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The benefits from translating biomedical research into the health care system

Report to Bio21 Australia

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Contents

Executive Summary	i
1 Introduction	1
1.1 Project Purpose	1
1.2 The Biomedical Research Context	1
1.3 The Bio21 Australia Biomedical Cluster	5
1.4 Report Structure	7
2 The Potential Benefits of Translating Biomedical Research to the Health Care System	8
2.1 Overview of Types of Benefits	8
2.2 Improved Health Outcomes	9
2.3 A high value for money health system	10
2.4 Productivity Benefits	13
2.5 Industry Development	15
3 Approaches to the Transfer of Biomedical Research Discoveries to the Health Care System	18
3.1 Channels for Biomedical Research Translation	18
3.2 International Experience	19
3.3 The Australian Experience	20
3.4 The Victorian and Bio21 Australia Experience	24
4 Assessment of the Need for Further Action in Translation of Research	29
4.1 Overview	29
4.2 The Need for Action	29
4.3 Potential Actions	32
4.4 Next Steps for Bio21 Australia	34
Appendix A:	
Additional evidence of available benefits from effective translation of biomedical research	35
Additional examples of benefits from research translation	35
International research translation initiatives	36

Executive Summary

Study objectives

The purpose of this report is to explore the potential benefits from aiding the translation of basic research in biomedical science into improved health care so as to optimise the benefits gained from this research. This report analyses the current situation in relation to the translation of research into clinical practice and considers the barriers that impede the effective translation of research into improved health care. It looks at the current institutional and funding arrangements and assesses how these affect who conducts research, the type of research that is undertaken, and the potential for this research to be of use to, and diffused within, the health care sector. This report considers the scale of benefits that could accrue from overcoming these barriers, and identifies actions required within the Bio21 cluster to optimise research translation within the cluster.

Study context

The Victorian Government has, over the last six years, made substantial financial outlays to build up the medical research sector in the state. A major motivation for this spending is to promote economic growth through industry development associated with infrastructure provision and the commercialisation of IP. By building up capacity in medical research the Victorian Government hopes to foster the emergence of new companies and attract investment from major multinational pharmaceutical companies.

The potential benefits of biomedical research are, however, much broader than financial outcomes associated with the commercialisation of research outputs. The benefits of biomedical research, and its improved application, are diverse. The main types of benefits that we would expect would be:

1. improved health outcomes;
2. a high value for money health care system;
3. economy wide productivity benefits; and,
4. industry development.

Effective systems for the translation of biomedical research to clinical practice can bring forward the delivery of benefits through each of these channels. More effective research translation systems may also minimise any costs currently associated with the diffusion of biomedical knowledge by making this process more efficient.

In Australia disease expenditure accounted for 87.5 per cent of total recurrent health expenditure in 2000-01, costing the country \$50.1 billion out of a total recurrent budget of \$57.3 billion.¹ Given the magnitude of these expenditures, small cost changes per treatment, or slight reductions in the rate of treatment, are likely to have substantial effects. For instance, a research informed change to clinical practice that reduces the cost of cardiovascular disease treatment in Australia by just 1 per cent would result in a direct cost saving of approximately \$55 million per year.

¹ Australian Institute of Health and Welfare, 2005, *Health System expenditure on disease and injury in Australia, 2000-01*. Second Edition, p1

Effective diffusion of research knowledge into clinical practice may also generate improvements in rates of diagnosis and subsequent treatment. This is a further area where significant benefits – in terms of both health and productivity outcomes – may be able to be obtained. For instance, a recent study found that on average workers with untreated depression are \$9,660 less productive per year.² Given the prevalence of depression, with around 300,000 Victorian's suffering from major depression in any given year³, this suggests that even small research led proportional improvements in rates of diagnosis and subsequent treatment would yield substantial productivity benefits.

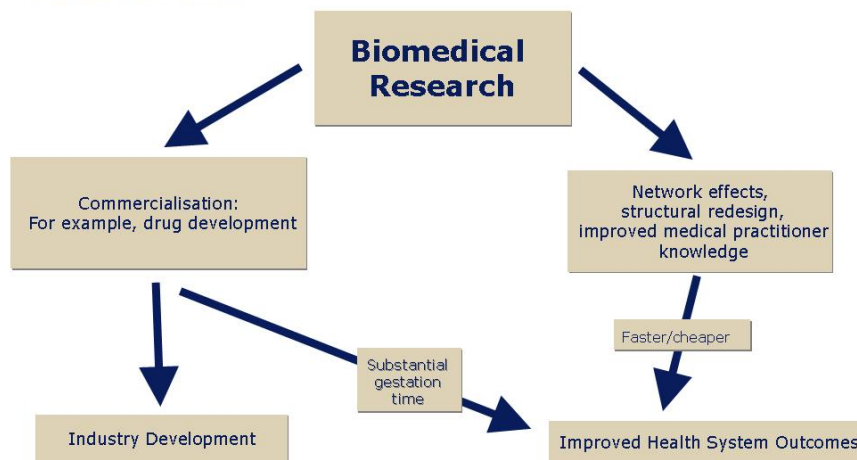
As part of its biotechnology Strategy, and recognising the importance of effective translation of research into practice, the Victorian Government has supported the development the Parkville Precinct, a leading biomedical cluster comprising a group of universities, research institutions and hospitals situated in the Parkville area. Bio21 Australia, a member funded company, aims to encourage and facilitate collaborative research, sharing of skills and infrastructure, communication of scientific knowledge and scientific education, commercialisation of research and the translation of research into clinical practice.

