers, spurring innovation.

However, no amount of fiscal discipline seems likely to fully inhibit the influence of interest groups on politics and governments, and it seems likely that costs of medical technology (including pharmaceuticals) will continue to rise. Thus while aggregate and public healthcare costs might rise less as a percentage of GDP than under the present system, they will still rise.

In short, such a system of funding would not really link healthcare funding for economic capacity to pay. Rather, even if growth in healthcare costs were restrained somewhat by other elements of reform, the levy and premiums to health funds plus co-payments and other private payments would, as already noted, have to rise relative to incomes and GDP. In other words, the system would still place increasing strain on economic capacity pay, rather than fully restrain health spending to economic capacity.

Addressing capacity to pay

Whatever the relative contribution in the future of utilisation versus ageing and population growth, I would observe that the beneficiaries of future healthcare spending will be disproportionately the older group in the population, comprising a much bigger proportion of the population in the decades around mid-century than they do now. Depending on how far ahead one looks, members of that group are predominantly in the working age population at present, anywhere from early career onwards.

This gives rise to my observation (set out and elaborated in my papers cited earlier) that the problem of how to fund future health costs sustainably is closely analogous to the problem of how to fund future retirement income sustainably – which has been addressed by the compulsory Superannuation Guarantee system of pre-funding in combination with a contemporaneously funded age pension. The Superannuation Guarantee system ensures that, while they are still working and earning income, future retirees meet a considerable part of the cost of their own future retirement income provision. Accordingly, the burden on future taxpayers of funding that provision is restrained. On Treasury estimates which may now be a little out of date, compulsory saving for retirement via superannuation has reduced the future increase in the cost of the age pension (relative to its cost now) to one to two per cent of GDP – as well as ensuring a much higher standard of living for future retirees than would have been in prospect without compulsory superannuation.

"…no amount of fiscal discipline seems likely to fully inhibit the influence of interest groups on politics and governments, and it seems likely that costs of medical technology (including pharmaceuticals) will continue to rise."

It is very important to note that the significant net additional saving[6] brought about by the compulsory superannuation system is invested either in additional capital in the Australian economy or additional earning assets overseas. Moreover, if the income earned is reinvested as the fund accumulates over perhaps several

decades, compound interest has very powerful effects.[7] Wherever the funds are invested, future Australia will be more asset-rich, and that, as distinct from contemporaneous taxation – particularly personal taxation – will become a major source of funding for future needs.

In the series of papers written by me circa 2000, cited earlier, I observed that the projected future increase in the Commonwealth's share of health-care costs alone (not including the states' or private costs) was roughly double the projected increase in the cost of the age pension (after allowing for compulsory super). I also observed that more than half of total healthcare costs (about 60 per cent as estimated then) would be incurred for the aged.

"…a pre-funding system for at least part of those future costs would be both more sustainable and inter-generationally fairer (small annual contributions now, mainly by the group that will be the future beneficiaries, to avoid, or reduce, heavy burdens on future taxpayers)."

It therefore seemed obvious that a pre-funding system for at least part of those future costs would be both more sustainable and inter-generationally fairer (small annual contributions now, mainly by the group that will be the future beneficiaries, to avoid, or reduce, heavy burdens on future taxpayers). The collection, administration and investment systems already in place for superannuation – a collection network extending into every workplace and linking to competing providers of the other services – could be used for this purpose.

A model very broadly of that type that I examined was the healthcare provision components of Singapore's Central Provident Fund (CPF) system. These comprised (circa 2000):

- A *Medisave* account, receiving contributions of six to eight per cent of salary (age-stepped) until a certain maximum balance is achieved – any excess being swept to the person's ordinary CPF account and available to them for retirement income provision or other permitted purposes;
- Premiums (again age-phased) paid to the M*edishield* scheme, insuring against catastrophic healthcare costs; and
- A *Medifund* safety net (funded from general taxation).

Such a scheme has much in common with that employed in the Netherlands and drawn upon in Professor Stoelwinder's proposed design principles for reform – although there are significant differences. The similarities are the use of a combination of what is, in effect, a payroll or personal income tax which is hypothecated to pay for healthcare, premiums paid into a risk pool and a component of general taxation funding (along with co-payments and other private payments).

One significant difference is that instead of competing funds exercising purchaser power and stimulating greater efficiency among providers, Singaporean individuals are expected to exercise that purchaser power. When purchasing healthcare services, they are using their own money (which would otherwise go to fund other needs), and except in the case of a catastrophic healthcare event, they meet the full cost – not just a co-payment. Transparency is complete and price signals are strong.

It is not clear, of course, whether the influence of purchasers on providers under such an individual purchaser-based system is likely to be as effective as under a "managed competition" framework such as Professor Stoelwinder envisages – in which competing health funds are well resourced, sophisticated and demanding purchases on behalf of their members. Those health funds (which could be public or private) would also operate community-rated risk pools, perhaps with some risk equalisation arrangements – i.e. direct or indirect cross-payments among funds – to make community rating effective, as in the Netherlands.

If a system were developed in Australia utilising a pre-funding component (contributions of say three per cent of salaries,[8] phased in, going into accumulation accounts to meet future needs), and premiums paid to health funds, as well as a substantial and fully hypothecated levy and a general taxation component to meet public costs, the funds built up through pre-funding could be drawn upon in future by individuals to pay for premiums and co-payments and possibly the levy or some post-retirement substitute for the levy, perhaps at a reduced rate.

> "Implementation of reforms along the proposed lines would obviously pose an enormous degree of political difficulty. But it would have the potential to create an environment in which there are much stronger incentives for innovation, productivity improvement and better balancing of benefits and costs of healthcare choices."

Means testing principles would no doubt need to be applied to relevant elements of the funding system and to co-payments, and safety net arrangements would also need to be considered.

Conclusion

Professor Stoelwinder's proposed design principles for reform, with or without the pre-funding component that I suggest, would imply a fundamental re-casting of our health system. One implication is that a purchaser/provider system within a managed competition framework would apply across the board, in both public and private sectors. This implies that all providers would be funded by purchasers paying for services (outputs or possibly, if and where practical, outcomes). They would need to compete on a level playing field – e.g. with similar treatment of costs such as capital costs and tax or tax equivalents and with the cost of Community Service Obligations (CSOs) such as the training of new professionals neutrally shared by some appropriate mechanism.

It also implies that there would be great pressure to break down the present rigid patterns of reservation of tasks to particular professional or occupational groups and other inhibitors to productivity improvement or restrictions on competition, and thereby to develop more flexible and more efficient provision generally – consistent with maintaining safety and quality.

Another implication is that there would need to be integrated administration, integrated public funding and unified regulation of the system. Obviously the Commonwealth would need to take the leadership role in the new system, but the states would be well placed to play key roles as well – in particular, in oversighting their own public providers (notably public hospitals), and possibly other providers in their territories, and in other aspects such as administering some of the regulatory frameworks.

With regard to public funding, to the extent that it comes from general taxation – Commonwealth and state – the arrangements for sharing of that between the two levels need to be stable and to share the burdens and risks according to fiscal capacity and as far as possible to eliminate any opportunity for cost-shifting.

Implementation of reforms along the proposed lines would obviously pose an enormous degree of political difficulty. But it would have the potential to create an environment in which there are much stronger incentives for innovation, productivity improvement and better balancing of benefits and costs of healthcare choices. Moral hazard would not be eliminated, but countervailing forces to it would be strengthened. It could be more fiscally sustainable and more consistent with economic capacity to pay – particularly with a pre-funding component.

Endnotes

1 In this volume.

2 "Ideas for the Funding of Healthcare in the Context of the Ageing of the Population", paper presented to Australian International Health Institute Symposium, November 1999, published in R. Galbally and J. Krupinski (eds), *Reform, Re–design or Revolution: Health Agendas for the 21st Century*, Australian International Health Institute (Melbourne University Ltd), 2000. A version of this paper with the same title was published in *The Geneva Papers on Risk and Insurance*, Vol 26, No 1, January 2001, pp 114–125, and another version entitled "Saving for Future Healthcare Needs: Health Aspects of a Comprehensive Retirement Policy for Australia", was published in *Australian Health Review*, Vol 23, No 3, 2000, pp 3–9.

3 One (possibly minor) element in this is the increasing use of medication to be taken on an ongoing (rather than episodic) basis – e.g. statins, used to control blood cholesterol.

4 It does not seem that, in general, doctors or other healthcare providers offer services that have no prospect of doing good, but if neither they nor their clients have a strong incentive to weigh costs into the balance (and providers may have the opposite incentive, as they will derive more income), then it is obvious that there is little economic (price signal) control over utilisation of services whose funding is not rationed – although rationing does substitute for price signals, to some extent, in parts of the system (notably public hospitals).

5 Community rating, as in the Dutch model, would be for "objective" risk factors only – such as age, gender, incidence of chronic disease, and not potentially controllable factors such as utilisation and provider unit costs.

6 For each dollar of compulsory saving, there is some partial offset in reduced other saving e.g. through people increasing debt, mainly housing debt, to finance additional consumption pre-retirement – i.e. reduced saving – in the expectation that they will be able to use part of a post-retirement superannuation lump sum to retire that debt. This sort of behaviour is permitted by allowing people to take all or much of their superannuation benefit as a lump sum.

7 E.g. at typical fund earning rates, to obtain $1 in say 30 years' time would require just eight to 13 cents invested now.

8 When I first canvassed these ideas circa 2000, the Superannuation Guarantee contribution rate was being phased up to an ultimate rate of nine per cent. I suggested that three per cent for healthcare could be phased in beyond that, taking the combined total to 12 per cent. Now that the Superannuation Guarantee rate is being phased up to 12 per cent without any ear-marking to healthcare, such ear-marking of part of the 12 per cent could be considered, or the 12 per cent increased somewhat.

3. The price is wrong: Pharmaceutical expenditure in Australia over the last decade and options for reform

Professor Philip Clarke

This chapter examines the rising cost of Australia's Pharmaceuticals Benefits Scheme and options for reform which would help contain costs.

Professor Philip Clarke has recently joined the School of Population Health at the University of Melbourne. He has had previous appointments at Oxford University and the University of Sydney. While a Research Fellow at the University of Oxford he was involved in the economic analysis of the United Kingdom Prospective Diabetes Study (UKPDS), a landmark trial of policies to improve the management of people with Type 2 diabetes. He also works on a broad range of other health economic research including: methodological and empirical research on measuring health inequalities and access to healthcare; international comparisons of drug prices; and the long term health of war veterans.

Disclosure statement

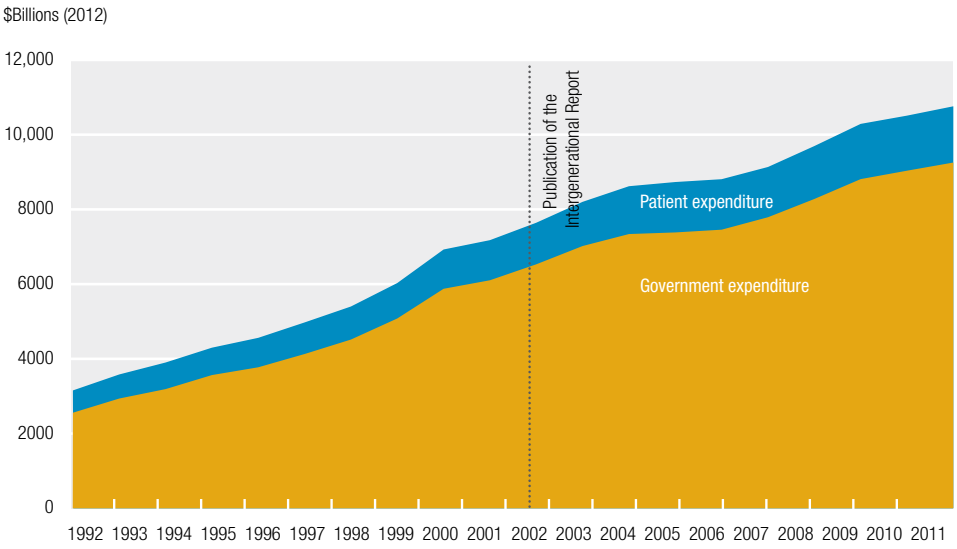
Prof Philip Clarke does not work for, consult to, own shares in or receive funding from any company or organisation that would benefit from this article, and has no relevant affiliations. This research has received no external funding.

Introduction

Just over 10 years ago the Australian Government's first Intergenerational Report projected that the Pharmaceutical Benefits Scheme (PBS) would be one of the fastest growing areas of expenditure.[1] In his budget speech the then Treasurer Peter Costello noted that: "The Intergenerational Report projects that the Pharmaceutical Benefits Scheme could be the most significant area of pressure in the health budget and in 40 years' time grow to around $60 billion in today's terms."[2] As Figure 1(a) illustrates, in the last 20 years total PBS expenditure has risen from around $3.1 billion to $10.7 billion (of which $9.2 billion represents contributions from Government) in the 2011 financial year. At the time of the first Intergenerational Report in 2002, total Government expenditure was $7.6 billion in real terms. While the growth in the PBS has been lower at an average of four per cent pa in real terms in the past decade, than it was in the 1990s, it has still been rising faster than most other Government outlays.[3]

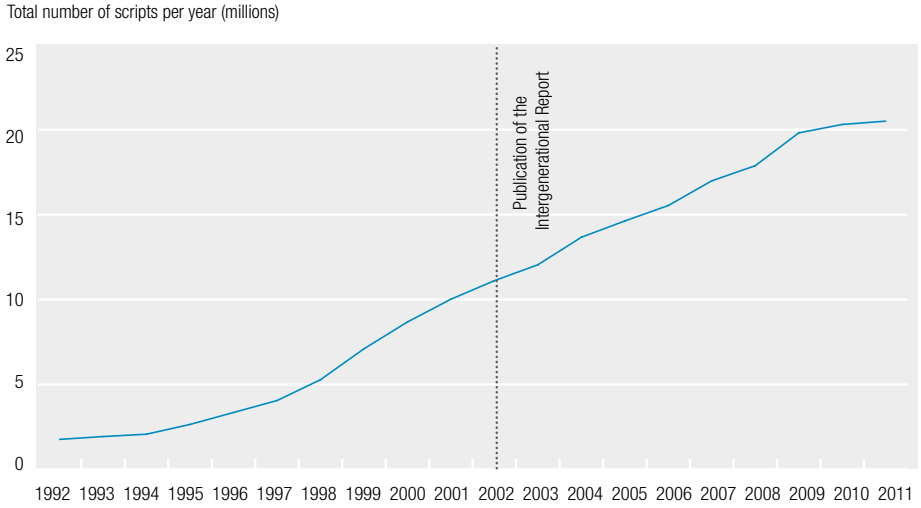
What has tended to drive the rise in expenditure has been listing of new products. For example, subsidisation of Ranibizumab a therapy for treating the eye problem macular degeneration was recommended for listing in March 2007.[4] At the time of listing it was forecast to cost more $100 million per year. Last year Ranibizumab

FIGURE 1A
PBS EXPENDITURE OVER TIME



Source: PBS statistics, adjusted to 2012 dollars using the CPI.

FIGURE 1B
TOTAL NUMBER OF SCRIPTS ON ALL STATINS



Source: PBS statistics from Medicare Australia.

received the third highest overall subsidy of all drugs listed on the PBS at $308 million per year.[5] The other pressure has been from increased use of high volume drugs such as cholesterol lowering drugs known as statins. Figure 1(b) illustrates the total volume of scripts for all types of statins since 1992. While growth has slowed in recent years, use still almost doubled since the publication of the first Intergenerational Report in 2002 and they have consistently been the class of drugs that has received the highest subsidy from the PBS. For example, the total Government expenditure on atorvastatin since its listing on the PBS in the mid-1990s exceeds $7 billion.[6] It is for this reason that they are used as an example to illustrate problems with current policies in the sections below.

How can pharmaceutical costs be contained?