Challenges for translation of research

The gap between biomedical research that is driven by scientific curiosity and the clinical application of the results of such study is often measured in decades.⁴ This is particularly the case where application of research relies upon the development of a new therapeutic drug intervention. There is however the potential for research generated knowledge to more immediately influence health outcomes by leading to changes to existing clinical practice.

Benefits from biomedical research

Comparing the various streams by which benefits are conferred



In Victoria the current arrangement of health research funding is a competitive research model where research institutes are separate (or to a great degree separate)

² M Sweet and S Price. *Bosses feel the pinch when workers battle depression*.

³ Mental Health Research Institute, 2004, *The Depression Awareness Research Project*, estimated the annual incidence of major depression at over 6 per cent of the Australian population. In Victoria this would translate to around 300,000 people.

⁴ UK Evaluation Forum, May 2006, *Medical research: assessing the benefits to society*

from hospitals and are considerably de-medicalised, in that they are predominantly staffed by scientists rather than clinicians undertaking research. This model has been very effective in generating medical research outcomes such as articles and patents but has been less effective in generating direct health outcomes in the short term.

Importantly, State Government funding for research is now primarily provided by industry departments rather than by the health departments and as a result research is often aimed at generating a commercial product rather than delivery of immediate health care benefits.

In this environment, barriers to effective diffusion of knowledge from research to clinical practice include:

- a lack of incentives and opportunities for researchers to interact with and share findings with clinicians;
- a lack of input from the health care system into research direction; and,
- a lack of time available to medical practitioners to uptake new information and practices.

Mechanisms for improving translation of research

This study considers three important channels by which new biomedical knowledge can be utilised within the health sector:

- Improved knowledge of both medical practitioners and researchers through network effects and training;
- Technological adoption, where new technologies represent the application of new research findings about the nature of the human body; and,
- Systematic or institutional reorganisation, where the processes and conventions of a health institution are changed to reflect increasing knowledge gained from biomedical science (and health science more generally).

A range of initiatives have been introduced in recent years, both international and Australian, to address each of the above channels. However, it is still too early to assess how effective such initiatives have been. Generally though, it can be observed that Australian governments have more heavily emphasised the importance of commercialisation as delivering benefits rather than the other two mechanisms of improving medical practitioner knowledge and institutional/systematic reorganisation.

This study suggests that at a fundamental level a rebalancing needs to occur within the health research sector, with a renewal of focus on directly linking research to current clinical issues of high priority. This should not be interpreted as an argument to redirect funding away from research and into translational activities. Rather, it supports the need for increased support for translational activities as a mechanism for increasing the benefits that are obtained from investment in research. Translational activities are a complement to, not a replacement for, biomedical research activity.

To this end, two immediate actions are recommended to improve knowledge flows between researchers and practitioners within Bio21 Australia:

- Building up the clinician researcher base within hospitals. This could involve: funding for clinician researcher fellowships; making more grant funding contingent on a hospital working in partnership with a research institute to look at a problem that faces the health system; and, provision of specific funding to hospitals so that they can allocate more clinician staff time to research and knowledge uptake.

- Increasing Bio21 Australia activities so as to strengthen formal and informal connections between researchers and clinicians in the cluster. This could involve: increased networking events and provision of seed funding for collaborative research projects.

However, in addition to immediate incremental actions to increase knowledge flows and collaboration, the issues highlighted in this study suggest that a more fundamental rethinking of biomedical research funding and practice may be warranted. Bio21 Australia is perfectly positioned to lead this debate and should examine:

- who should fund biomedical research;
- the reasons for funding biomedical research and the relative prioritisation of health system and industry development outcomes;
- the potential benefits of a physical overhaul of the system – increasing space for research within hospitals for instance; and,
- the potential benefits from increasing funding for collaborative projects which are directed at immediate health system benefits.

We therefore recommend that the next steps for Bio21 Australia in improving the translation of biomedical research into clinical practice should be to:

- Establish a detailed case for a range of discrete actions focused on improving collaboration between its member organisations so as to capture the benefits available from increased knowledge flows. The case for each action should articulate the need for action, consider the costs and benefits associated with the action, identify appropriate funders of the action and detail an implementation plan for the action. The case for each action may form the basis for submissions to appropriate funding bodies.
- Continue its efforts to seek increased government funding for the support of the Clinician Researchers Fellowship program and also advocate the allocation of more grant funding to projects involving strong research/practitioner collaboration.
- Take a “thought leadership” role in investigating structural issues around how biomedical research is funded and conducted. It could establish a working group to focus on the long term structural issues that we have outlined in this report and play a leading role in informing future health and health research policy.

1 Introduction

1.1 Project Purpose

Biomedical research discoveries have advanced our understanding of disease and led to novel and effective diagnostic tools such as vaccines, new medical procedures and new health technology. The uses of biomedical research and biotechnology are broad, and some even suggest that biomedical R&D may act as an enabling technology, opening up future avenues for research.⁵ The global industry in biotechnology is large with biotechnology sales in the OECD alone worth \$35.9 billion in 2001.⁶ The OECD's survey of the biotechnology industry estimates that there are almost 290,000 biotechnology employees in the 21 member countries that responded to the survey.⁷ Public and private expenditure on research in this area is growing both domestically and internationally.

The purpose of this report is to explore the potential benefits from aiding the translation of basic research in biomedical science into improved health care to optimise the benefits gained from this research. This report analyses the current situation in relation to the translation of research into clinical practice and considers the barriers impeding effective translation of research into improved health care. It looks at the current institutional and funding arrangements and assesses how these affect who drives research, the type of research that is undertaken, and the potential for this research to be of use to, and diffused within, the health care sector. This report considers the scale of benefits that could accrue from overcoming these barriers, and identifies actions required within the Bio21 cluster to optimise research translation within the cluster.