There are three main approaches that governments can adopt. One strategy that the Howard Government adopted in 2005 was to reduce the PBS subsidies by increasing the patient contributions, as a way of shifting some pharmaceutical costs from government to consumers. No doubt this had an impact on expenditure, but part of its effect was also to reduce dispensing of prescription medications[7] and it is unclear if these reductions can be justified clinically. PBS co-payments are now higher than in many comparable OECD countries. For example a study by Kemp[8] indicates we rank fourth out of the 15 OECD countries with universal pharmaceutical subsidies. It is hard to see how additional increases would be consistent with one of the key goals of PBS to make medications affordable.[9]

Another approach is to reduce or alter the quantities of drugs prescribed. Here there are two margins that Government can operate on. Firstly the listing of new types of pharmaceuticals can be stopped or delayed and this was explicitly a policy during part of 2011 when to save costs the listing of seven new medications recommended by the PBAC was deferred.[10] Even before this policy came into effect there have been increasing delays in the listing medications on the PBS. As Pearce[11] notes the average time from TGA approval of drug to PBS listing had increased steadily from 13.6 months in 2000 to 34.2 months in 2009. While these delays no doubt reduce upward pressures on PBS expenditure, they also impact on the welfare of Australian patients who are denied access to the latest pharmaceuticals.

A second approach is switching consumers from more expensive to cheaper drugs within the same therapeutic class. For example, there are four main types of statins and while there are differences in the degree to which they lower cholesterol and in some side-effects there is considerable scope for substituting between them. In Australia there has been very high use of higher cost statins when they are under patent. Just prior to expiry of the patent on atorvastatin in 2012 PBS data indicate that prescriptions for off-patent (simvastatin and pravastatin) constituted only 22 per cent of statins prescribed in Australia at that time. In contrast, generic statins comprised more than 50 per cent of prescriptions in the United States and over 75 per cent in England at that time.[12] The high use of patented formulations in Australia has substantially contributed to the increase in PBS expenditures. Clarke and Fitzgerald (2010) estimated that spending on the PBS could have been reduced by $1087 million prior to 2009 if generic substituting of statins had matched that of England.

"The high use of patented formulations in Australia has substantially contributed to the increase in PBS expenditures. Clarke and Fitzgerald (2010) estimated that spending on the PBS could have been reduced by $1087 million prior to 2009 if generic substituting of statins had matched that of England."

Why are Australians such high users of patented drugs? In the United States the price difference between patented and generic formulations is typically very large

and so there are incentives for consumers and other payers such as HMOs to opt for drugs which are off patent. In England the greater use can be traced to specific recommendations of peak bodies such as the National Institute for Clinical Excellence (NICE), which is the English equivalent to the Pharmaceutical Benefits Advisory Committee. In the case of statins NICE recommended that patients be initiated on the lower cost versions of these drugs[13] and the high generic use suggests this recommendation was widely followed. In Australia there have been few incentives for patients or GPs to choose generic versions of the drugs and this represents a major weakness of the PBS scheme.

The final option for the control of PBS expenditure is to reduce drug prices. Again this can be applied when negotiating the listing of new drugs, or the prices paid for existing drugs, particularly when their patent expires. The last time the Productivity Commission undertook an international comparison of pharmaceutical prices was prior to the publication of the first Intergenerational Report.[14] At that time bilateral comparisons indicated that overall prices were low in Australia compared to many OECD countries (e.g. prices paid in the United Kingdom were around 50 per cent higher). The lower prices attained under the PBS were the subject of criticism by the United States Government, of Australia's pharmaceutical pricing policies. In particular in 2004 the US Department of Commerce argued that features of the PBS including reference pricing (in which all drugs within the same therapeutic group receive the same price) and monopsonistic buying powers that flow from having a national scheme meant that prices for patented drugs were substantially lower in Australia.[15]

The price Australia pays for its generic drugs have received less attention. Before the recent reforms (see below) Australia had no systematic way of reducing the price of generic drugs beyond a relatively small regulatory cut in the price after patent expiry.

Reforms to the PBS

The pricing of pharmaceuticals in Australia has also undergone significant changes in recent years. As indicated above, reference pricing has traditionally been an important feature of the PBS system of pricing pharmaceuticals. This involved PBS subsidies to patients being set at the level of the lowest-priced drug in a therapeutically equivalent group.[16] If a generic equivalent for a drug became available at a lower price, the level of reimbursement was reset to that lower price for all drugs in the therapeutic class. However, this policy was modified in July 2005 when atorvastatin was deemed by the PBAC to have greater efficacy and so was granted a price premium.[17]

The scope of reference pricing was further reduced in 2007, when the PBS was divided into two separate formularies: F1 is intended for single-brand patented medications (this currently includes atorvastatin); and F2 is for medications whose patent has expired and for which generic medications can become available (this includes simvastatin and pravastatin).This split in the formulary greatly reduced

the potential for the expanded range of generic medications to reduce PBS expenditure as price reductions of drugs listed on F2 will not affect the prices of those that remain on F1 that were formerly in the same therapeutic class.[18]

Other reforms in 2007 included a regulatory price cut to some generics of 25 per cent and a move to a system price disclosure in which the price the Government pays reflects the actual price at which the medicine is being sold. The 2007 reforms were in part motivated by the need to address the high relative cost of generics in Australia. As Tony Abbott the then Minister for Health and Ageing noted at the time:

> *"The common cholesterol-lowering drug simvastatin, which currently costs the PBS about $300 million a year, we here in Australia pay more than $50 for this drug. In the UK, they pay less than $10 for that drug. Now the difference in price under our system as it currently stands is mostly accruing to pharmacists by way of discounts and so what we are trying to do with these changes is to harvest most of those discounts for the benefit of taxpayers."*[19]

This system of price disclosure was also the basis of the most recent agreement between the Department of Health and Ageing and the peak industry body, Medicines Australia, dating from May 2010.[20] This agreement commonly known as the Memorandum of Understanding (MOU) included a provision to reduce the price of older medications on the PBS, starting with regulated reductions of between two and five per cent for existing off-patent medications and a 16 per cent reduction when a drug's patent expires. After a period of almost two years the price would then be determined through a policy known as expanded and accelerated price disclosure, in which pharmaceutical companies were legally obliged to reveal to the government the actual price at which they sell their products to pharmacies. Future prices are then set using a weighted average of these disclosed prices. Importantly, in return for these cuts, the Australian Government agreed not to introduce any further price savings during the four year term of the agreement. In effect the MOU fixed the price setting arrangements for around $36 billion worth of pharmaceutical expenditure.

The first round of these price disclosure reductions came into effect in April 2012. What became clear is that discounting in wholesale price of generics was pervasive to the retail pharmacy sector.[21] The government pays a fixed fee to pharmacists each time a drug on the PBS is dispensed, which is intended to cover the cost to the pharmacist of the drug, a mark-up by the pharmacist, and dispensing and any other fees.

A recent study indicated that the dispensed price of generic simvastatin 20 mg was $34 in 2011, $22 of which is intended to cover its wholesale cost.[22] The price reductions from the first round of price disclosures for simvastatin indicate that pharmacists have actually been paying, on average, $10 for this drug.[23] Using data from Medicare Australia, it is possible to estimate that total PBS payments to cover the wholesale cost of all doses of simvastatin amounted to around $150 million between May 2010 and October 2011. Price disclosure data reveal that pharmacies only spent $70 million on the drug, due to discounts from manufacturers and kept the additional $80 million PBS payments. Five years after the

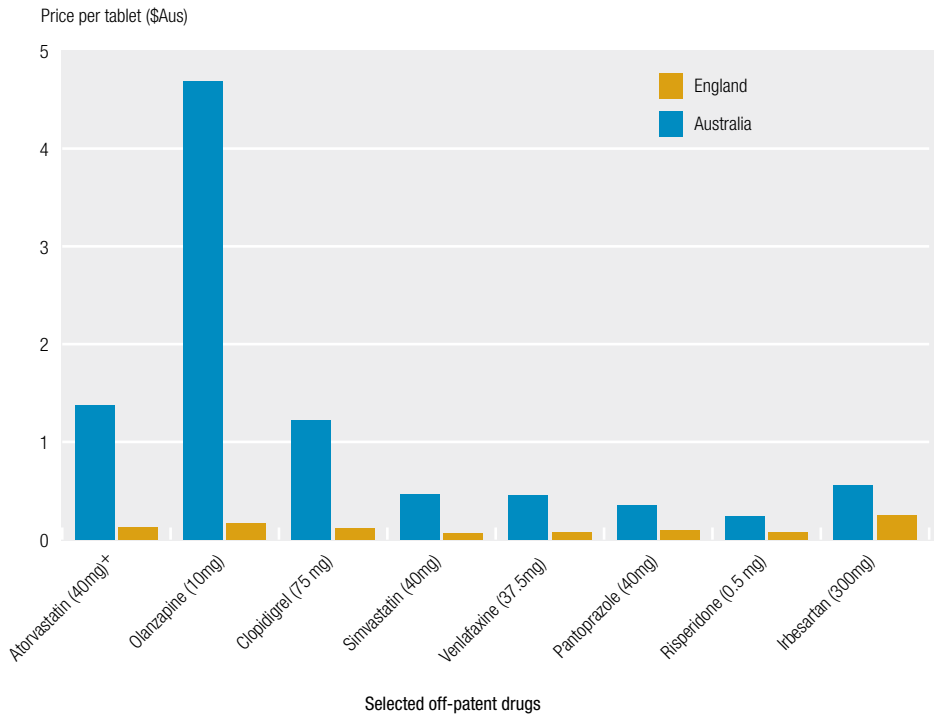
2007 reforms, pharmacists continued to receive very large financial benefits from discounting of generic drugs.

These discounts are likely to be a continuing feature of the Australian system, in part because many new drugs are coming off patent. For example it has been widely reported that pharmacists have been offered discounts of 90 per cent on Atorvastatin[24] after its patent expiry in 2012. While the disclosure of these discounts will reduce future prices, it is a slow adjustment mechanism, as a reduction in the supply price under current arrangements takes more than 18 months to produce savings for the PBS.

Some international price comparisons

There have been no recent comprehensive international comparisons of pharmaceutical prices conducted by the Department of Health and Ageing or other Australian Government agencies such as the Productivity Commission. Other countries such as England regularly undertake such comparisons.[25] Most recently the Office of Health Economics (which is the peak pharmaceutical industry body in the United Kingdom) provided an updated estimates of the comparative price level, calculated using a basket of the top 250 most prescribed drugs in 2011

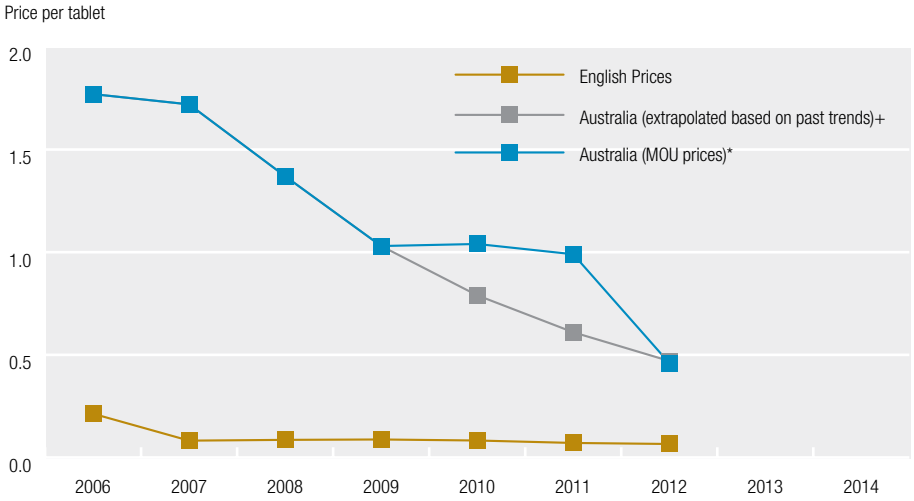
FIGURE 2
INTERNATIONAL COMPARISON* OF EX-MANUFACTURER PRICES



Notes:
Selected drugs from annual PBS expenditure statistics of the highest cost to Government in 2011–12 ranked in order of total cost.
* Comparisons based on five year average of the exchange rate between 2008–12 of $1=0.57 pence.
+ Price of atorvastatin in Australia takes into account the 25 per cent reduction on 1 Dec, 2012.

Sources: Data calculated from PBS schedule (Jan 2013); England from Category M price lists (Jan 2013).

FIGURE 3
PRICE OF SIMVASTATIN 40MG IN AUSTRALIA*



Notes: *Comparisons based on five year average of the exchange rate between 2008-12 of $1=0.57 pence.

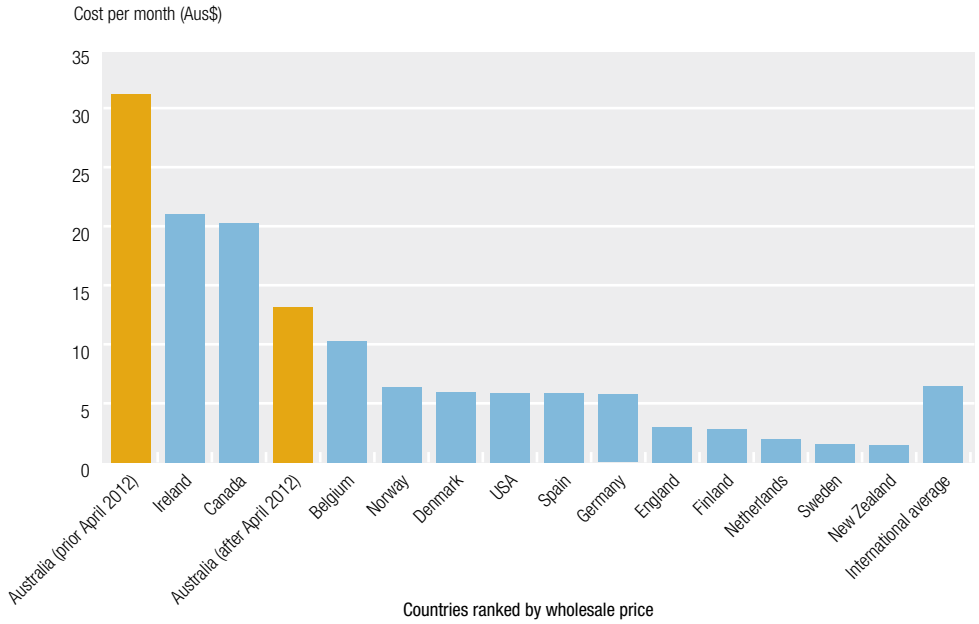
Source: Prices calculated from various PBS schedules and for England from Category M price lists.

in England and used this to compare against 13 countries, including Australia.[26] At current exchange rates, overall prices in Australia are higher than in all other countries except for Germany and the United States. For example, prices are 40 per cent higher than in the UK. While some of the difference is the high exchange rate, even using a five-year average Australia is still paying higher prices amounting to more than $1.5 billion of extra government expenditure through the Pharmaceutical Benefits Scheme every year.

The major contributor to the higher prices are very substantial cost differences for many generic drugs. Figure 2 compares eight generics which were receiving the largest total subsidy under the PBS in 2011/12. The price differences range from around two (IRBESARTAN) to almost 30 times higher (Olanzapine) in Australia, with the average being around a ten-fold difference in prices. These eight drugs collectively amount to around $1.3 billion of Government expenditure per year and if Australia had paid prices equivalent to England, savings of more than a billion a year could have been attained.

A key driver of the higher prices has been the weak mechanisms for adjustment in the prices of drugs when their patent expires. It is instructive to examine changes in the price of simvastatin since the expiry of its patent in 2005. Figure 3 provides such a comparison of prices in England[27] and Australia. At the time of introduction of price disclosure, prices were around five times higher in Australia than England. While there have been price reductions the relative difference between the countries has been maintained. What it also illustrates is the hidden cost of the changes to the pricing system established under the MOU in 2010. Rather than continue to implement cuts flowing from the existing system of price disclosure, the Government agreed to holt these cuts for a two-year period and only impose small regulatory price cuts between two to five per cent for generic drugs until the new system came into effect in April 2012. The price we are currently paying for simvastatin follows its long term trend, so it is unclear how current policies have in any way “accelerated” price disclosure.

FIGURE 4
COMPARISON OF THE WHOLESALE PRICE OF SIMVASTATIN 40MG



Even after the first round of price disclosure, prices of generics are still high compared with other countries (see Figure 4). Australia's ranking in regard to the price it pays for Simvastatin has gone from highest to third highest.

Current state of play

Since the mid-2000s the patents of an increasing number of widely used pharmaceuticals have been expiring and many Governments in other countries have taken advantage of this dividend from the lack of technological change to dramatically lower prices of generics. In this context it is particularly hard to understand the policy objectives of the Australian Government's pharmaceutical pricing policy. It is six years since the introduction of price disclosure and generic prices are still vastly higher than those other countries overseas. Given the first Intergenerational Report highlighted the need for measures to reduce pharmaceutical expenditure a decade ago, it is unclear why successive Australian Governments have struggled to reduce the price of generic drugs.

There is surprising little public rationale for why the Australian Government entered into the MOU with Medicines Australia in 2010. Unlike patented drugs there is no need to negotiate with an individual monopoly supplier and governments in other countries that face high generic prices have undertaken major reforms without an explicit agreement from industry.[28] The Department of Health and Ageing website has an explanation that is just a few lines long. It mentions the "need to provide some certainty about pricing policy for the Australian pharmaceutical industry", while giving Australians access through the PBS to a wide range of pharmaceuticals "at the lowest possible prices for consumers".[29]

If it's an industry policy, paying more than a billion dollars a year extra on generics is an expensive one. In 2007 the industry claimed there were just over 14,000 jobs in pharmaceutical manufacturing in Australia, only a proportion of which are likely to be producing generics.[30] As these generic drugs were developed long ago, paying high prices for them is like assisting the Australian car industry by subsidising the price of second-hand cars. Policies that maintain high generic prices are an inefficient form of industry assistance and potentially highly distortionary. Why would a pharmaceutical company invest in any new research when there is such a high profit margin in Australia on selling generics? Further, if savings from reducing the generics are reallocated to fund the listing of new drugs the effect on pharmaceutical industry as a whole are likely to be relatively minor. While those firms selling generics will lose from pricing reforms, firms manufacturing new innovative products will gain as they will face much greater certainty about the timing of the listing of their products.

The pharmacy sector is also a major beneficiary of current policies, particularly since 2012 when atorvastatin came off patent. Pharmacists already receive very large taxpayer funded subsidies to provide services through the 5th Guild – Government Community Pharmacy Agreement which totals over $15 billion over five years.[31] Each billion dollars in discounts translates into an additional $200,000 per pharmacy – what additional services are they providing to justify these payments from Government?

The main losers from these policies are people with chronic diseases who must pay higher prices relative to other countries for many common medications. Take for example a person who is not eligible for a concession card, the cost of one year's supply of Simvastatin 40mg in Australia is around $275 (i.e. 12 months at $22.78 per month). To put this into perspective, in the United States a year's supply of the same drug could be purchased from a retail pharmacy for only $60.[32]

Lowering the cost of generics medications not only benefits consumers financially, but has the potential to significantly improve overall health as the prescribing of many generic medications should be expanded as their cost declines. Again taking cholesterol as an example, a large drop in its price should also be coupled with its much wider use. A recent synthesis of all major clinical studies suggests there is compelling evidence of benefit to lower risk patients[33] (Cholesterol Treatment Trialists' Collaborators 2012), but it is much less cost-effective to treat such patients if generic statins remain at high cost. Increasing the volume of generic prescribing of lower cost generics would also benefit the pharmaceutical industry and pharmacists.

Given this evidence it is hard not to conclude that current generic pharmaceutical price setting arrangements are subject to a high degree of regulatory capture and have a considerable negative impact on economic welfare.

Where to now?

The current pricing agreement with Medicines Australia is due to expire in July 2014. The Government has only indicated that it would enter into discussion with representatives from the Pharmaceutical Industry and the Consumers Health Forum to develop a framework for pharmaceutical pricing after expiry of the MOU.[34] To put the pricing agreement into context, the existing MOU involves the purchase of around $36 billion dollars' worth of pharmaceuticals over its four year duration. The one-off cost of purchasing or constructing submarines to replace the Collins Class has been estimated to be around the same amount. In the May 2012 budget, the Government committed over $200 million to conduct studies to assist the decision on replacement submarines. There has also been an extensive discussion and analysis about the relative merits of purchasing submarines from overseas, or constructing them locally.[35] There has been no similar process of evaluation or debate around the purchasing of pharmaceuticals despite a potentially much larger ongoing cost. Nor is the generic pricing issue on the "to do" list of the Productivity Commission.[36]

If it is the aim of the current or a future Australian Government to reduce generic prices to levels that are comparable to the rest of the world there are a variety of policy options that could be pursued. At a minimum the existing system of price disclosure needs improvement. A key limitation of the Australian system is the slow rate at which prices are adjusted. The existing MOU specifies that each price disclosure cycle which is the period before which prices can be adjusted is 18 months. England also employs a system of price disclosure but it has quarterly rather than annual cycles. Reducing the price cycle to match that of England alone would save many hundreds of millions of dollars.[37] It is also unclear why the initial regulated price cut is only 16 per cent in Australia. When a generic is introduced its price typically declines more than 50 per cent in the first year.[38]

It is important to note, that existing recommendations for price reforms have not been implemented. After a recent review, the PBAC recently recommended fixing the price difference between atorvastatin and simvastatin to an average of 12.5 per cent. This review was in response to a request from the Australian Senate at the time it passed the MOU. While pharmaceutical manufacturers voluntarily cut the price of atorvastatin by 25 per cent, it is not sufficient to meet the PBAC recommendation and the Government has not enforced further cuts at a cost of $260 million annually for taxpayers and consumers.[39]

More substantive options to consider are use of external reference pricing or the introduction of a tending system especially for high volume generic drugs.

External reference pricing involves using a basket of prices from other countries as a benchmark when setting domestic pharmaceutical prices. It is widely used in Europe with 24 out of the 27 countries within the European Union using a form of external reference pricing.[40] While such an approach effectively transfers the determination of price setting to other markets (which may not experience the same conditions) its implementation would avoid the current situation where Australia pays some of the highest prices in the world for many generic drugs.

Tendering processes were pioneered in New Zealand by its Pharmaceutical Management Agency PHARMAC and these can dramatically lower the prices of generic drugs. For example Pfizer, manufacturer of Lipitor, recently won the tender to supply a generic version of this drug for between $1–$5 per month depending on dose. While in Australia the comparable ex-manufacturer price is currently between $18 and $54 per month. Tendering processes have been adopted in The Netherlands and Germany[41] and are already employed by state governments in Australia for the supply of pharmaceuticals for use in hospitals. Such a tender could be conducted at national level for the right to supply certain categories of drugs on the PBS.

A key difference between PBAC and PHARMAC is that the latter effectively manages a capped pharmaceutical budget in New Zealand. While in Australia the PBS is uncapped, the PBAC can only make recommendations that must be approved by Federal cabinet for any drug costing over $10 million. Given that such drugs have been through a rigorous economic evaluation by the PBAC before they are recommended, it is unclear on what basis the cabinet is making its decisions to approve or delay listings. In New Zealand PHARMAC can reallocate the savings from reducing prices of generics to list new drugs without an explicit cabinet approval. There are now several drugs such as the anti-coagulant dabigatran that have not been listed on the PBS despite positive recommendations by the PBAC,[42] but are subsidised in New Zealand.

To summarise, the purpose of this policy review has been to highlight deficiencies in the aspects of the PBS and to make the case for reform. It is highly inefficient for Australia to pay prices for generics that are often an order of magnitude higher than those in comparable countries such as England. In the current tight fiscal environment high generic prices greatly limits the scope for listing new therapies or expanding use of effective medications such as statins. Hence current policies have detrimental health as well as financial consequences. A necessary precondition for reform will be to instigate a policy development process that goes beyond limited stakeholder consultations to one that is open and transparent and explicitly considers the best long terms outcomes for *all* Australians.

Endnotes

1 Australian Government (2002) Intergenerational Report 2002–03 Budget Paper No. 5 of the 2002–03 Budget.

2 Costello P. (2002) APPROPRIATION BILL (NO. 1) 2002–03 Second Reading, 14 May 2002, Hansard.

3 These estimates were based on the historic Pharmaceutical expenditure series (Table 15b which can be downloaded from http://www.pbs.gov.au/info/statistics/expenditure-and-prescriptions-30-06-2012) deflated using the Consumer Price Index, series for Australia ABS 6401.0.

4 Pharmaceutical Benefits Advisory Committee (PBAC), (2007)PUBLIC SUMMARY DOCUMENT: Ranibizumab, solution for intravitreal injection, 3.0 mg/0.3 mL, Lucentis®, March 2007.

5 PBS Information Management Section (2012), Expenditure and prescriptions 12 months to 30 June 2012, Department of Health and Ageing.

6 Clarke PM. (2012b) No public benefit in price drop, The Australian, April 7 2012.

7 Hynd A, Roughead EE, Preen DB, Glover J, Bulsara M, Semmens J. "The impact of co-payment increases on dispensings of government-subsidised medicines in Australia." Pharmacoepidemiology and Drug Safety. 2008 Nov;17(11):1091–9. doi: 10.1002/pds.1670.

8 Kemp A, Preen DB, Glover J, Semmens J, Roughead E. How much do we spend on prescription medicines? Out-of-pocket costs for patients in Australia and other OECD countries. *Australian Health Review*; 2011; 35, 341-349.

9 As Medicare Australia website notes that it purpose of the PBS to: "The Pharmaceutical Benefits Scheme (PBS) gives all Australian residents and eligible overseas visitors access to prescription medicine in a way that is affordable, reliable and timely." (http://www.medicareaustralia.gov.au/provider/pbs/)

10 Department of Health and Ageing (2011), Submission to the Senate Finance and Public Administration References Committee. Inquiry into: the government's administration of the pharmaceutical benefits scheme, 15 July 2011.

11 Pearce, A.M., Van Gool, K., Haywood, P., Haas, M.R. 2012, "Delays in access to affordable medicines: putting policy into perspective", *Australian Health Review*, 36, 412–418.

12 Clarke PM. (2012a), Challenges and opportunities for the Pharmaceutical Benefits Scheme. Medical Journal of Australia; 196: 153–154.

13 National Institute for Health and Clinical Excellence. (2006) Statins for the prevention of cardiovascular events. Technology Appraisal 94. London: NICE.

14 Productivity Commission (2001) International Pharmaceutical Price Differences, Research Report, AusInfo, Canberra.

15 Henry, DA. Hill, SR. Harris, A. (2005) Drug Prices and Value for Money. The Australian Pharmaceutical Benefits Scheme, JAMA. 2005;294(20):2630–2632.

16 Searles A, Jefferys S, Doran E, Henry DA. (2007) Reference pricing, generic drugs and proposed changes to the Pharmaceutical Benefits Scheme. Medical Journal of Australia; 187: 236–239.

17 The PBAC recommended since 2005 a fixed differential between the price of atorvastatin and simvastatin of 12.5 per cent and so the price of atorvastatin should have fallen in line with declines in the price of simvastatin. However, this recommendation has not been implemented by successive Australian Governments.

18 Clarke PM, Fitzgerald EM. (2010) Expiry of patent protection on statins: effects on pharmaceutical expenditure in Australia. Medical Journal of Australia 2010; 192: 633–636.

19 Abbott T. (2006) Transcript of Press Conference – PBS reform commonwealth parliamentary offices, Sydney, 16 November 2006.

20 Australian Government and Medicines Australia. Memorandum of Understanding. September 2010. http://www.pbs.gov.au/industry/usefulresources/ memorandum/MOU-MA-Sep2010.pdf (accessed Jan 2013).

21 The degree of discounts flowing from the first round of Extended and Accelerated Price disclosure for many drugs was greater than that that foreshadowed by the Pharmacy Guild. As they noted in a comment on the earlier system of price disclosure "This initial announcement confirmed what those in the sector have been saying for several years – that significant trading terms by manufacturers to community pharmacies is not the norm." Pharmacy Guild (2008) PBS Price Disclosure, Information Sheet..

22 Medicare Australia. (2011) Explanation of PBS pricing. Canberra: Australian Government, 2011. http://www.medicareaustralia.gov.au/provider/pubs/ program/files/2526-explanation-of-pbs-pricing.pdf (accessed Feb 2012).

23 Australian Government Department of Health and Ageing. National Health (Weighted average disclosed price – main disclosure cycle) Determination 2011(No. PB 80 of 2011). http://www.comlaw.gov.au/Details/F2011L02702 (accessed Jan 2012).

24 Davey M. (2012) "Pharmacists use loophole to boost profits" Sydney Morning Herald, 22 March 2012, p.1.

25 There have been three bilateral international price comparisons of drug prices undertaken by Australian researchers: Bulfone L. (2009) High prices for generics in Australia - more competition might help. Australian Health Review; 33: 200-214.Spinks, J., Richardson, J., (2011), Paying the right price for pharmaceuticals: A case study of why the comparator matters, Australian Health Review, vol 35, issue 3, CSIRO Publishing, Collingwood Vic Australia, pp. 267-272; Duckett, S.J. Breadon, P., Ginnivan, L. and Venkataraman, P., (2013), Australia's bad drug deal: high pharmaceutical prices, Grattan Institute, Melbourne. All have shown Australia pays more for generic drugs.

26 O'Neill, P., Puig-Peiró, R., Mestre-Ferrandiz, J. and Sussex, J. (2012) International comparisons of medicines prices, 2011 indices, methodology and results. Consulting Report. London: Office of Health Economics.

27 It should be noted that patent for Simvastatin expired in England in 2003.

28 Take for example reforms to prices in Canada which is also a country that has also paid high prices for generic drugs. Reforms have been implement without an industry agreement: http://www.theglobeandmail.com/globe-investor/pharmacies-take-hit-as-ontario-cuts-generic-drug-payments-again/article4170794/

29 http://www.pbs.gov.au/info/industry/useful-resources/memorandum.

30 Medicines Australia (2007) Australian pharmaceutical industry at a crossroad? Report Of The 2007 Medicines Australia Member Economic Survey.

31 Pharmacy Guild 2010. Details of the agreement can be found at: http://www.health.gov.au/internet/main/publishing.nsf/Content/fifth-community-pharmacy-agreement-copy

32 Many large retail pharmacies in the USA have several hundred generic medications available for a few dollars per month. For example the pharmacy chain Rite Aid list 400 generic drugs at $16 for 3 months' supply (http://www.riteaid.com/pharmacy/rx_savings.jsf)

33 Cholesterol Treatment Trialists' (CTT) Collaborators (2012) The effects of lowering LDL cholesterol with statin therapy in people at low risk of vascular disease: meta-analysis of individual data from 27 randomised trials, *The Lancet*, Volume 380, Issue 9841, Pages 581–590.

34 See http://www.pbs.gov.au/info/news/2011/09/pbs-deferrals-statement-of-principles-of-commitment.

35 See for example Cowan, Simon. (2012) Future submarine project should raise periscope for another look. CIS Policy Monographs, 130.

36 Banks G. (2012) Economic and Social Outlook Conference, 'Securing the Future', Melbourne, 1 November 2012.

37 Another important reform is to remove section 13(f) of the MOU in which the first month data for any new brand is collected but not used in calculating the weighted average price. This clause has resulted in some manufacturers selling up to a year's supply to pharmacies in the first month to avoid these discounts flowing through to lower prices in future.

38 Kanavos et. al. 2011 Figure 9, p. 27 indicates that among EU Member States the reductions ranged from 55 per cent (Italy) to 90 per cent (Denmark and Sweden).

39 Clarke PM. (2013) The pricing of statins and implications for Pharmaceutical Benefits Scheme expenditure, Medical Journal of Australia, 198(5).

40 Kanavos P. Vandoros S. Irwin R. Nicod E. and Casson M. (2011) Differences in costs of and access to pharmaceuticals, Report for the Policy Department A: Economic and Scientific Policy of the European Parliament.

41 Kanavos, P., Seeley, L., and Vandoros, S. 2009, Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands, Germany and Belgium. LSE Report.

42 Sansom L. (2012) Review of Anticoagulation Therapies in Atrial Fibrillation, Report for the Department of Health and Ageing.

4. Ensuring Australia's comparative advantage in biotechnology

Dr Anna Lavelle

This chapter examines Australia's comparative advantage in medical research, export opportunities and challenges and the policy changes needed to support innovation.

Dr Anna Lavelle was appointed inaugural Chief Executive Officer of AusBiotech in June 2005. Previously Dr Lavelle was an Executive with the Australian Red Cross Blood Service (ARCBS) commencing in 1998 as Director responsible for Strategic Planning and Business Development.

In 2002, Dr Lavelle was appointed Director of Intellectual Capital and was responsible for management of the national research and development program, evaluation of emerging technologies and international and national business development activities including technology transfer and intellectual property management.

Prior to joining ARCBS, Dr Lavelle held positions of Chief Executive Officer of a public health organisation, industry lobbyist for a member organisation and was an academic at Monash University, Melbourne. Dr Lavelle holds a Doctor of Philosophy in Genetics from the University of Melbourne.