1.2 The Biomedical Research Context

1.2.1 The Value of Biomedical R&D

Global and local interest in biomedical research is increasing as governments, corporations and not for profit research groups recognise the social and economic benefits that can flow from new discoveries in this area. Currently, more than 100 cities in the world are pursuing biotechnological related economic development agendas. The total benefits from biomedical research are potentially large, particularly the improvements that biomedical discoveries can deliver to health outcomes. According to a 2003 Access Economics report entitled '*Exceptional Returns: The Value of Investing in Health R&D in Australia*', which applied the methodology developed by a Funding First report of the same name⁸, our investment in health R&D 'surpasses every other source of rising living standards in our time'.⁹

⁵ Health and Medical Research Strategic Review, 1998, Discussion Document, *The Virtuous Cycle: Working together for health and medical research*, p14

⁶ OECD, 2006, *OECD biotechnology Statistics – 2006*, p25

⁷ Data only refers to the 21 reporting countries and not all OECD nations. OECD, 2006. *OECD Biotechnology Statistics – 2006*. p20

⁸ Funding First, 2000, *Exceptional Returns: The Economic Value of America's Investment in Medical Research*. New York.

⁹ Access Economics, September 2003, *Exceptional Returns: The Value of Investing in Health R&D in Australia*, prepared for the Australian Society for Medical Research. Canberra. p1

This report notes that over the period 1960-1999 Australians gained eight years on our life expectancy, and estimates that this is worth \$5.4 trillion for Australians in 2003 dollars.¹⁰ This is a result of the particular way that the report places a value on human life; it ties this to individual assessments of the value of their life. By the valuations Access uses, the improvements in lifespan account for almost half the gain in Australian living standards in the past 40 years. The report argues that much of this improvement is the result of improved diagnosis, treatment and prevention of disease that has occurred as a result of biomedical research.¹¹ Historically, annual rates of return to Australian health R&D were assessed at up to \$5 for every \$1 spent on R&D.¹² These are even higher for cardiovascular specific research (8:1) and digestive system research (6:1).¹³

Access' numbers have gained substantial currency in the literature, and the rate of return of \$5 to every \$1 of research is widely cited as a sensible measurement of the social value of investment in health R&D. Access' numbers are high because they included the value that individuals place on improvements to their own standard of living. If only direct financial impacts are considered such as cost reductions in the health care system and increased labour force participation and productivity, the benefit/cost ration would be far lower than the commonly cited 5:1 figure.

Another example of the scale of impacts that are being sought from health research is the goals of the CSIRO's Preventative Health Flagship which aims to improve the health of Australians and, by the prevention and early detection of chronic disease, save \$2 billion in direct health costs by 2020. To further this objective, \$70 million has been allocated to the flagship over its first three years, with funding for 2006-07 of \$28.6 million.

The recent ACIL-Tasman assessment of this flagship, *Preventative Health Flagship – Real Options Analysis*¹⁴, uses options value theory to assess the prospective future impact of the Flagship's research programs. The analysis particularly focuses on the Flagship's research surrounding Alzheimer's and colorectal cancer. It puts forward an estimate of the probability that the Flagship's work will bring forward more effective prevention and treatment of these illnesses and then explores what such an eventuality would mean for future health system costs. Using this interesting, but necessarily heavily assumption driven, methodology, ACIL Tasman suggest an expected future value of \$376 million for the Flagship's research. When compared to the costs to date, but ignoring any future costs associated with application of research findings, this gives approximately a 5:1 benefit:cost ratio. It must be stressed, however, that this valuation approach does not involve actually looking at what has been achieved by the Flagship's research (which is of course not possible given the recent formation of the Flagship), but rather uses probability analysis to project a possible future outcome value from the research.

1.2.2 Funding for Biomedical Research

Notwithstanding the above issues around how medical research impacts are economically valued, it is certain that there are significant benefits that flow from biomedical research. The Australian Government has recognised this, and recently substantially increased the funding of research in the medical and health sciences, with expenditure rising by 46 per cent over the period from 2002-03 to 2004-05.¹⁵ In May 2006, the Federal Government

¹⁰ Access Economics, September 2003, *Exceptional Returns: The Value of Investing in Health R&D in Australia*, prepared for the Australian Society for Medical Research. Canberra. p1

¹¹ Ibid.

¹² Ibid.

¹³ Ibid.

¹⁴ www.csiro.au/csiro/channel/pchfg.html

¹⁵ ABS, Cat 8109.0, *Research and Experimental Development: Government and Private Non-Profit Organisations 2004-05*, p7

announced an additional \$905 million for Australian health and medical research.¹⁶ These increases are in line with the adoption of the national research priority of promoting and maintaining good health. The increase in funding to this area comes despite real government funding for all R&D declining by 4.3 per cent over the same period.¹⁷ Moreover, in response to three major reviews, the government has made the National Health and Medical Research Council (Australia's peak body for supporting health and medical research and developing health advice) an independent statutory agency within the Department of Health and Ageing.¹⁸

The Victorian Government has, over the last six years, made substantial financial outlays so as to build up the medical research sector in the state. A major motivation for this spending is to promote economic growth through industry development associated with infrastructure provision and the commercialisation of IP. By building up capacity in medical research the Victorian Government hopes to foster the emergence of new companies and attract investment from major multinational pharmaceutical companies. Excluding the \$200 million allocated to the Synchrotron, annual funding provided by the Victorian Government to build up capacity in medical research averages over \$100 million per annum.