"Biology is likely to become the greatest single driver of the global economy...The life code is a lever and perhaps the most powerful instrument human beings have ever used. It will make the Industrial Revolution seem simple, even quaint. It will become the world's dominant language, and all of us will have to be literate to thrive."

Juan Enriquez
Managing Director at Excel Venture Management and Founding Director of Harvard Business School's Life Sciences Project. He also serves on a number of boards including The Genetics Advisory Council of Harvard Medical School and The Chairman's International Council of the America's Society.

Since its emergence in the early to mid-90s, the biotechnology industry in Australia has achieved a great deal in its short and productive history.

Respected commentators and intellectuals agree that biotechnological innovation is the foundation-stone of our future, and a game changer. It is anticipated that it will underpin our economy and provide solutions to intractable problems of human and animal diseases, climate change, fuel alternatives, food security – as well as improving our quality of life.

Despite the challenges of the global economy and the degree of difficulty in building a biotechnology and life sciences sector from scratch, Australia is doing very well by any comparative measure, with an impressive return on investment from a maturing stock of quality companies. Australian biotechnology boasts a raft of success stories and a world-class industry.

Australia is already a leading location for biotechnology companies with over 900 biotechnology companies (400 therapeutics and diagnostics and 500 – 900 medical technology companies)[1]. The Australian biotechnology sector is still dominated by human therapeutics companies, but encompasses the fast-growing sectors of agriculture, food technology, medical devices and diagnostics, industrial applications and cleantech.

With respect to industry credentials, there are currently 100 ASX-listed life sciences companies, with a market capitalisation of $40.7 billion.[2] In a global context, the Australian biotech sector boasts the largest listed biotechnology sector as a proportion of GDP in the world[3].

In addition, the PricewaterhouseCoopers 10 year report[4] shows the Australian Life Sciences Index has consistently outperformed the NASDAQ Composite Index and the All Ordinaries since mid-2006. Despite the GFC and the reduction in venture capital availability, biotechnology has delivered to investors.

Take away the three majors from the Life Sciences Index and in 2008 the Index parted ways with the All Ordinaries and has dramatically out-performed it since, almost quadrupling its performance in the latest reading. In four years the often-cited index has failed to come anywhere close to biotechnology's SME performance.

"In a global context, the Australian biotech sector boasts the largest listed biotechnology sector as a proportion of GDP in the world."

The NASDAQ Biotech Index, perhaps the best comparative measure of US biotechs, hit a 12-year high in July, but is nevertheless trailing behind the performance of the Australian Life Sciences Index. Admittedly the Australian stocks have come off a lower base but the result demonstrates that a portfolio approach is an attractive investment option.

Australia's comparative advantage comes from its world-class science and medical research, its capacity for international partnerships, cost effectiveness, and a transparent and effective regulatory system. More recently the Federal Government has introduced a research and development tax incentive, which is attracting global investor attention.

Times have changed since we perceived ourselves as an industrialised country or simply a mine and a farm. We now prefer to think of ourselves as a smart country, where we compete on a world stage in the knowledge economy. Along with the trend in all developing and growing countries, the shift from industrialisation to the service and knowledge industries is well underway. For example, the factors of production in the 20th Century – land, labour and capital – have been superseded in the 21st Century by creative, human and social capital. We live in a time where technological innovation, knowledge and networking are the drivers of our productivity. Australia has expertise in these areas that could and should be leveraged to our economy's advantage.

Jobs of the future will be found in innovative industries like biotechnology. The biotechnology industry already provides an estimated 40,000 direct Australian jobs[5] in the biotech and pharmaceuticals sector, plus at least 10,320[6] in the medical technology sector. In addition, there are many thousands of direct jobs in the agricultural and industrial biotechnology sectors and indirect jobs in dependent

areas such as clinical trial teams, high-tech manufacturing, medical research and supplies to the medical technology sector and in services such as those provided by patent attorneys. Innovative industries provide high-skilled jobs with long term prospects.

When it comes to fundamental discovery in science and biomedical research, Australia is a legitimate and impressive global contributor, producing three per cent of the world's research publications with only 0.3 per cent of the population. However, our ability to translate this strength into tests, cures, treatments and vaccines to benefit the Australian community could be so much better than it is currently.

The Global Innovation Index[7] ranks Australia 13th in terms of innovation input and 31st in innovation output. Impressive, but when these figures are converted to an innovation efficiency ratio of output over input, Australia dives to a ranking of 107 out of 141 countries assessed. This stark measure shows that Australians are brilliant at coming up with ideas but inefficient at translating them into products.

"When it comes to fundamental discovery in science and biomedical research, Australia is a legitimate and impressive global contributor, producing three per cent of the world's research publications with only 0.3 per cent of the population."

In a recent submission to the (McKeon) Strategic Review of Health and Medical Research on how to increase the levels of commercially sponsored translation of research, the Association of Australian Medical Research Institutes (AAMRI) used triadic patents to measure commercialisation success, as these patents are registered for the same invention in the US, Europe and Japan. AAMRI found Australia ranks 20th in the OECD in terms of triadic patents per capita, which accounts for less than 0.8 per cent of the world's triadic patents.

AAMRI said: "Australia's commercial translation of Government-funded research is poor by international standards…This represents tens of thousands of inventions not capitalised on each year, and means as a nation we are losing out on returns on our investment in research in terms of attracting private and foreign investment for product development, profits from the sale of products, taxation revenue, and patient benefits."

So why is Australia's performance so poor in translating its demonstrated advantage in the area of biotech innovation into products and services for the community?

One often-cited reason is the poorly-targeted and under-resourced government programs for commercialisation, particularly at the early stages of company development. Australia's biopharmaceutical industry outperforms the wine or automotive industries' exports and yet there is still little industry support for commercialisation in the life sciences sector.

The Federal Government spends more than $8 billion annually[8] on research and experimental development, with about 98.5 per cent provided to the research end of the spectrum, leaving only about 1.5 per cent of that spent on commercialisation: translating the research into products. It is estimated that half of the commercialisation funding goes to the automotive industry.

It's often said in industry circles that the Australian Government is good at supporting the research end of the R&D spectrum, but the development end is continually left wanting. Different types of government support is needed, from direct industry assistance to business environment changes like taxation and reduced compliance costs.

It takes a minimum of 6.3 years for evidence to reach peer-reviewed publication, followed by an average of 9.3 years to implement the evidence into clinical practice. It takes an average of 12 years and $1 billion dollars to bring a medicine from discovery to regulatory approval. This is an area that requires long term and patient investment, well beyond the scope of an electoral cycle.

In reality Australia's manufacturing cannot compete on high volume, low cost manufacturing, especially with Asia. However, we do have a competitive and comparative advantage in high tech, high cost, low volume manufacturing, for example as is used in the production of elaborately transformed goods such as medical devices and biologics (large molecule pharmaceuticals), which are the future of medicines.

Australia's comparative advantage is shining through as pharmaceutical manufacturing exports are on the rise. Pharmaceuticals have officially taken over as Australia's number one export, with $4.1 billion in 2011–12. This is substantially more than the car industry at $2.8 billion and more than double the wine industry at $2 billion, for the same period. This illustrates the economic significance of the sector to Australia and provides a very different view from 20 years ago.

While there is huge sympathy for those whose jobs are under threat as Australia structurally changes, the fact remains that the shift from the industrial revolution to the knowledge revolution is irreversible and pervasive. The macroeconomic shifts will bring different opportunities in the future and if we can plan and re-train appropriately, all Australians will benefit across the spectrum of jobs.

Manufacturing can and will play a role in the future prosperity of Australia by providing diversity that will underpin the economy with added strength and greater resilience, if we are able to let go of our traditional views and re-shape our thinking to play to our comparative strengths. That strength is in niche pockets of high-tech manufacturing; it's in our science and medical research capabilities; it's in our ability to incubate innovative companies that return benefits to our economy as well as our lifestyle. This path will lead to a more sustainable future and new industries and employment opportunities.

As we as a nation position ourselves and build for the future as best we can, there appears to be a growing disconnect between the rhetoric – what we say we believe will be good for our future – and Australia's public policy actions.

As the window of mining-driven prosperity shows signs of closing, it is widely acknowledged that building Australia's capacity as a technologically innovative country is vital for our economic future. We largely agree that high-tech industries generate globally competitive economies and sustainable jobs.

The introduction of the $1.8 billion Research and Development (R&D) Tax Incentive program legislation last year was a momentous and pivotal inflection point for Australian innovation; the type we as a community will look back on in admiration and congratulate its architects' foresight. It was the culmination of years of campaigning and planning that was initially flagged as part of the Australian Innovation Review of 2008, known as the Cutler Review.

The specifically-targeted program offers a 45 per cent cash refund for eligible research and development for companies with turnover under $20 million and a 40 per cent offset for other companies.

Funds are now flowing back into the industry, particularly to small companies in the technology sector, to be re-invested, and the interest of overseas investors has grown rapidly, leading to increased foreign direct investment in Australian companies.

Disappointingly, less than two months after the Incentive's application form was released last year, the 40 per cent offset was under threat, from the Treasury-appointed Business Tax Working Group. The Group recommended the reduction or removal of the offset as a trade-off for a corporate tax cut. Industry representatives, including AusBiotech, opposed the plan and the Group abandoned its plan to wind back the program. Since then, the February 2013 launch of the Federal Government's innovation and industry plan included the capping of the offset to exclude companies with turnover over $20 billion.

"While governments around the world are making strong and large commitments to build the foundation stones of innovation-driven economies, Australia is consulting. Countries as diverse as the UK, Israel and China, understand the need for nation building based on innovation and have made strong commitments."

The episode underscores a huge problem for industry: the uncertainty that is being created by continual government consultations on the same issues, such as patents, and sudden policy changes. The negative impact that uncertainty of policy and funding support has on product development/innovation companies is terribly destabilising and the Government's actions in making program changes cause substantial costs to business, in practical terms.

While governments around the world are making strong and large commitments to build the foundation stones of innovation-driven economies, Australia is consulting. Countries as diverse as the UK, Israel and China, understand the need for nation building based on innovation and have made strong commitments. They understand the need for long term, uninterrupted, cleverly-targeted government investment based on intelligent planning and bipartisan support.

Amid the raft of Federal Government consultations and reviews in recent months, a record number of which impact biotechnology, the Strategic Review of Health and Medical Research in Australia, also known as the *McKeon Review* released a discussion paper after the first phase of its consultation. Its job was to recommend a 10-year strategic health and medical research plan for the nation, which it did at the end of 2012. While the final report is currently being considered by

Government before publication, it is expected to reflect the draft report, which called for at least three per cent of Australian and state and territory government health expenditure (an additional $2–3 billion per year) over the next 10 years to be invested in research to deliver a better health system.

Like its response to the Cutler Review of innovation, AusBiotech warmly welcomed the draft report's recommendations, particularly the themes in regard to the translation of research outcomes into health and economic benefits for the Australian community. The biotechnology community welcomed the well-articulated plan to build our nation's healthcare, although the industry would like to see stronger commercialisation recommendations and a commitment to implement them.

AusBiotech recently responded to the Prime Minister's Science, Engineering and Innovation Council (PMSEIC), Chaired by Professor Chubb, which asked:

> *"What are the top breakthrough actions that the Commonwealth and state/territory government, research agencies, universities and the business community can take to utilise Australia's substantial research capability to contribute to national productivity growth through innovation?"*

AusBiotech made a submission recommending the following actions be addressed:

1) Articulating innovation as a priority

There is a need for governments to consistently articulate the importance of innovation to our future and how we see ourselves as a nation. It will take time to permeate, but if that attitude can flow through governments to the general public, then it will mean a substantiative change in the way we approach investment in high-technology industries, such as scientific and medical research.

Improving innovation in Australia requires it to be placed as and talked about as a national priority, particularly by governments. We have a strong education system, stable government, good regulatory and legal environment and a proven track record in innovation – although this is not widely known.

In contrast, Australians and often their governments still perceive their future nation more as a mine, farm or factory. Take the recent report by the Prime Minister's Manufacturing Taskforce. While the report gives a cursory nod to advanced manufacturing in pharmaceuticals and medical devices, it proposes little to promote those high technology industries and a lot to save existing low technology manufacturers, which are clearly in decline.

2) Reforming how we measure success

Currently poor value is allocated to the translation components of the R&D spectrum, particularly in relation to patents and associated activities. The existing reward system mitigates against translation with academics recognised and rewarded for publications, while patents and broader industry experience are not valued as an equal or celebrated measure of success.

It is recommended that the National Health and Medical Research Council (NHMRC) reform to encourage translational research, without jeopardising basic discovery. The NHMRC manages over $780 million a year, and competition for project grants and fellowships is fierce. Therefore whatever criteria it places on awarding funding, become the goals for most medical researchers in this country.

Because the NHMRC's remit is about supporting health and medical research, not health and medical commercialisation, the metrics of success are typically academic. Any time spent producing patents, working with industry or spinning off a biotechnology company is time not spent publishing papers in top tier journals. And less publications means less money for researchers. As a result, indirectly, the Australian medical research funding system punishes those who spend the time involved in commercialisation.

"We have a nonsensical situation where we fund a research project right up to the point where we can find the final answers: Does it in fact work or not, and is it a commercially viable discovery? And at that point, cease support, which makes no sense from a logical, from an academic, or from an economic point-of-view."

This doesn't necessarily mean wholesale changes to the way the NHMRC operates, or require explicit funding of commercialisation, but a simple change in the metrics used to evaluate funding applications could have a substantial impact in encouraging researchers to take their ideas out of the lab and into the market.

3) Proving the concept

The so-called "valley of death" could be bridged by moving a discovery from the point where it looks good on paper to where it looks enticing to an investor. This is the precipitous gap between the point a discovery is made, typically as a result of publicly-funded research, and the point where it is attractive enough to receive private funding to take it down the development pathway. Currently there is little capital available to fund this crucial step, meaning many potential medical breakthroughs remain dormant with respect to community impact.

This can be as simple as doing one pivotal proof-of-concept experiment – the "killer experiment" – that will reduce the risk of investing in a discovery to the point where an enterprising venture capitalist or angel investor might be willing to invest.

The current system fails at this point. We have a nonsensical situation where we fund a research project right up to the point where we can find the final answers: Does it in fact work or not, and is it a commercially viable discovery? And at that point, cease support, which makes no sense from a logical, from an academic, or from an economic point-of-view. A small proportion of funding to finish that process, and provide evidence of the science and the commercial concept, would be money well spent.

Something as simple as a "killer experiment" fund could go a long way to rectifying this situation. It could be run in a similar way to current NHMRC Development Grants, which are assessed centrally by peer-review. However it is managed, if

only a fraction of the dollars that are put into discovery research are contributed to providing proof-of-concept funding; this would enable small biotechs to better attract investors.

4) Expert critical mass

There are commercialisation units attached to virtually all universities and research institutions across the country. Their performance varies widely as many are understaffed and under-resourced.

Often they have to provide services to a startling array of technologies with only limited expertise in those areas. The problem is often one of never reaching critical mass of people, expertise and resources.

Once critical mass is achieved, then things can be radically different, as demonstrated by UniQuest, the commercialisation arm of the University of Queensland. Besides the well-known Gardasil vaccine, UniQuest has been involved in spinning out companies such as QRxPharma and ImpediMed. From an initial $10 million in funding, and using a "hub-and-spoke" model, it has delivered over $320 million in revenues over the past five years.

One way to help other institutions benefit from similar critical mass is to aggregate commercialisation organisations into clusters, each of which service multiple research institutions. Such a notion was recommended by the Association of Australian Medical Research Institutes in its recent submission to the McKeon Review of Health and Medical Research in Australia.

5) Supercharging investment

Another way to more effectively transform translational research in Australia is in accessing the tremendous wealth contained in Australia's superannuation funds. If only a tiny fraction of this money could be invested in biotechnology, it could give commercialisation a much needed "shot in the arm".

AusBiotech added its voice to the growing chorus of eminent Australians who believe that the governments have a role to play in encouraging the superannuation industry to invest in next generation industries, which require a long term view of sustainability and growth.