The State Government has supported biomedical research and medical research more generally, through a range of mechanisms like the recent Life Sciences Statement – which in April 2006 allocated a further \$200 million over three years to investment in medical research.¹⁹ Other mechanisms include the Operational Infrastructure Support program, which provides support for essential infrastructure research that is not provided for within competitive peer-reviewed research grants, and the Science Technology and Innovation Infrastructure Grants program. Other recent programs initiated by the Victorian Government include:

- the support for a new bioprocessing facility;
- rolling out the Bio21 Molecular Medicine Informatics Model across all metropolitan and regional cancer centres;
- providing \$53 million for the integration of four institutes into the Australian Centre for Neuroscience and Mental Health Research;²⁰
- merger of the Austin Research Institute and the Burnet Institute, supported other closer collaborations so as to gain from economies of scale;²¹
- providing \$35 million towards the development of a new Australian Regenerative Medicine Institute (ARMI) at Monash University; and,
- providing the Austin Biomedical Alliance with \$9.2 million to allow it to construct a major teaching, training and research (TTR) project.²²

In addition to these programs the Science Technology and Innovation Infrastructure grants program (STI) has so far awarded approximately \$60 million per round.²³ Moreover, the Government recently gave further support to commercialisation of biomedical research. In February the State Treasurer launched a \$30 million dollar fund aimed at filling the gap

¹⁶ NHMRC, 2006, *National Health and Medical Council Submission to the Productivity Commission's research study on public support for science and innovation in Australia*, p8

¹⁷ *Ibid.* p5

¹⁸ *Ibid.* p3

¹⁹ <http://www.hawkerbritton.com/hawker-britton-public-affairs/victoria-budget-2006.htm>

²⁰ <http://www.business.vic.gov.au/busvicwr>

²¹ <http://www.ari.unimelb.edu.au/>

²² <http://www.business.vic.gov.au/busvicwr>

²³ <http://news.researchcentre.com.au/rndinfo/rndinfo040603.htm>

between NHMRC grants and the Commonwealth Pre Seed Fund. The Victorian Government has contributed \$1.2 million (matched by the NSW Government) to cover the administration costs of the fund. The fund itself has attracted \$30 million in private funds. The fund will be located at the Baker Heart Research Institute; 15 medical research institutes have indicated that they will join. This initiative is aimed at helping research institutes establish spin-out companies and IP so that they will see a larger return from their research.²⁴

The majority of the Victorian spending has been geared towards supporting the development of shared infrastructure, research institute collaboration and support for commercialisation of research. Fostering industry development has been an explicit goal underpinning much of this funding. Though collaboration has been emphasised, there has been less of a focus on funding hospitals so that they may undertake research, or funding biomedical research solely for health sector outcomes.

While there is currently no robust and consistent set of figures that allows country by country comparison on biomedical R&D, there is data on more general biotechnology and health related R&D. Australia ranks in the middle of the OECD spectrum on both health R&D and health spending overall.²⁵ Biotechnology led economic development represents a partnership between industry, the academy and government – the “triple helix effect”.

*Measuring health R&D internationally*²⁶

Any measurements of inputs and outcomes of health R&D have their limitations as a result of different assessments of what should be included as health expenditure in different countries, as well as reflecting differing domestic priorities.²⁷ Government budget appropriations or outlays on R&D for instance, an OECD measurement often used as a proxy for health related R&D, only includes government expenditures. Moreover, it only includes federal governments – which means it omits a large supporter of health R&D state and provincial governments. Gross domestic expenditure on research and development is the other approach used by the OECD, which collects gross domestic expenditures on R&D and includes expenditures by business, government, higher education and private not for profit enterprises. However, not all countries have adequate data for this response. So, while there is relatively good data in many cases, we should be cautious about comparing between countries.

²⁴ <http://www.pharmainfocus.com.au/>

²⁵ Access Economics, September 2003, *Exceptional Returns: The Value of Investing in Health R&D in Australia*, prepared for the Australian Society for Medical Research. Canberra. p30

²⁶ Similar discussion undertaken in Access Economics, September 2003, *Exceptional Returns: The Value of Investing in Health R&D in Australia*, prepared for the Australian Society for Medical Research. Canberra.

²⁷ NHMRC, *Productivity Commission Submission*, p12

1.2.3 Growing Focus on Translation of R&D to Clinical Outcomes

Given the size of spending in health R&D area, many governments are now directly targeting some funding to promote the translation of R&D to commercial application and to its application in the health care system. Australia already has significant initiatives in place to aid the application of knowledge. These initiatives are, however, primarily focused on commercialisation. Countries like the US, Canada and the UK are also now very focused on commercialisation and knowledge transfer. Evidence of this is assessed in Chapter 3.

Translational funding for commercial and/or clinical application is predicated on the assumption that some type of market failure exists. Externalities in the form of knowledge spillovers are often used to justify public funding of basic research. This is because the group undertaking the research is unable to capture the total benefits of their work – as a result of the public good nature of R&D. As a result, the market will under provide as private groups will only undertake research which generates an adequate private return. In the case of translational funding for biomedical R&D, spillovers are also relevant; informational asymmetries and high transaction costs may also provide a rationale for intervention in the market. In short, the market will under-provide translational research and programs and government action has the potential to improve on this outcome. Some increased spending on translational research, or on translating research findings into practice, might yield significant dividends. Examples of potential benefits are discussed in Chapter 2.

In the context of increasing R&D translation, an area of particular interest to public policy makers is the biomedical research cluster. If properly managed, clusters can help improve research and translational research performance as a result of the agglomeration effects – which facilitate the translation of knowledge between various research, teaching and health care groups as well as reducing costs of shared infrastructure.

1.3 The Bio21 Australia Biomedical Cluster

Bio21 Australia is a leading biomedical cluster within Australia, comprising of a group of universities, research institutions and hospitals situated in the Parkville area in Victoria. Bio21 Australia Ltd is a not for profit company which has a number of core members²⁸:

Austin Biomedical Alliance (ABmA) www.armc.org.au/Pages/abma.htm

Located at Austin Health, the Alliance is a research and development enterprise integrating independent research groups with a vision of “turning science into health” by using common platform technologies to address a variety of clinical problems.

Cancer Trials Australia (CTA) www.cancertrialsaustralia.com

Cancer Trials Australia is a cancer clinical trials collaboration between four major hospitals and three cancer research institutes. Its strength is in early phase trials with an emphasis on functional imaging and translational studies through its trials laboratory

CSIRO Molecular and Health Technologies (CSIRO MHT) www.csiro.com.au/mht

CSIRO Molecular and Health Technologies is a new division arising from the merger of CSIRO Molecular Science and CSIRO Health Sciences and Nutrition. Chemists, biologists and physicists work together to address key challenges in health and in a range of industries.

Howard Florey Institute (HFI) www.hfi.unimelb.edu.au

The Howard Florey is focused on neuroscience. Currently around 300 staff work in eight different research teams. Some research areas include Parkinson's disease, stroke, motor neurone disease, and spinal cord injury.

Ludwig Institute for Cancer Research (LICR) www.ludwig.edu.au

The Melbourne Branch of the Ludwig Institute for Cancer Research is the largest of the Institute's ten branches. Research and clinical facilities are situated at the Royal Melbourne and Austin Hospitals. The research program combines with clinical activities to create new opportunities for the development of effective anti-cancer treatments.

²⁸ http://www.bio21.com.au/files_to_upload/bio21_summary_4p2.pdf

Melbourne Health (MH) www.mh.org.au/researchandeducation

Melbourne Health incorporates the Royal Melbourne Hospital, Victorian Infectious Diseases Reference Laboratory and North West Mental Health. It has teaching and research facilities in the acute, sub-acute and community settings. The service has a focus on clinical research in oncology, neurosciences, infectious diseases, diabetes, colorectal cancer and mental health. Clinical trials are a particular strength.

Murdoch Children's Research Institute (MCRI) www.mcri.edu.au

The Murdoch Children's Research Institute is the largest research centre in Australia specialising in child health. Located within the Royal Children's Hospital. It has 520 researchers, and attempts to combine innovations in community health and medical laboratory research with clinical know-how.

Neurosciences Victoria Ltd (NSV) www.neurosciencesvic.com.au

NSV is a company representing the neuroscience biocluster in Melbourne. It offers neuroscience research, opportunities in licensing, co-development, drug validation and testing, drug discovery and development technology platforms, collaborative R&D, animal modelling, spin-off company equity, participation and access to coordinated neuroscience clinical trials.

Peter MacCallum Cancer Centre (PeterMac) www.petermac.org/research

The Peter MacCallum Cancer Centre is Australia's only comprehensive cancer centre. Its fundamental and clinical cancer research is often integrated with the treatment of cancer patients. Its laboratory based research and clinical research programs cover a wide spectrum: from studies into the basic mechanisms of cell growth, translational studies that seek more accurate cancer diagnosis, clinical trials with novel treatments, to research aimed at improving our supportive care approaches.

St. Vincent's Health (SVH) www.svhm.org.au/research

St. Vincent's Health is a 3-campus tertiary health service and teaching hospital of the University of Melbourne. Major clinical and research foci include cancer, mental health, transplantation immunology and neurosciences. Co-located research institutes include St. Vincent's Institute, Bernard O'Brien Institute of Microsurgery and components of the Howard Florey Institute.

St Vincent's Institute (SVI) www.svimr.unimelb.edu.au

SVI conducts basic and clinical research programs into high impact community diseases including bone diseases (osteoporosis), cancer, metabolism (obesity/cardiovascular disease), diabetes, neurological diseases and infection. Skills include protein chemistry, structural biology, bone biology and virology. SVI is an independent Institute, affiliated with St Vincent's Health and The University of Melbourne.

The Cancer Council of Victoria www.cancervic.org.au

An independent volunteer-based charity that conducts and supports research, delivers state-wide support and prevention programs and advocates regulation and other interventions to reduce the physical and emotional burden of cancer. The CCV conducts research in cancer epidemiology, behavioural science and tobacco control, administers state, national and international clinical trials, and provides a range of funding opportunities for cancer research in Victorian institutions.

The Royal Children's Hospital (RCH) www.rch.org.au

The Royal Children's Hospital is a 253-bed pediatric teaching hospital and provides clinical services, tertiary care and illness prevention programs for children and adolescents. The RCH is a leading centre for research and education, having partnerships with the Murdoch Children's Research Institute and the University of Melbourne.

The Royal Women's Hospital (RWH) www.rwh.org.au

The Royal Women's Hospital is dedicated to improving the health of all women and newborn babies. The RWH provides comprehensive health services ranging from health promotion to clinical intervention. It also provides clinical expertise and leadership in maternity services, gynaecology, cancer services and care of newborn babies.

The University of Melbourne www.unimelb.edu.au

The University of Melbourne is an internationally-focused, research-intensive University with 11 faculties, over 6,000 staff, and over 33,000 students. It is the largest research University in Australia, with research strengths spanning most fields of biomedical science, and ranging from fundamental research into the molecular basis of disease through to applied clinical research. The Bio21 Institute is a focus for the University's biotechnology efforts. The Bio21 Institute has world-class research facilities, multi-disciplinary research programs in health-related and environmental biotechnology, and a unique model for industry engagement. Industry and academic researchers can access cutting edge platform technologies, fully equipped visitor laboratories, opportunities for R&D partnerships and a business incubator for start-up companies.