Peter Beattie, quoted in *The Australian*[9], said:

> *"Australia's superannuation industry has a key role to play in innovation and may offer part of the solution.*
>
> *"In a time of relative prosperity, Australia should establish a pool of capital to invest in next-generation industries. Superannuation investment returns are taxed at 15 per cent. A fraction of a percentage of this should be invested in innovation translation and commercialisation, creating a knowledge-based economy and leading to jobs and wealth creation."*

Alan Dormer, Leader, Innovation for Services in Science at CSIRO, has argued publicly in *The Conversation*[10] that superannuation funds investing in innovation companies could be a win: win with both short and long term benefits.

Australia's fast-growing superannuation funds, the world's fourth largest pool of managed funds, totals $1.3 trillion at present and is expected to grow to $3 trillion by 2022, with the proportion of self-managed superannuation funds set to increase within the total pool.

At present, little of that money flows to innovation. This is largely because superannuation companies are highly constrained in terms of where they invest, and how much risk they're willing to take. They also often don't have the specialised expertise it takes to assess life science companies, or have the agility and opportunity to make small investments in individual companies. AusBiotech recommends a forum, which gathers key interests together, including the superannuation industry, the finance industry, and small innovative industries to talk about what vehicle could be designed that will be acceptable to the trustees of super funds and to superannuants, and would benefit innovation in this country.

> "With 2013 looming as another challenging year on the economic front, and uncertainty created by an election, the biotechnology industry pins its hopes on the vision and commitment of our country's policy makers and their will and capability for nation-building leadership."

In addition to AusBiotech's active stake in policy and advocacy activities, the organisation is supporting the industry with a range of projects. Of note is AusBiotech's international investment series and the most recent project is supporting the governance of boards to increase their attractiveness to investors.

AusBiotech Investment offers a comprehensive series of national and international investor events as a global platform for Australian life sciences companies to showcase their company's offering for partnership and investment. Biotechnology and mining are the only Australian industries to actively seek investment in this way and it has proven to be a successful formula.

At AusBiotech 2011, research and consulting firm, Insync Surveys, conducted an independent and confidential review[11] of the Australian Summit, which has been held annually since 2009.

While it's difficult to quantify, investors were asked to estimate the value of deals they expect from investment discussions they initiated at ALSIS 2011, and the actual value of deals that were done. The results show that between $33 and $99 million had been invested in the presenting companies as a result of the 2010 and 2009 events. At the conclusion of the 2011 event, $228 million worth of deals were in discussion, suggesting the Summit would generate substantially more investment than previous years.

The "Board Enhancement" project, which commenced in 2012, was designed to support and enhance the governance of boards of directors leading life sciences companies, with two documents. In addition to the best practice message that the project's resulting documents will provide to investors and others, it also, very importantly, seeks to support and build the capability and understanding of less experienced directors or those new to life sciences. Providing clear guidelines assists the company executive by reinforcing the necessary steps that the company and its directors will need to consider in its responsibilities.

What is well appreciated is that innovative, technically-focussed companies in the life science sector have different pressures, such as mandatory regulatory considerations and a different business cycle than many other industries. Therefore, directors of such companies do require additional knowledge, not generally learnt from available materials or taught in mainstream governance courses.

In partnership with the Victorian Government, the ASX, venture capitalists and company CEOs and chairs, the project will have two prongs (resulting in the two documents):

- Part 1: Update and reproduce a *Code of Best Practice* for use by innovative life science companies, which is now nearing completion; and
- Part 2: Produce a practical guide for directors of public and private life sciences companies.

With 2013 looming as another challenging year on the economic front, and uncertainty created by an election, the biotechnology industry pins its hopes on the vision and commitment of our country's policy makers and their will and capability for nation-building leadership. It also pins its hopes on the proven ability to attract overseas investment and to develop technology to a stage that represents value and opportunity for partners and ultimately the community.

References

Medical Research Institutes (AAMRI), 2012, submission to McKeon Review, http://www.aamri.org/library/news//aamri_response_to_mckeon_review_consultation_paper_oct_2012.pdf

IBIS World, 2005, *IBIS World Industry Report: Medical and surgical equipment manufacture in Australia*

Juan Enriquez, McKinsey, 23 Feb 2009, What Matters, 'How biotech with reshape the global economy', http://www.whatmatters.mckinseydigital.com/author/juan+enriquez

Strategic Review of Health and Medical Research in Australia, 2012, http://www.mckeonreview.org.au/

Endnotes

1 Innovation Dynamics, 2008, BioIndustry Review – Australian and New Zealand.

2 BioForum, Feb 2013, PricewaterhouseCoopers, Edition 40.

3 Beyond Borders: global biotechnology report 2011, Ernst and Young, http://www.ey.com/Publication/vwLUAssets/Beyond_borders_global_biotechnology_report_2011/$FILE/Beyond_borders_global_biotechnology_report_2011.pdf

4 BioForum, Spring 2012, PricewaterhouseCoopers, Edition 39, "Ten years on: volatility, value and resilience"

5 Commonwealth of Australia, 2008, Report: *Pharmaceutical Industry Strategy Group.*

6 IBIS World, 2008, *IBIS World Industry Report: Medical and surgical equipment manufacture in Australia.*

7 INSEAD, 2012, Global Innovation Index, http://www.globalinnovationindex.org/gii/main/2012rankings.html

8 Australian Bureau of Statistics, 2012, Research and Experimental Development, All Sector summary, Australia, 2008-09, http://www.abs.gov.au/ausstats/abs@.nsf/mf/8112.0

9 Peter Beattie, *The Australian*, 23 June 2012, "Our ideas, we should prosper from them", http://www.theaustralian.com.au/national-affairs/opinion/our-ideas-we-should-prosper-from-them/story-e6frgd0x-1226405826722

10 Alan Dormer, *The Conversation*, 13 June 2012, "Preparing for the end of the boom: should super funds invest in science and innovation?", http://theconversation.edu.au/preparing-for-the-end-of-the-boom-should-super-funds-invest-in-science-and-innovation-6182

11 AusBiotech, 2012, on website, http://www.ausbiotech.org/content.asp?pageid=146

5. Traversing the valley of death

Dr Julian Clark

This chapter examines the "valley of death" in drug development and healthcare and opportunities to bridge the gap between academia and industry and in turn improve Australia's performance.

Dr Julian Clark is Head of Business Development at the Walter and Eliza Hall Institute and has more than 30 years of international experience in leading biomedical research enterprises. Building on senior executive experience in Europe, Japan, North America, India and Australia, Julian has been particularly active in translating business opportunities across the public-private interface. Julian is a Fellow of the Australian Academy of Technological Sciences and Engineering, has a PhD (University of Glasgow), and an Honorary Doctorate (University of South Australia). Julian has been a director or CEO of several biomedical companies, is Chairman of the CSIRO P-Health Flagship Advisory Board, and a member of the Medical Research Commercialisation Fund Investment Committee (Brandon Capital).

Our challenge

Imagine an economy where rising healthcare costs present an economic burden rivalled only by the disease burden that they are failing to address. The US already invests more than 17 per cent of its GDP in healthcare; Australia is approaching 10 per cent of GDP. Imagine these same economies investing significantly in research but failing to reap rewards through approved products and therapies that help reduce the burden of health. No need to imagine, this is the reality of the therapeutic drug and vaccine industry where, in spite of more than a doubling in investment since the 1990s, new drug approvals have fallen by one half to only about 21 drugs per year[1] and the total industry cost has now reached a US$1.9 billion investment to achieve each approved new drug.[2] This sets the scene for the notorious “valley of death”, a wasteland of exceptionally poor productivity where potentially exciting research discoveries funded largely by taxpayers fall off the precipice on one side of the valley, fail to traverse the development terrain in the valley, and fail to make the onward journey to benefit patients.

The “valley of death” as a metaphor for economic failure is not restricted to drug development and healthcare, it is seen in many industry sectors such as engineering, chemical processes, ITC and automotive. The “valley of death” can be seen as a “chicken and egg” conundrum where manufacturers wait until there is a demonstrated demand before they develop and commercialise technologies, and buyers wait to see the product on the market before they demonstrate that they will buy it.[3] The challenge is so great that it is currently the subject of a House of Commons Public Enquiry in the UK.[4] Testimony to date shows that while the

"valley of death" appears universal to science, technology and engineering, each sector has its own challenges due to different responses to knowledge transfer, supply chain management, networks and standardisation.[5] Importantly, in evidence presented to the enquiry Sir John Chisholm observed that the biotechnology, biomedical and chemical process sectors remain highly fragmented while sectors based on engineering disciplines are more integrated.[6] This phenomenon was recognised in Japan a decade ago when there was a simultaneous rise in research spending and decline in global competitiveness for Japan based on a "valley of death" discontinuity between basic research and applications in many sectors.[7] The US Department of Energy cites the "valley of death" as being a major technology transfer challenge where failure to link the laboratory bench with the market results in "countless lost opportunities"[8].

We will now focus on the biomedical sector, particularly as it relates to therapeutic drug development. This focus is provided from the viewpoint of the author being a practitioner working internationally at the academic/industry interface for more than 30 years and having experienced many personal expeditions across the "valley of death". Critically, experience from such journeys reveals a major gap between the complexities of reality, and the relatively sparse academic and policy literature that attempts to address technology transfer across the "valley of death". Despite heavy investments of time and money, only 14 per cent of new health related scientific discoveries are applied to day-to-day clinical practice, meaning a wastage of 86 per cent, and translation takes an average of 17 years from discovery[9] when the life of a patent is normally 20 years. This sobering reality shows that there is little time to reap the rewards of an exclusive commercial monopoly provided by a granted patent.

Consequently, Australia's challenge is to creatively embrace, through a whole of sectors approach, the multiple key drivers that can reduce the impact of the "valley of death" through recognition of the broad challenges, and implement targeted actions.

The terrain

The "valley of death" is familiar to any researcher and entrepreneur who has tried to translate an invention into tangible outcomes and returns. It has been variously described as a technology transfer challenge[10], a Darwinian process selecting against uncompetitive innovations[11], and a challenge of supply chain risk management.[12]

Irrespective of these different perspectives, the "valley of death" is much larger than often portrayed. It is an economic rift valley that is wide and deep and made up of several valleys, each with different drivers and occurring at different stages. A tendency to focus on economic or policy intervention addressing only a single problem actually reflects the basic reductionist challenges of drug development – focusing on one drug for one target when biology works as a complex network of cross talking pathways, paralleled by our tendency to focus on a single economic

intervention when we are dealing with a curiously complex system. The following will show that the "valley of death" results from a complex system failure, and as such requires a systems approach to overcome.

While the "valley of death" is apparent in both the private and public sectors it is most marked in the public sector where we attempt to transfer high risk tolerance from the public account to a lower risk tolerance in the private capital investment sector in the absence of capital from either sector. In fact it is this mismatch of risk perception that creates the psycho-economic gap where a relatively small investment in proof of concept and intellectual property positions could lead to progression across the valley floor. Rather than naively thinking that venture capitalists will address the problem through an unlimited appetite for high risk, it is quite clear that investment decisions in the innovation sequence require a strong intellectual property position, including investment, and a proof of concept requirement that varies significantly between potential investors.[13] Such a conclusion means that, irrespective of the total public sector investment in healthcare, the distribution of the investment must be considered in the context of at least seed funds available to establish a robust intellectual property position and proof of concept to catalyse downstream investment.

The process and its challenges

The challenge of bringing a new drug to market spans many sequential stages – each one frequently a victim of the "valley of death" on the journey between bench research and clinical application. The journey starts with the drug target, which once discovered, must be validated both alone and increasingly in consort with other drug targets. As a consequence of the Human Genome Project and the rapid development of gene sequencing and expression technologies in the last decade, the system is almost "awash" with potential drug targets. Ironically, in the last decade or so this plethora of important basic but unvalidated information has led to the rise and success of "phenotypic drug screening" where the effect of a chemical compound is measured in terms of a biological outcome, such as stopping cell division, before the specific target has been identified[14]. This trend is particularly relevant to the context of the "valley of death" because the detailed understanding of the molecular mechanism of action of a drug required for proof of concept increasingly requires the depth of knowledge from the academic side of the "valley of death".

Then translation must occur whereby molecules that bind specifically to the target are constructed. These are not yet drugs but start the journey of proof of concept that must at least have data in credible animal models before further investment can be attracted.[15] This is the first "valley of death" because there are insignificant public funds available for proof of concept and a market that will not invest without proof of concept.[16] Now comes the second "valley of death" where preclinical development requires significant resources to optimise the candidate drug molecule, but in an environment where there is a decline in resources for skilled

clinician researchers who are vital for "design-in", ensuring that the drug design concepts address a clinical need, safely and efficaciously.[17]

We now have a major confounding factor – both of these valleys must be traversed with a strong intellectual property position, but unfortunately this is usually attempted in the face of inadequate funds for patent application and prosecution, and critical exemplifying evidence. At the very least the inventors must ensure a strong provisional patent application, have the resources necessary to exemplify the invention within 12 months, and then have the funds necessary to prosecute a PCT (patent cooperation treaty) application – usually beyond the means of most publically funded biomedical research groups.

The third "valley of death" is in fact a series of valleys as the candidate drug progresses through clinical trials. During these stages costs escalate dramatically and real safety and efficacy in human patients must be demonstrated. These stages put our knowledge of the drug, target and disease on full display, and the high attrition rates are testimony to major deficiencies that must be addressed through improved knowledge, better processes and sharper development decisions. The final "valley of death" occurs around the time of product approval. At this final hurdle, regulators may decide that the new drug has little benefit over existing options or may present unacceptable risks. Insurers may decide that the cost/benefit ratio is unacceptable and deny reimbursement. Once a product is approved then of course it will be subject to all the normal pressures of the market based on price, benefit, positioning, competition and intellectual property challenge.

"…translation of discoveries into patient benefits requires attention to resources, skills, interactions, regulations, decisions, and policy before we can successfully traverse the 'valley of death'."

Compounding the above process is the reality that translation has moved from a simple linear process into one that requires frequent iterations between "patient bedside and lab bench" similar to a practise well established in, for example, the aerospace industry. The drivers here are the increasing understanding that disease and patients must be stratified for effective therapy and the basis of this stratification is driven by molecular biomarkers – this being the genesis of personalised medicine. Consequently, we now require access to skilled molecular biologists, medicinal chemists, clinician researchers and molecular pathologists in a team environment never before experienced.

The scene is set – translation of discoveries into patient benefits requires attention to resources, skills, interactions, regulations, decisions, and policy before we can successfully traverse the "valley of death". Basic research requires resources and skills for proof of concept and an intellectual property position before being able to contemplate the journey to market. Patients and insurers need more cost effective treatments. Governments and company shareholders want greater certainty of returns from their investments.

Range of causes

The journey across the "valley of death" is intimately linked to the psychology and reality of risk, risk mitigation, understanding the drivers of project attrition and having the courage to invest on the basis of, initially at least, relatively little proof of concept data. By way of example, the Walter and Eliza Hall Institute recently embarked on a major drug discovery and development collaboration where industry experience would show that the initial chance of commercial success was only two per cent, i.e. a 98 per cent chance of failure. As a consequence of investment by the commercial partner, intellectual property was created, the project de-risked and after a successful phase one clinical trial the project now has a 25 per cent chance of reaching the market, based on previous experience. But this is still less than halfway across the "valley of death" and the Institute and its commercialisation partners still face a 75 per cent chance of failure based on market experience.

"A worsening of the medical 'valley of death' over the last decade is primarily due to two major compounding factors – inadequate early stage investment and declining clinician researcher resources."

The "valley of death" is clearly a complex economic and social phenomenon. There has always been a temptation to simplify analysis through reductionism and view the situation as being one of inadequate funds alone. For example, Beard *et al* report that the main contributor is inadequate funds "upstream" but not "downstream" and "a valley of death arises when there is more output at stage one than the private sector is willingly to fund at stage two"[18] thereby expecting fewer problems if the ratio of investment size to sunk costs is small.