The Walter and Eliza Hall Institute (WEHI) www.wehi.edu.au

WEHI has made contributions to immunology, haematology, cancer, malaria and autoimmune diseases. By combining its strengths in structural biology, high throughput chemical screening and medicinal chemistry with those in biology, WEHI provides opportunities for translation of basic biology and drug targets into potential clinical candidates.

Victorian College of Pharmacy (VCP), Monash University www.vcp.monash.edu.au/research

The Victorian College of Pharmacy at Monash University is a key research centre in the Pharmaceutical Sciences and Pharmacy. The breadth of disciplines includes drug discovery, drug development and drug evaluation. A key element of the drug discovery and development portfolio is the Centre for Drug Candidate Optimisation (CDCO).

Bio21 Australia aims to encourage and facilitate collaborative research, communication of scientific knowledge and scientific education, commercialisation of research and the translation of research into clinical practice.²⁹

The establishment and initial operation of Bio21 Australia was supported by the State Government of Victoria through the STI (Science Technology Innovation) fund. Bio21 Australia was responsible for making recommendations to the State Government on six collaborative projects that were supported from the STI funds. It is also responsible for ensuring that Bio21 Australia members have access to facilities and that projects are adequately monitored and reported on. Bio21 Australia does not own, manage or operate any of the individual facilities or projects in the cluster; these things are done by one or more of the Bio21 cluster members.³⁰

1.4 Report Structure

The report is structured as follows:

- Chapter 1 has outlined the purpose of the report and placed the task within the context of Australia's biomedical research industry, with some reference to international practice in this area. It also has given an explanation of the nature of the Bio21 Australia cluster.
- Chapter 2 will give an outline of the potential benefits that can be derived from improving the translation of biomedical research findings into the health care system, and more generally. This chapter will also provide evidence of benefits that have already been captured in Australia and internationally by improving the translation of research findings to the health care system.
- Chapter 3 will delineate the current approaches to facilitating the translation of biomedical research findings to the health care system. It will do this by firstly, outlining the main mechanisms by which the effective translation of research occurs and then by looking at specific examples both in Australia and internationally. This chapter will focus on what approaches have been used, what is working effectively and what is not working well. It will also focus on what is being done in Bio21 Australia and where potential gaps exist that could be filled.
- Chapter 4 will outline a methodology for determining whether action in this area is justified, determining what stakeholders should act, and what the most efficient manner of action might be. This chapter will then present a number of different options for action and evaluate which is likely to be the most successful, and might deliver the biggest economic and social benefits.
- Appendix A provides additional examples of some of the benefits delivered by effective translation of biomedical research into health care and also explores a range of international initiatives that are targeting improved research translation outcomes.

²⁹ <http://www.bio21.com.au/profile.asp>

³⁰ Ibid.

2 The Potential Benefits of Translating Biomedical Research to the Health Care System

2.1 Overview of Types of Benefits

Generally the justifications given for public expenditure on R&D are the existence of positive externalities. Many benefits of R&D cannot be captured by those undertaking it, and instead accrue to the wider community. This means that the market will under invest in R&D as the social rate of return is higher than the private rate of return. When this situation occurs there may be a case for government action. It is also important to note that the benefits of research are not entirely captured by the nation undertaking it; some of the benefits of the effective translation of biomedical research will spread beyond national borders. Similarly, Australia can capture considerable benefits from the 98 per cent of medical research that is conducted overseas. However, Australia's ability to benefit from this international research depends upon having the skills and knowledge necessary to effectively adopt and apply it.

Another important justification for public funding of R&D is that 'increased freedom in the type of research that can be undertaken when research is divorced from the imperatives of profit maximisation, means that innovation can often generate positive social and environmental outcomes'.³¹ The potential benefits of biomedical research are broader than financial outcomes associated with the commercialisation of research outputs. The benefits of biomedical research, and its improved application, are diverse. The main types of benefits that we would expect would be:

1. improved health outcomes;
2. a high value for money health care system;
3. economy wide productivity benefits; and,
4. industry development.

Effective systems for the translation of biomedical research to clinical practice can bring forward the delivery of benefits through each of these channels. More effective research translation systems may also minimise any costs currently associated with the diffusion of biomedical knowledge by making this process more efficient.

In addition to the examples of benefits set out below, a range of additional examples are provided in Appendix A.

³¹ Insight Economics, October 2006, *The impact of public ICT R&D in Australia*, p8

2.2 Improved Health Outcomes

The translation of biomedical research into the health care system can result in positive impacts on health. There is clearly a gain to society that results from improving the population's health. The difficulty lies in determining the nature and magnitude of these improvements, and assigning a dollar value to them. This type of undertaking is difficult, and often controversial, as it necessitates making value judgements about what type of health gains are important, how we value human life and so forth.

Many studies deal with this problem by assigning a value to a human life and then using this to assess the benefit of new medical advances on the basis of their effects on lifespan. This value placed on human life is often determined using hedonic pricing techniques. That is, policymakers estimate which portions of the price of a good or service are related to various characteristics of that good such as the part of the price of a car that is related to its increased safety features. They then use this to estimate the implicit value placed by consumers on their own life. Other estimations are created by looking at compensating wage differentials. For instance, economists will look at the wage that people will accept in order to work in occupations where there is a known higher likelihood of injury or death.