A worsening of the medical "valley of death" over the last decade is primarily due to two major compounding factors – inadequate early stage investment and declining clinician researcher resources. The "valley of death" persists after nearly two decades due to inadequate discipline focus including pathology and physiology, pharmacokinetics, preclinical models, drug delivery and formulation, and clinical translation expertise – all implying serious flaws, invalid assumptions and inadequate knowledge before drug candidates enter the clinical translation stage.[19]

> *"The growing gap between the research and clinical enterprises has resulted in fewer scientists with a true understanding of clinical problems as well as scientists who are unable to or uninterested in gleaning new basic research hypotheses from failed clinical trials."*[20]

Another contributor to the "valley of death" is the lack of training and experience required for merger and post-merger integration of organisations that is a natural consequence of an industry sector under stress. More than 67 per cent of biomedical acquisitions fail and few are adequately trained in post-merger integration[21] and such mergers and acquisitions can have a negative impact right across the "valley of death" as organisations attempt to survive resources shortages and project failure. Barr *et al* have a different approach to addressing the "valley of

death" and stress the importance of the teaching of entrepreneurship and integrating it into the higher education curricula, having identified the contribution of failed teaching when it is not "real, intensive, interdisciplinary and iterative."[22]

Markham *et al* recognise the "valley of death" as a metaphor that suggests more resources on one side of the valley in the form of research expertise and early IP and on the other side product development and commercialisation expertise and resources. Importantly, they emphasise role behaviour in innovation, the dynamic set of relationships required to turn a discovery into an innovation and a product, and not just static positions.[23] Consequently, the "valley of death" is also due to cultural priority and strategic differences between academic, industry and government players that in turn contribute to translation inefficiencies.

> *"Despite their long-standing appetite for drug discovery, these sectors continue to advance largely as distinct constructs whose character and internal workings invite challenges and dissonances counter to their high-return synergism within a research-based discovery enterprise."* [24]

Other contributors to the "valley of death" relate to the importance of private sector price setting and the need for a return on investment, stimulating innovation activity, and the need for education of consumers[25] about the benefits of breakthrough products such as new therapeutics and vaccines. The problem of the difficulty of reproducing experimental results contributes to failure when traversing the "valley of death" but is rarely mentioned. Flawed experimental data with inadequate methodological description to enable reproduction contribute to the challenge at a scale much greater than previously admitted.[26]

High level Australian perspective

With a high public investment in research, a relatively low business investment in research, a small industry with few large players and risk discerning capital resources, it is reasonable to assume that Australia is particularly vulnerable to the "valley of death". Table 1 presents indicative metrics that illustrate aspects of the challenge. Australia has less than one half of the OECD level of patents on a population basis. When considered in the context of the relatively close relationship between academia and business in the US, Europe and Japan we may find some cultural rather than economic answers. Could it be that Sweden and Switzerland have a patenting rate four – five times greater than Australia because there is a long history of academic engagement in transferring technology and engineering innovations to industry? Could their success be partly due to a long history of joint academic/industry appointments and mobility between the sectors, something that rarely happens in Australia?

Residential patent applications in Australia are one half those in Sweden and one quarter those in the US. Australia's investment in research and development (R&D) is nearly 50 per cent below that of the OECD average, a metric exacerbated by Australia's even greater relative underperformance in the level of business R&D as a proportion of GDP. The OECD business investment in R&D is 60 per cent

greater than that in Australia. Swedish company investment in R&D is nearly three times that of their counterparts in Australia.

Australia's relatively high participation rate in global science publications, reflecting significant public investment in basic research, is matched by a venture capital industry underinvesting at a level around one quarter of the OECD average. Australia published nearly 60 per cent more scientific articles than the OECD on a population basis but has venture capital investment at one quarter of the level in the OECD. Even before exploring details, our challenge in traversing the "valley of death" is evident.

TABLE 1
INDICATIVE METRICS RELEVANT TO THE "VALLEY OF DEATH"

Metric	Australia	US	Sweden	Switzerland	Japan	OECD
Triadic patent families per million population [27]	18	53	80	108	117	43
Residential patent applications per $bn GDP [28]	3.7	17.8	8.2	5.5	82.2	n/a
Gross domestic expenditure on R&D (per cent GDP) [29]	1.8	2.6	3.7	2.9	3.4	2.8
Business expenditure on R&D (per cent GDP) [29]	1.0	1.8	2.8	2.1	2.6	1.6
Scientific articles per million population [29]	780	700	1,100	1,180	420	500
Venture capital investment (per cent GDP) [29]	0.04	0.20	0.23	0.13	n/a	0.17
Health expenditure (per cent GDP) [30]	9.2	17.2	9.3	11.5	8.2	n/a

With respect to innovation, Australia performs well below the OECD average, and most innovation is incremental with only seven per cent of SMEs and 12 per cent of large firms introducing new-to-the-market product innovations.[29] Of approximately 6.7 million patents in force globally in 2008, only 31,000 (0.5 per cent) were of Australian origin, although 108,000 (1.6 per cent) of the global total had Australia as a destination.[31] This is a major intellectual property trade imbalance that underpins our relative weakness in being able to traverse the "valley of death" and is contrary to our 4.4 per cent global share of highly cited scientific articles.[30]

Australia's competitive position has just become worse because underfunding of universities and medical research institutes means that funds that could be used to capture and nurture intellectual property and establish proof of concept will be increasingly diverted to funding generic infrastructure charges. It is well established internationally that each direct dollar invested in public research requires a further investment of 60 cents to fund infrastructure.[32] Unlike their US

counterparts for example, Australian medical research institutes have never had fully funded infrastructure and have typically had to divert returns on endowments and bequests into maintaining infrastructure at the expense of direct innovation investment. This situation has now spread to Australia's universities where the Federal Government has removed more than $1 billion from future university investment.[33] Such a major shortfall in funding Australia's public sector research will clearly result in a further erosion of our competitive position and increased casualties in the "valley of death".

"Such a major shortfall in funding Australia's public sector research will clearly result in a further erosion of our competitive position and increased casualties in the 'valley of death'."

What are the institutional barriers in Australia?

Experience working in the "valley of death" in Australia reveals several critical areas where we are less competitive than our peer economies, particularly with respect to the journey for publically funded biomedical and health research:

- Intellectual property: There are few resources for intellectual property protection, inadequate awareness of the importance of strong composition of matter claims and early stage abandonment due to a lack of financing partners. Patenting is not considered to be important enough to be funded through competitive research grants.
- Proof of concept: Basic research is relatively well funded in Australia. However, the system rapidly abandons the innovator needing to provide proof of concept. Such an investment is essential to attract further funding both public and private and in its absence a journey across the "valley of death" cannot even commence. Together with the lack of funds for patent protection this sets the scene for increasing underperformance, loss of competitiveness and economic wastage.
- Research infrastructure funding: The current reality of the highly fragmented Federal/state research funding industry is that medical research institutes and universities have increasingly fewer discretionary funds to invest in intellectual property and proof of concept. We have a system where our main research organisations are internationally handicapped due to the need to divert funds into infrastructure.
- Mobility and supply chain: Employment relationships, terms and sector culture in Australia do little to encourage significant two way mobility and dual appointments between the public and private sectors. As a consequence there is a limitation to sharing of experience and skills in translation, and a tendency to reinforce the disconnect that can occur between basic research, product development and commercialisation. The human resources challenge has also become greater due to an increasing reliance on recruiting international early career researchers, often of Asian background. This sets the scene for a two

fold human resource challenge – firstly a supply chain issue to address a pipeline of people to train in science, technology and successfully traverse the "valley of death", and secondly a cross-cultural experience and communication issue.

- Clinical translation resources: Translation of biomedical discoveries requires close engagement with the public hospital and health system. It is precisely this system that has suffered from years of declining investment in the translational research agenda in Australia's public hospitals. As a consequence there are insufficient experienced clinician researchers to help us navigate the "valley of death".

Benchmark initiatives

To date there have been no holistic initiatives that recognise the system's challenges presented by the "valley of death". However, recently the US has broadened its approach through two actions, albeit both in their infancy. The Cures Acceleration Network (CAN) has been established to address the chasm between basic scientific discoveries and treatments and specifically the issue of the early drug target validation stage in the "valley of death".[34]

Under this scheme it is proposed that the government funds grants and contracts up to $15 million per year to companies, academics and patients to help bridge the "valley of death" as it relates to early translational challenges.[35] CAN is authorised to spend $500 million per year through partnership awards that require matching funds at the rate of one non-federal dollar per three dollars of NIH award, and smaller grants that have no requirement for matching funds.[36]

The Clinical Translational Science Awards (CTSA) initiative also funded by the US National Institutes of Health in many ways complements the CAN program by focussing on skills development.

Major goals are:

- To solve complex problems by supplying cost effective research support such as bioinformatics;
- To encourage career development of investigators interested in translational research;
- To work collaboratively so as to improve and reengineer the clinical research enterprise; and
- To maximise results by partnering with for-profit and non-profit institutions in order to advance medical discoveries.[37]

Thirdly, such is the power of the concept that the "valley of death" is the cause of the stalling of the pharmaceutical industry pipeline, that it has recently led to the structural reconfiguration of the NIH to create the National Centre for Advancing Translational Sciences (NCATS) which was authorised by US congress in December 2011 with a 2012 budget of US$574 million.[38]

To date there have been some significant initiatives in Australia that have made a positive contribution to reducing wastage and attrition across the "valley of death". An example is the creation of the Medical Research Commercialisation Fund (MRCF) managed through Brandon Capital. The MRCF is driven by an academic membership model and invests at an earlier stage in biomedical research than any other current source of capital in Australia. While the MRCF does not have the scale to address the nation's "valley of death" it has to date been a very successful vehicle, investor and developer of commercial translation skills.

In parallel, Australia has a pioneering example of an academic/business consortium specifically created to bridge the "valley of death" for the development of new cancer treatments – the Cancer Therapeutics Cooperative Research Centre.[39] This organisation has established global best practice in integrating disciplines, both basic and clinical, to maximise the chance of a successful journey across the "valley of death".

"This Catalyst Fund has to date returned more than three times the investment and has demonstrated that decisions to invest in proof of concept are best made when the decision is close to source. As a consequence several opportunities have been accelerated across the 'valley of death'."

The recent investment by the Victorian Government in the Molecules to Medicines business development intern scheme sets the scene for a potential national initiative that focuses on developing researcher's skills and capacity to navigate the "valley of death". This scheme is based on four year's experience at the Walter and Eliza Hall Institute in experiential training and mentoring of early career researchers in translation. In parallel the Institute has also successfully experimented with an internal early stage fund to establish proof of concept. This Catalyst Fund has to date returned more than three times the investment and has demonstrated that decisions to invest in proof of concept are best made when the decision is close to source. As a consequence several opportunities have been accelerated across the "valley of death".

Opportunities and actions

In spite of Australia's relatively weak skills and resources for traversing the "valley of death" there exist some important opportunities to improve performance.

Firstly, the "valley of death" should be specifically addressed as it relates to health and medical research in the McKeon Strategic Review of Health and Medical Research in Australia. An interim consultation paper from this review sets the scene with a recommendation for a more targeted distribution of funds to the translational arena[40] where clearly securing an intellectual property position and proof of concept are critical to a return on public and private investment.

Secondly, a significant opportunity exists for public/private partnerships being initiated by a relatively small university and medical research organisation investing in upstream activities that establish proof of concept and the beginnings of a

strong intellectual property position. The declining number of venture capital deals over the last three years and the ongoing global financial realignment has encouraged upstream academic organisations to invest in critical proof of concept and intellectual property securing activities.[41,42] Is this the beginning of a change in academic behaviour that could co-invest with government through decentralised "biomedical precinct" investment funds?

Thirdly, by addressing the issue of infrastructure funding for medical and health research Australia can become genuinely competitive in the quest to translate basic research findings into meaningful and effective clinical interventions. This action to support infrastructure funding must also be in the context of changes to the peer review process, greater funding for translational research, significantly more resources for training and early career support of potential clinician scientists.[43]

In this process we can build on the successful experience of the MRCF, expansion of the Molecules to Medicines intern training program, proof of concept investment schemes and a strengthening of the clinical research precinct strategy that is emerging across the nation. Each of these activities will help reduce cultural differences between academia and industry[44] and make academic researchers and their partners better equipped for translational research and the journey across the "valley of death". Downstream our efforts must focus on reducing fragmentation and overlapping regulatory reviews as well as harmonising and simplifying safety and licensing regulations.[45] Government intervention must be conditional on a multifaceted program to address the issues specifically of securing intellectual property and proof of concept and a belief that such intervention at an early stage is vital.[46] Intelligent government support at the beginning of the journey into the "valley of death" would greatly catalyse the prospects of success, clinical benefit and community return.

Endnotes

1 Williams RS, Desmond-Hillman S (2011) Making translation work. Science 332:1359

2 Mestre-Ferrandiz J, Sussex J, Towse A (2012) The R&D cost of a new medicine. London: Office of Health Economics (www.fiercebiotech.com/press-releases/new-ohe-study-pharmaceutical-rd-costs-released

3 European Commission Directorate General Environment (2009) Bridging the valley of death: public support for commercialisation of eco-innovation (www.cowi.com)

4 UK Parliament (2012) www.publications.parliament.uk/pa/cm201213/cmselect/cmselect/uc348-ii/uc34801.htm

5 House of Commons (2012) Bridging the valley of death: improving the commercialisation of research. Science and Technology Committee (www.parliament.uk)

6 Engineering the Future (2012) Bridging the valley of death: improving the commercialisation of research. Frances.downey@raeng.org.uk

7 Normile D (2002) Japan asks why more yen don't yield more products. Science 296: 1230–1231

8 US Department of Energy (2010) Accelerators for America's future. www.acceleratorsamerica.org; www.sceince.energy.gov

9 Pozen R, Kline H (2011) Defining success for translational research organisations. Sci Transl Med 3(94):1–5

10 Frank C, Sink C, Myatt L, Rogers R, Rappazzo A (1996) Surviving the valley of death: a comparative analysis. Journal Technology Transfer 21:61–69

11 Auerswald P, Branscomb (2003) Valleys of death and Darwinian seas: financing the invention to innovation transition in the United States. Journal Technology Transfer 28:227

12 Golda J, Philippi C (2007) Managing new technology risk in the supply chain. Intel Technology Journal 11:95

13 Ford GS, Koutsky TM, Spiwak LJ (2007) A valley of death in the innovation sequence: an economic investigation. Phoenix Centre (www.phoenix-center.org) for US Commerce Department Contract SB1341-0520023

14 Swinney DC, Anthony J (2011) How were new medicines discovered? Nature Rev Drug Disc 10:507–519. In the period 1999–2008, 62 per cent of approved first-in-class small molecule drugs originated from phenotypic rather than targeted approaches

15 Animal models are indicative only and assumptions that they are relevant to humans must be verified at a very early stage in the journey across the "valley of death"

16 For example, in Australia there are totally inadequate funds to translate biological discoveries through the early stages of High Throughput Chemical Screening and hit-to-lead medicinal chemistry required to establish proof of concept *in vitro* and *in vivo*

17 At this critical step of "design-in" (or fit for purpose) two major highly linked resource shortages conspire to result in either poorly understood drug candidates or death of the opportunity – few resources for drug optimisation in the context of clinician researcher input

18 Beard TR, Ford GS, Koutsky TM, Spiwak LJ (2009) A valley of death in the innovation sequence: an economic investigation. Research Evaluation 18(5):343–356

19 Adams DJ (2012) The valley of death in anticancer drug development: a reassessment. Trends Pharmacol Sci 33(4):173–180

20 Roberts SF, Fischoff MA, Sakowski SA, Feldman EL (2012) Perspective: Transforming science into medicine: how clinician-scientist can build bridges across research's valley of death. Acad Med 87(3):266–270

21 Paul M (2008) A walk through the valley of death. Nature Biotech 26(7):833–834

22 Barr SH, Baker T, Markham SK, Kingon AI (2009) Bridging the valley of death: Lessons learned from 14 years of commercialisation of technology education. Acad Management Learning Education 8(3)370–388

23 Markham SK, Ward SJ, Aiman-Smith L, Kingon AI (2010) The valley of death as context for role theory in product innovation. J Prod Innov Manag 27:402–417

24 Janero DR (2012) Productive university, industry, and government relationships in preclinical drug discovery and development: considerations toward a synergistic lingua franca. Expert Opin Drug Discov 7(6):449–456

25 Weyant JP (2011) Accelerating the development and diffusion of new energy technologies: Beyond the valley of death. Energy Economics 33:674–682

26 Begley CG, Ellis LM (2012) Drug development: raise standards for preclinical cancer research. Nature 483:531–533

27 OECD (2008) Compendium of patent statistics. www.oecd.org/sti/innovationinsciencetechnologyandindustry/oecdpatentdatabases.htm

28 WIPO (2010) World IP indicators (www.wipo.int/ipstats/en/

29 OECD (2008) OECD Science, Technology and Industry Outlook www.oecd.org/publishing ISBN 978-92-64-04991-8

30 OECD (2010) Measuring innovation: a new perspective ISBN 978-9264-95947

31 WIPO (2010) World IP indicators. www.wipo.int/ipstats/en/

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

33 Universities Australia. Media release 23/12 ($1 billion lost fro future university investment) www.universitiesaustralia.edu.au

34 Schreiber SL (2011) Organic synthesis toward small-molecule probes and drugs. Proc Nat Acad Sci US 108(17)6699-6702

35 Kaiser J (2010) Health bill backs evidence-based medicine, new drug studies. Science 327:1562

36 Nabel EG (2010) On board with the Cures Acceleration Network. Sci Transl Med 2(32):1

37 Portilla LM, Evans G, Eng B, Fadem TJ (2010) Advancing translational research collaborations. Science Trans Med 2(63):1 4

38 Kahn JD (2012) Connecting the dots in translational research. Nature Rev Drug Disc. Sep 24, doi:10.1038/nrd3357-c2

39 Moran N (2007) Public sector seeks to bridge valley of death. Nature Biotech 25(3)266

40 McKeon S (2012) Strategic review of health and medical research in Australia: consultation paper summary issues and proposed recommendations. (October 3, 2012) www.mckeonreview.org.au/10857/Consultation_Paper/

41 Christini A (2012) Why universities should step up in venture investing. Nature 30(10): 933–936

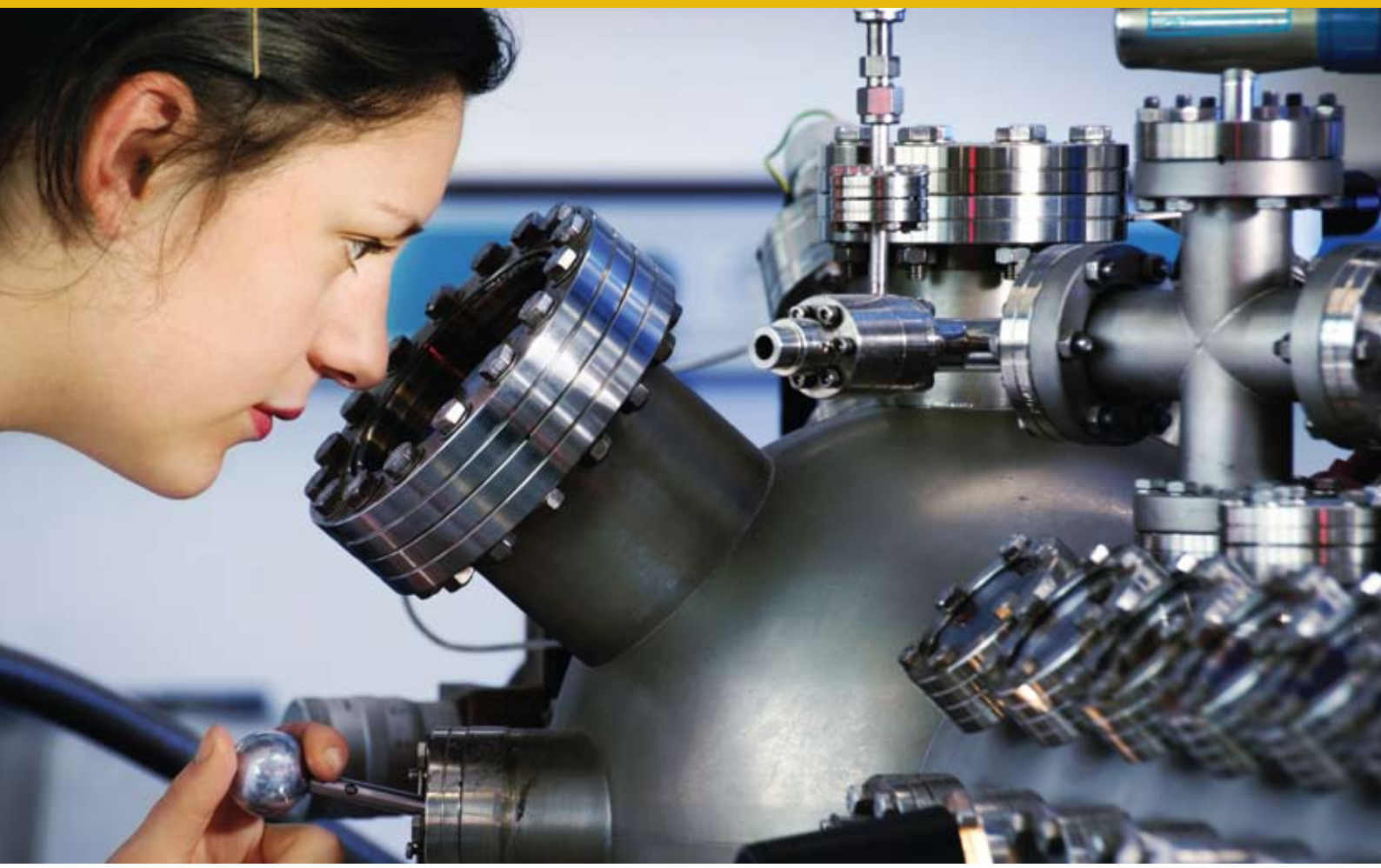
42 Coller BS, Califf RM (2009) Traversing the valley of death: a guide to assessing prospects for translational success. Sci Transl Med 1(10):10

43 Roberts SF, Fischoff MA, Sakowski SA, Feldman EL (2012) Perspective: Transforming science into medicine: how clinician-scientist can build bridges across research's valley of death. Acad Med 87(3):266-270

44 Finkbeiner S (2010) Bridging the valley of death of therapeutics for neurodegeneration. Nature Medicine 16(11)1227-1232

45 Frederickson RM (2012) Escaping the valley of death. Mol Therapy 20(3):476–478

46 Wessner CW (2005) Driving innovations across the valley of death. Res Technol Management January–February:9-12



6. Why STEM skills are important for innovation

Professor Ian Chubb AC

This chapter examines the importance of science, technology, engineering and mathematics (STEM) skills and how to address the potential shortfall of these skills in Australia.

Professor Ian William Chubb, AC, MSc, DPhil (Oxford), Hon DSc (Flinders), Hon DLitt (CDU), Hon DUniv (ANU), Hon LL.D (Monash) is currently Australia's Chief Scientist and has held the position since 23 May, 2011.

His previous roles have included:

- 2001–2011 Vice-Chancellor, The Australian National University
- 1995–2000 Vice-Chancellor, Flinders University of South Australia
- 1993–1995 Senior Deputy Vice-Chancellor, Monash University
- 1990–1995 Chair of the Commonwealth's Higher Education Council
- 1986–1990 Deputy Vice-Chancellor, University of Wollongong.

Professor Chubb's research has focussed on the neurosciences and he has co-authored some 70 full papers and co-edited one book.

Professor Chubb was appointed a Companion of the Order of Australia for "service to higher education including research and development policy in the pursuit of advancing the national interest socially, economically, culturally and environmentally and to the facilitation of a knowledge-based global economy" in 2006. He was made the ACT's Australian of the Year in 2011 for his contribution to higher education.

Why STEM skills are important for innovation

Science, technology, engineering and mathematics (STEM) education is well placed to teach skills that are relevant in the information-rich modern economy, such as problem solving and evidence-based thinking. The creative and analytical talents of STEM graduates can be harnessed in business and other sectors, as well as academic research.

Australian STEM graduates in a wide range of careers report finding their STEM knowledge and skills helpful in their work, as well as in their personal lives. Earlier this year saw the release of *A Background in Science: What science means for Australian society* by Dr Kerri-Lee Harris, a report that had been commissioned by the Australian Council of Deans of Science.

Dr Harris asked 805 science graduates in what ways their science degree was useful. One in four respondents were working in scientific or medical research, and 12 per cent worked in scientific or engineering industries.[1]

But the rest had found jobs across sectors including law, government, health, education, food, agriculture, mining and construction. Regardless of where they were working, 97 per cent of all respondents said their science knowledge or skills were useful in their work.

My office followed up by mapping employer attitudes to STEM graduates for the fourth of its Occasional Paper series – *STEM Education and the Workplace*.[2] It cited a study done for the UK's Department of Business, Innovation and Skills (BIS) which showed a diverse range of employers seeking to attract STEM graduates, citing numeracy, analysis, and problem solving as key skills of value.[3]

It is likely we will see more employer demand for STEM skills, especially as technology transforms developed economies. From manufacturing and retail to law and banking, STEM graduates will continue to be in demand in a range of sectors.

If Australia is to remain an innovative nation, we must build more bridges and better ones between employers and universities. We need to improve on the statistic that I think best illustrates how Australia's science and industry sectors tend to reside in silos – just four per cent of our doctorate holders work in manufacturing.[4]

So what needs to be done, to ensure we get the best and brightest into the right job at the right time? Universities need to ensure their degree programs are more responsive to the broad range of occupations that STEM graduates might enter, not just academic research positions. That means adjusting their curriculum settings, for one.

"It is likely we will see more employer demand for STEM skills, especially as technology transforms developed economies. From manufacturing and retail to law and banking, STEM graduates will continue to be in demand in a range of sectors."

The former Australian Learning and Teaching Council recommended that universities map their science curricula against a set of "threshold learning outcomes" which include many of the skills valued by employers.[5]

The Australian Government's Research Workforce Strategy argued for the development of both "soft" or generic skills and innovation capabilities in university research training programs, which could then support students' productivity in a wide range of jobs.[6]

Similarly, in the US, an advisory committee to the National Institutes of Health has recommended a shift away from degree programs "aimed almost exclusively at preparing people for academic research positions", to include diverse training in entrepreneurship, project management, and research translation.[7]

Business-relevant STEM degree programs, such as the Professional Science Masters taught at some US institutions, provide examples of such a transition. It is important that Australian students interested in pursuing STEM degrees are not deterred by a false perception that their only option is a research career.

There are avenues at all stages of the student cycle to signal the possibilities that STEM capabilities unlock. As part of recruitment efforts for prospective students,

and career services for current students, universities can highlight the applicability of STEM skills to a wide range of professions and sectors.

The UK House of Lords committee recommends that universities and employers collaborate to expose more students to the workplace through internships and other means.[8] In Australia, for example, the Cooperative Research Centres (CRC) program can provide an environment to foster industry-relevant skills.

Universities and employers need to engage with each other and reach consensus about what those skills should be and how to best deliver them.

Australia needs them to succeed in this endeavour, if we are to remain an innovative nation.

How to address potential STEM skill shortages

The *Health of Australian Science* report prepared by my office warned that enrolments in many Australian STEM university courses are flat or declining. But it might all be taking hold earlier, in our schools, as suggested by our report – *Mathematics, Engineering and Science in the National Interest*.

It used a survey completed for us by the Australian Academy of Science, which revealed Year 11 and 12 students have a fairly low understanding of how valuable science is.[9] Of those actually studying science, just 33 per cent thought science was "almost always" relevant to their future although 47 per cent thought it "almost always" relevant to Australia's future.

Only 19 per cent thought it "almost always" useful in everyday life. When those students not studying science (roughly one-third of the cohort) were surveyed it got worse. Just one per cent thought it relevant to their future "almost always" and 42 per cent thought never. Four per cent thought it "almost always" useful in everyday life, 42 per cent thought sometimes and 18 per cent thought never.

Given this attitude, it was not surprising that *Mathematics, Engineering and Science in the National Interest* revealed that the proportion of enrolments in mathematics and science in Year 12 has decreased over the years and that it continues to fall slowly.

Nationally, 51 per cent of students take a science subject or subjects (including psychology) which amounted to 110,328 students in 2010.[10] Between 1992 (after which school retention rates were fairly stable) and 2009, the proportion of Year 12 students taking physics, chemistry and biology fell by 31 per cent, 23 per cent and 32 per cent respectively.[11]

While 72 per cent of the Year 12 cohort in 2010, it was important to note the shift from advanced to intermediate or elementary mathematics.

The consultation we undertook to try to understand the reasons behind the decrease, allowed us to hear some important messages. One was that, like everywhere else it has been studied, inspirational teaching is seen as the key

– both to the quality of our science education system, but just as importantly to raising student interest to higher levels.

Inspiring teachers will generally be those who are confident that they know their subject well, and can transmit that confidence, and their passion, into the classroom. We have many teachers like that, but we need more. We require coherent in-service support for teachers, and quality pre-service education.

It is time to re-think how we prepare our teachers and how we support them: Support to strengthen their content knowledge, to maintain it at contemporary levels and to instil the confidence to deliver the curriculum in interesting and novel ways.

The other key message was that the way we teach science, especially the techniques we use, needs to change. That does not mean dumbing it down, but it is important to note that many students said they found the way science was being taught to them was too didactic, even boring.

They thought that the scientific facts were not related to what they saw around them, and practical classes were largely about recipes or watching teachers following recipes, with little time for reflection.

> "Universities and employers need to engage with each other and reach consensus about what those skills should be and how to best deliver them. Australia needs them to succeed in this endeavour, if we are to remain an innovative nation."

It was a theme we followed up on in the *Health of Australian Science Report* which cited a survey of students on how to improve science classes.

The most common suggestion they provided for improving science classes was to make those classes more interactive by including more investigations, excursions, practical lessons or class discussions. Thirty per cent of students suggested this.

During our consultations (for the *Mathematics, Engineering and Science in the National Interest* report), teachers themselves acknowledged the issues and thought that health and safety guidelines restricted their ability to offer interesting practicals, and the lack of technical support meant that too much of the preparation was left to teachers with too little time.

The importance of technical support for science teachers was emphasised time and again. The issue is that science is not taught as it is actually practised: hypothesis, experimentation, observation, interpretation and debate. And interesting ways of getting the facts into context are not used often enough.

There are novel ways of enhancing support for teachers and bringing practitioners into the classroom and the best of these draw on the expertise and enthusiasm of the mathematics, engineering and science community – the active practitioners.

For example, school principals and teachers spoke positively about some innovative pilot programs to bring mathematicians, scientists and engineers into schools involving the Australian Academy of Science, the Australian Academy of Technological Services and CSIRO.

There were also some helpful ideas in a submission from the Australian Council of Deans of Science.

The ACDS explained two notable reasons for teachers favoring dry theory over laboratory activities. One was the enactment of much more stringent occupational health and safety requirements, which many teachers lack the expertise and resources to meet. The other was teachers' lack of laboratory experience, which might result in them finding it hard to produce educationally sound activities and to adapt creatively to limited resources.

The ACDS suggested extending the ASELL project (Advancing Science Education by Learning in the Laboratory) to include not just tertiary science teachers, but those teaching Year 7–10 science as well. The first ASELL Schools Workshop was conducted just two months after the publication of our report.

> "Today, Australian biomedical research shares the tale of two cities: it is the best of times, and the worst. In some ways, the field is experiencing a golden age: the amount of basic research being conducted and budgets are far larger than they were in the 1980s or 90s…paradoxically, research advances (in quality and quantity) have not led to a marked increase in new cures."

Three experiments were submitted for evaluation at that first workshop in Sydney, so I think it is fair to say we have some way to go in establishing ASELL in schools on a larger scale.

But it is a start, as is the Australian curriculum for secondary schools including the strands *Science as a human endeavour* and *Science inquiry skills*[12] and hopefully more students will experience the joy of scientific discovery through fieldwork and laboratory experiments.

This year's Federal Budget allocated $54 million to begin to address issues related to training teachers and inspiring students to a greater interest in science and mathematics.[13]

In order to drive inspirational and high quality teaching in high school maths and science, this commitment included:

- $10.9 million to improve the quality of teacher training through innovative delivery of maths and science teaching programs for prospective teachers.
- $3 million for national support and advice for teachers, including funding for a national advisory and linking service, online videos to illustrate new teaching standards, practical activities for school science laboratories and to provide advice for school science laboratory technicians and science teachers on safe practices.
- $5 million for the Science Connections program to equip teachers with the ability and confidence to deliver inquiry-based science education and to provide a suite of high quality curriculum resources linked to the Australian Curriculum for Science (Foundation to Year 10) which I just mentioned.

These and other measures are all important steps to ensuring Australia has enough STEM-skilled workers to meet the job demands of the future.

The picture for biomedicine

When it comes to biomedical research, Australia has two main priorities.