In 2000, the influential Funding First report '*Exceptional Returns: The Economic Value of America's Investment in Medical Research*' valued the prevention of a fatality at US \$3 million.³² Using this assumption, and calculations relating to the contribution that research makes to the decline in mortality in a range of cases, they were able to estimate the social rate of return on investment in medical research.³³ This approach, however, has some limitations as often medical advances do not simply prolong life, but they can also improve the quality of life.

The Access Economics Study '*Exceptional returns: The value of investing in health R&D in Australia*' used the same methodology as the American report but also added the concept of disability adjusted life years (DALYS) to allow for reduction in morbidity as well as mortality.

2.2.1 Examples of Health Benefits

Recent examples of health improvements that have resulted from the application of the results of biomedical R&D in the Australian context are:

- The UK National Audit Office's report *Reducing Brain Damage: faster access to stroke care* estimates that that thrombolytic drugs, which were developed in the 1990s to dissolve blood clots and have a benefit to a significant minority of stroke patients, have generated significant savings to the health system and considerable health benefits to patients.³⁴ Melbourne's Box Hill Hospital has used this treatment for stroke patients with the potential to benefit from it (9 per cent of total stroke patients) and has had considerable success in aiding stroke recovery. Patients who underwent treatment had a 41 percent recovery rate compared with the normal 26 per cent.³⁵
- The CRC for Sensor Signal and Information Processing's collaboration with the Howard Florey Institute has resulted in advances to Magnetic Resonance Imaging (MRI) technology. These MRI technologies are used in understanding brain

³² Buxton, Martin et al. 2004. *Estimating the economic value to society of the impact of health research: a critical review*. Bulletin of the World Health Organisation. 82. 733-739

³³ Ibid.

³⁴ NAO, 2006, *Reducing Brain Damage: Faster access to better stroke care*.

³⁵ Ibid.

structure and function, and have application in the diagnosis of conditions such as breast and cervical cancers, and the detection of hearing impairments in new-born infants. Breast cancer is the most common cause of cancer-related death in Australian women, with over 11,000 women diagnosed with breast cancer every year. The annual incidence of this cancer continues to increase, rising from 94.6 per 100,000 in 1990 to 115.3 per 100,000 in 2000. Because the cause of breast cancer is not known, the key strategies for improving morbidity and mortality depend on early diagnosis, in which imaging techniques and devices play an important role. MRI technological advances therefore have the potential to improve the quality and cost-effectiveness of health care systems³⁶.

2.3 A high value for money health system

There are a number of different effects that the adoption of new medical knowledge, processes, or technologies can have on costs to the health system. When a new treatment becomes available we will have what is called a ‘treatment substitution effect’ which means that old treatments will be replaced by new, more effective, treatments.³⁷ This can have two different results. On the one hand, new therapies can either reduce the number of patients needing treatment or the cost of treatment per patient. A clear example of this type of breakthrough is the use of vaccines which can reduce or virtually eradicate some diseases.³⁸ This may result in significant cost savings for the health care system. On the other hand, if the new treatments are more expensive than the old ones the costs to the health care system can increase. However, it is important to note, that in this case we would still expect the *quality-adjusted price of medical care to fall over time* as new technologies, and processes, are adopted.³⁹

Another effect that we would expect to see would be the ‘treatment expansion effect’ which means that as diagnostic tools and treatments improve, the number of people likely to be treated for particular illnesses will increase – rather than decrease.⁴⁰ This occurs when a new treatment is not preventative.⁴¹ In this case doctors will be more likely to test for illnesses due to improved diagnostic tools and are more likely to suggest treatment as treatments become more effective. Patients too, will be more likely to undertake treatment if it is more effective, less painful or less time consuming. While this increase in the volume of individuals treated may increase the short term direct cost burden on the health care system it will also lead to improvements in community health outcomes and may reduce long term costs.

Another benefit of improved translation of biomedical R&D is that improved health outcomes will increase labour force participation as some people who were previously unable to work as a result of bad health may be able to return to employment, or increase their hours of work. This may also lead to a decrease in disability pensions and other receipts which would mean a cost saving to the government. However, improvements in life span may also result in an increased cost for government (as well as a potential benefit to those who experience it) if this means that the elderly spend more years on the aged pension.

³⁶ Ibid.

³⁷ Cutler D.M. et al. 2001, *Is technological change in medicine worth it?* *Health Affairs* 20.5

³⁸ Buxton, M. *Estimating the economic value to societies of the impact of health research: a critical review*

³⁹ Cutler, D.M. et al. September 2001 *Is Technological Change in Medicine Worth It?* *Health Affairs* Vol. 20

⁴⁰ Ibid.

⁴¹ Ibid.

We can see that there are a number of contradictory effects on government finances that would result from increased translation of biomedical research findings. The interaction of these various effects mean that determining the effect on health costs on an aggregate level is difficult. The exact effect will depend on the illness being treated and the new technology/knowledge being diffused – as well as the broader public policy settings adopted. Moreover, accurately delineating the various research findings that combine to create a particular medical innovation is difficult in all but a few cases. We look at Australian and international evidence later in the chapter in order to evaluate the likely interaction of these different effects.