The first is to ensure that Australia continues to contribute to the world's stock of knowledge through basic research. Australian expenditure on medical research is estimated to be 1.1 per cent of the global expenditure but the proportion of world health returns attributable to Australian research is three per cent.[14] As a developed and rich country in a rapidly changing world, we have a responsibility to continue to strive to be a world leader in research. Australia spent $2.8 billion on health R&D in 2004–05 (0.38 per cent of gross domestic product – GDP) ranking in the middle of comparable countries in the Organization for Economic Cooperation and Development (OECD). New Zealand (NZ), The Czech Republic and Japan spend less relative to GDP while the United Kingdom (UK), United States (US), Germany, France, Denmark and Canada spend more, of the 10 countries studied.[15] It is important that we contribute the knowledge and our skills to the world's stock. We need to be an anticipator and not just an adaptor.

The second priority is to improve the lot of the Australian people. Every time a researcher receives funding for a study into a certain gene, or a protein, there is an underlying hope that it will matter in a big way. That it will change the way we treat patients. That it will improve the health of our citizens. It is not necessarily about making money and filing patents, although they help, but most taxpayers want to see results that will help them and their loved ones.

Today, Australian biomedical research shares the tale of two cities: it is the best of times, and the worst. In some ways, the field is experiencing a golden age: the amount of basic research being conducted and budgets are far larger than they were in the 1980s or 90s.

Professor Julio Licinio MD is the editor of *Molecular Psychiatry*, the highest-ranking journal in its field. He receives over 1000 papers per year, but can only publish three per cent of submissions. According to him, the avalanche of outstanding research is overwhelming. I quote: "The amount of fundamental discovery is staggering and medical journals are choked with quality science."[16]

That being the case, why is this the worst of times? Because, paradoxically, research advances (in quality and quantity) have not led to a marked increase in new cures. Much of what we now use to treat many common ailments is based on research from years ago.

In order to address both these priorities, we must ensure that we have a workforce that is capable of contributing to both basic research, as well as the ability to use that research to develop innovative solutions.

I mentioned earlier, declines in science, maths and engineering in universities. However, enrolments in health disciplines have been almost immune to these declines. In health, which includes medicine, dentistry, pharmacy and nursing, enrolments actually increased by more than 70 per cent between 2002 and 2010. Importantly, almost equal numbers of both men and women enrol in these areas

– a stark contrast to the discrepancies found in engineering, where less than 20 per cent of undergraduate students are female.[17]

However, it is estimated that by 2019, almost 6500 members of the health and medical research workforce will have retired, 4000 of whom have PhDs.[18] We currently have sufficient rates of medical research PhD completions to maintain our current workforce over the next 10 years[19]. But if Australia is to have the most highly educated, best skilled and highly trained health and medical research sector in the world, which must be our aim, the number of PhD qualified researchers would need to expand 2.5 fold to be on par with the European workforce.[20]

In order to achieve this, or at least help to move it along, we need to look at how we support medical research and the jobs in medical research. Let me ask: Does our present system of scholarships, numerous post-docs, grants, grants and more grants lead to jobs that are satisfying and secure? The answer from a fair number of people would be no. Therefore, we need to rethink how we support our best and brightest – at all ages and at all stages. Because we care – and because we need them.

In order to achieve this, or at least help it along, we need to look at how we support medical research and the jobs in medical research. From 2000–10, funding from the NHMRC quadrupled in size. However, funding is now on a plateau with no expected increases on the horizon.[21]

At the same time though, the size of grants has been increasing and is set to continue to increase. As a result of greater collaborations, more expensive equipment and more staff, the average size grant today is valued at $550,000 over three years. In 2000 the average grant size was around $260,000.[22] But we have seen a huge increase in the number of applications. They have grown from around 1500 in 2000 to 3226 in 2010. In 2000 the success rate was around 30 per cent; today it is about 23 per cent.[23]

"The number of grant applications that received scores high enough to be 'worthy of funding' but do not receive funding has been steadily increasing. In year 2000 it was 37 per cent of applications; in 2009, it was 58 per cent."

It would be easy to blame the falling success rate on falling quality, but this is not the case. The number of grant applications that received scores high enough to be "worthy of funding" but do not receive funding has been steadily increasing. In year 2000 it was 37 per cent of applications; in 2009, it was 58 per cent.[24]

So we have the number of applications rising, the quality of applications improving, funding which has flat lined and grants that are getting bigger. A tough combination. And then there is the need to replace or grow the medical research workforce, the place of young people: the researchers we will need to carry the torch when some of the present flame carriers decide to do something else.

This needs to begin in our primary and high schools, and extend into our university enrolments. I have outlined above, some means for improving the number of students taking STEM subjects, and the importance of doing so. These are not gradual changes to be made. Australia needs a step change and this will not be easy.

We need to change the number of students excited about science. We need to change the number pursuing science at school and then at university. We need to change the trajectory and skill base of and increase the science-trained numbers in the Australian workforce. And that last point means that we need to ensure that we can tell highly talented young people that there are careers in science – careers that will mean that they won't have to wait too long (a time that appears to be forever to some of them) to get their house or start their family.

Change is a part of our lives – some changes we can control and some we can't. Thinking about the future workforce and how we encourage people to see it as a fantastic career, in the numbers we need, is a challenge we can't ignore – and a change over which we can exert some control.

Endnotes

1 Harris, K.L. 2012. A background in Science: What science means for Australian Society. Centre for the Study of Higher Education, University of Melbourne, Australia. Available: http://www.cshe.unimelb.edu.au/research/disciplines/docs/BackgroundInScience per cent20_web.pdf P VIII

2 Office of the Chief Scientist, 2012. STEM Education and the Workplace. Available: http://www.chiefscientist.gov.au/wp-content/uploads/OPS4-STEMEducationAndTheWorkplace-web.pdf

3 UK Government Department of Business Innovation and Skills, 2011. *STEM Graduates in Non STEM Jobs*, p156

4 Access Economics – Australia's future research workforce: supply, demand and influence factors 30 April 2010

5 Australian Learning and Teaching Council, 2011., *Academic Standards Statement – Science*, p11–16

6 Australian Government, 2011. *Research Skills for an Innovative Future*, p25

7 US National Institutes of Health Advisory Committee to the Director, 2012. *Biomedical Research Workforce Working Group Report Page 8*

8 UK Government House of Lords Select Committee on Science and Technology, 2012. *Higher education in STEM subjects*, p54–56

9 Australian Academy of Science, 2011. *The Status and Quality of Year 11 and 12 Science in Australian Schools*

10 MES in the National Interest – Pg 20

11 MES – Pg 20

12 ACARA – The Australian Curriculum – Version 3.0

13 http://ministers.deewr.gov.au/evans/budget-2012-13-investing-science-and-maths-smarter-future

14 Australian Society for Medical Research. 2008. The value of Investing in Health R&D in Australia. Available: http://www.asmr.org.au/ExceptII08.pdf

15 Ib id

16 Licinio, J. 2011. Why does the United States need a national center for new cures? Molecular Psychiatry, 16: 882–884

17 Office of the Chief Scientist, 2012. Health of Australian Science, Canberra, Australia. p 102

18 Australia Society for Medical Research, 2010. People make research happen: Planning the Health and Medical Research Workforce 2010–2019. Available: http://www.asmr.org.au/workforce09.pdf

19 Department of Innovation, Industry, Science and Research, Research Workforce Strategy 2011

20 Australia Society for Medical Research, 2010. People make research happen: Planning the Health and Medical Research Workforce 2010–2019. Available: http://www.asmr.org.au/workforce09.pdf

21 National Health and Medical Research Council, Annual Report 2009–10, p.32

22 National Health and Medical Research Council, 2011. CEO presentation 2011, slide 16. Available: http://www.nhmrc.gov.au/_files_nhmrc/file/about/senior_staff/articles/nhmrc_ceo_presentation_newcastle_uni_june_2011.pdf)

23 National Health and Medical Research Council, 2010, Working to build a healthy Australia presentation, CEO Warwick Anderson http://www.nhmrc.gov.au/_files_nhmrc/file/about/senior_staff/articles/nhmrc_ceo_presentation_oct2010.pdf)

24 National Health and Medical Research Council, 2010. Research Funding Fact Book

acknowledgements

CEDA would like to acknowledge the contribution of the following CEDA members and individuals who have contributed to CEDA's general research fund between March 2012 and March 2013.

CEDA undertakes research with the objective of delivering independent, evidence-based policy to address critical economic issues and drive public debate and discussion. It could not complete its research agenda without the support of these contributors.

National

Accenture Australia

ACCIONA

AECOM

AEMO

Aon Risk

Arup

Asciano

Australia Post

Australian Petroleum Production and Exploration Association

Baulderstone

BHP Billiton

Cardno

Clayton Utz

Coffey International

Commonwealth Bank of Australia

CPA Australia

CSC

Deloitte

Ernst & Young

Evans & Peck

Herbert Smith Freehills

IBM Australia

Institute of Chartered Accountants in Australia

KPMG

Marchment Hill Consulting

McKinsey & Company

MWH

Nous Group

OAMPS

Pitt & Sherry

Reserve Bank of Australia

Rio Tinto

Shell Company of Australia

Siemens

Sinclair Knight Merz

TRILITY

URS

ACT

Australian Bureau of Statistics

Australian National University

Department of Education, Employment and Workplace Relations

Michael Clifford AM

Universities Australia

NSW

ACCA

AGL

Allan Moss AO

Ashurst

Australian Catholic University

Australian Computer Society

Australian Energy Market Commission

Australian Payments

Clearing Association

Barangaroo Delivery Authority

Be Learning

BOC

Caltex Australia

Challenge Consulting

COAG Reform Council

Coal Services

Richard Haddock AM

Department of Trade & Investment, Regional Infrastructure & Services

Downer EDI

EFTPOS Payments Australia

Energy Action

Phillip Isaacs OAM

Eraring Energy

Export Finance and Insurance Corporation

Four Seasons Hotel Sydney

FuturePlus Financial Services

Gadens Lawyers

Gilbert + Tobin

Holcim (Australia)

Independent Pricing and Regulatory Tribunal

Infigen Energy

Insurance Australia Group

JP Morgan

John Holland

Lander & Rogers Lawyers

Leighton Contractors

Leighton Holdings

Macquarie Group

Maddocks

Manpower Services

Marsh

Mercuri Urval

MetLife

Mitsui & Co

MLC

National Australia Bank

New South Wales Treasury Corporation

Department of Attorney General and Justice

Department of Planning & Infrastructure

Department of Premier and Cabinet

Oracle Corporation Australia

Parramatta City Council

Pottinger

Regional Development Australia - Hunter

Royal Bank of Canada

Serco Australia

Snowy Hydro

Standards Australia

Stockland

Sydney Airport Corporation

Sydney Catchment Authority

Sydney City Council

Sydney Water

TAFE NSW Strategy

Talal Yassine OAM

Telstra

The Bank of Tokyo-Mitsubishi

The BPAY Group

The Royal Bank of Scotland

The Smith Family Foundation

The University of Sydney Business School

The Waypoint Group

Daryl Hull

Transport NSW

University of Newcastle

University of Technology Sydney

UNSW Australia

Weber Shandwick

WorkCover NSW

Xstrata Coal

QLD

Ashurst

Bank of Queensland

BHP Billiton

Brisbane Airport

Brisbane Marketing

Catherine Sinclair

Chesterfield Group

Civil Contractors Federation

ConocoPhillips

Construction Skills Queensland

Cutting Edge

Department of State Development, Infrastructure and Planning

Energex

Ergon Energy

FA Pidgeon & Son

Gadens Lawyers

GHD

Gold Coast City Council

Hastings Deering

Ipswich City Council

KDR Gold Coast

Logan City Council

Lutheran Community Care

National Australia Bank

New Hope Corporation

NEXTDC

QER

QIC

Queensland Competition Authority

Queensland Law Society

Queensland Motorways

Queensland Rail

Queensland Treasury and Trade

Queensland Treasury Corporation

Queensland University of Technology

RBS Morgans

Robert Walters

SunWater

TechnologyOne

The Public Trustee of Queensland

The University of Queensland

SA

Adelaide Airport

Adelaide Casino

Adelaide City Council

BankSA

Bedford Group

City of Onkaparinga

City of Prospect

Coopers Brewery

Department for Manufacturing, Innovation, Trade, Resources and Energy

Department of Further Education, Employment, Science and Technology

ElectraNet

Finlaysons

Flinders University

Funds SA

Health Partners

Investec Bank

Macquarie Private Wealth

Masonic Homes

National Australia Bank

Nous Group

SA Power Networks

SA Unions

South Australian Water Corporation

The University of Adelaide

University of South Australia

WorkCover SA

TAS

Aurora Energy

Department of Premier & Cabinet

Hydro Tasmania

Transend Networks

VIC

Allen Consulting Group

Australian Unity

BASF Australia

Box Hill Institute

Cabrini Health

Chase Performance

City of Greater Geelong

Janice Van Reyk

Committee for Geelong

CSL

Data #3

Department of Business and Innovation

Department of Human Services

Department of Planning and Community Development

Department of Primary Industries

Department of Sustainability and Environment

Department of Transport

ExxonMobil Australia

FleetPartners

GHD

Gilbert + Tobin

GlaxoSmithKline Australia

Grocon

Guild Group Holdings

Holden

Independent Schools Victoria

Industry Funds Management

Insync Surveys

JANA Investment Advisers

Jemena

La Trobe University

Lanier (Australia)

Linking Melbourne Authority

Litmus Group

Macquarie Bank

Maddocks

Make A Wish Australia

Medibank

National Australia Bank

New Zealand Trade and Enterprise

NHP Electrical Engineering Prod

Nous Group

Open Universities Australia

P.G.A. (Management)

Parks Victoria

Port of Melbourne Corporation

Public Transport Victoria

PwC Australia

REA Group

RMIT University

Royal Automobile Club of Victoria

Rural Finance Corporation

Russell Reynolds Associates

Serco Australia

SMS Management & Technology

South East Water

St Vincent's Hospital (Melbourne)

The Bank of Tokyo-Mitsubishi

The Future Fund

Treasury Corporation of Victoria

United Energy Distribution

University of Melbourne

Veolia Transdev

Victoria University

Western Water

Wilson Transformer Co

WorkSafe Victoria

Yarra Trams

WA

ACIL Tasman

Alcoa of Australia

Apache Energy

ATCO Australia

Australian Bureau of Statistics

Bankwest

Black Swan Event Financial Planning

Bontempo Investment Group

Chamber of Commerce & Industry - Western Australia

Chevron Australia

City of Greater Geraldton

City of Perth

Clifford Chance

ConocoPhillips

Curtin University

DBNGP (WA) NOMINEES

Department of Agriculture and Food

Department of Finance

Department of Regional Development and Lands

Department of Transport

Department of Treasury

DORIC Group

Edith Cowan University

Fortescue Metals Group

Fremantle Ports

Gene Tilbrook

Georgiou Group

Gerard Daniels

Herbert Smith Freehills

International Mining for Development Centre

K&L Gates

Leighton Contractors

Murdoch University

Nous Group

OptaMAX

Perth Airport

Pilbara Development Commission

Prime Super

The Chamber of Minerals and Energy of Western Australia

The Smith Family Foundation

The University of Western Australia

Sue Ash

Verve Energy

Wesfarmers

Western Australia Police

Western Australian Treasury Corporation

Western Power

Woodside Energy

National
Level 13, 440 Collins Street
Melbourne VIC 3000
GPO Box 2117
Melbourne VIC 3001
Telephone 03 9662 3544
Fax 03 9640 0849

New South Wales and the ACT
Level 14
The John Hunter Building
9 Hunter Street
Sydney NSW 2000
GPO Box 2100
Sydney NSW 2001
Telephone 02 9299 7022
Fax 02 9232 7559

Queensland
Level 17, 300 Adelaide Street
Brisbane QLD 4000
GPO Box 2900
Brisbane QLD 4001
Telephone 07 3229 9955
Fax 07 3229 8166

South Australia and the Northern Territory
Level 7
144 North Terrace
Adelaide SA 5000
PO Box 8248, Station Arcade
Adelaide SA 5000
Telephone 08 8211 7222
Fax 08 8211 8222

Victoria and Tasmania
Level 13, 440 Collins Street
Melbourne VIC 3000
GPO Box 2117
Melbourne VIC 3001
Telephone 03 9662 3544
Fax 03 9640 0849

Western Australia
Level 5
105 St Georges Terrace
Perth WA 6000
PO Box 5631, St Georges Tce
Perth WA 6831
Telephone 08 9228 2155
Fax 08 9228 2166