2.3.1 Examples of value for money gains

In Australia disease expenditure accounted for 87.5 per cent of total recurrent health expenditure in 2000-01, costing the country \$50.1 billion out of a total recurrent budget of \$57.3 billion.⁴² The residual represents capital expenditures, expenditure of community health (except community mental health), public health programs (except cancer screening programs), health administration and health aids and appliances.⁴³

The seven disease groups that accounted for the greatest health expenditure in Australia in 2000-01 were:

- Cardiovascular disease, which accounted for \$5.5 billion (10.9 per cent of allocated health expenditure);
- Nervous system disorders, which accounted for \$4.9 billion (9.9 per cent);
- Musculoskeletal diseases - \$4.6 billion (9.2 per cent);
- Injuries - \$4.0 billion (8 per cent);
- Respiratory diseases - \$3.7 billion (7.5 per cent);
- Mental disorders - \$3.7 billion (7.5 per cent); and,
- Oral health - \$3.4 billion (6.9 per cent).⁴⁴

Expenditure to treat or prevent cancer or other neoplasms in 2001-01 was \$2.9 billion which is 5.8 per cent of total health care spending as allocated by disease.⁴⁵ The categorisation of disease follows the International Statistical Classification of Diseases and Related Health Problems. Nervous system disorders refer to diseases which affect the nervous system whereas mental disorders refer to diseases which affect the brain and mind.⁴⁶

Given the magnitude of these expenditures, small cost changes per treatment, or slight reductions in the rate of treatment, are likely to have substantial effects. For instance, a research-informed change to clinical practice that reduces the cost of cardiovascular disease treatment in Australia by just 1 per cent would result in a direct cost saving of approximately \$55 million per year.

Because of the complexity of pathways of innovation it is difficult to provide any general estimate of the potential reduction in costs to the health care system as a whole from biomedical R&D. However, a number of case studies where breakthroughs have occurred

⁴² Australian Institute of Health and Welfare (AIHW 2005). *Health system expenditure on disease and injury in Australia*, 2000-01. Second Edition. p1

⁴³ Ibid. p1

⁴⁴ Ibid.

⁴⁵ Australian Institute of Health and Welfare, 2005, *Health System expenditures on cancer and other neoplasms in Australia, 2000-01*. p1

⁴⁶ <http://www.who.int/classifications/apps/icd/icd10online/>

suggest that impacts can be high. It is important to note that for any particular research project the probability of success may be low. It is also important to note that where research is successful there is often a problem of attribution, as many different groups claim at least some responsibility for the research that lead to a particular breakthrough.⁴⁷

Some examples of direct cost savings in the US resulting from biomedical research are:

- Polio: The discovery of the polio vaccine has meant that the disease has been eradicated in the United States. Some estimate that the health care costs would be approximately \$30 billion higher per year.
- New drugs have allowed some with mental health issues to be treated on an outpatient basis rather than being institutionalised, saving an estimated \$25 billion annually. Lithium treatment for manic depression is estimated to have saved over \$9 billion annually since wide-scale use commenced 30 years ago.
- Tuberculosis – prior to the development of antibiotics, tuberculosis patients often spent years in treatment with a very low chance of success but now patients typically recover within a year as a result of antibiotics. As a result, the U.S health care system saves approximately \$5 billion a year in institutional care costs of the 300,000 or so patients who would have had this disease.

Other savings in medical costs in the US have resulted from advances in the management of chronic disability.⁴⁸

A significant Victorian example of biomedical research translating into large health benefits is the development of the Cochlear hearing implant. In 1966 Graeme Clark started his research at the University of Melbourne's Department of Otolaryngology in 1967, but the first implant was not inserted until 1978. In December 1984, the Australian cochlear implant was approved by the United States Food and Drug Administration to be implanted into adults in the United States.⁴⁹ By 2005, over 64 000 patients across 120 countries had received Cochlear implants. Of these recipients 16 300 have been in the Asia-Pacific region.⁵⁰

A 1994 study by the Centre for Health Evaluation at Monash University into the economic impacts of the Cochlear Implant found that the implant delivers a wide range of health and general quality of life benefits to recipients. Overall, through use of extensive survey data, the study found that for profoundly deafened adults the improvement in health-related quality of life through use of an implant ranges from 11 to 37 per cent while for children the improvement ranges from 17 to 37 per cent.⁵¹ The use of Cochlear implants generates significant social and economic benefits, for example enabling children with hearing impairments to participate in mainstream education which results in estimated savings of \$100,000 to \$200,000 per student.⁵²

The savings that result from biomedical research are rarely quarantined to national borders – new treatment for peptic ulcers was made possible by the work of Australian researchers Professor Barry Marshall and Dr Robin Warren, who discovered that stomach ulcers were caused by a bacterium and not stress as had commonly been assumed. These researchers won the 2005 Nobel Prize for Physiology or Medicine for their work.⁵³ This discovery - and

⁴⁷ UK Evaluation Forum, May 2006. *Medical Research: Assessing the benefits to society*, p23

⁴⁸ National Institutes of Health, 2000. *The Benefits of Medical Research & the Role of the NIH*, NIH, May. p14

⁴⁹ Cochlear company timeline. www.cochlear.com

⁵⁰ Ibid.

⁵¹ Carter R, Hailey D. (1994), *Economic evaluation of the cochlear implant*. CHE Working Paper 44

⁵² CRCA supplementary submission to the Productivity Commission review of public science in Australia

⁵³ <http://www.abc.net.au/science/news/stories/2005/1474064.htm>

the further research that it has prompted - has resulted in greatly reduced costs of treatment worldwide. In the US, operations for peptic ulcers plunged 80 per cent during the 1980s and it is estimated that this resulted in direct cost savings to the US of approximately \$600 million annually.⁵⁴

In Victoria spending on health is significant, and small increases in efficiency in the translation of research results to the health care system could save the State substantial amounts. The total budget for the Department of Human Services (DHS) for 2004-05 is \$10.9 billion.⁵⁵ This represents only part of the total health spending in Victoria which was \$21.9 billion for this period.⁵⁶ Total recurrent spending was \$20.593 billion.⁵⁷ We assume that spending on disease is roughly in the same proportions in Victoria as it is at the federal level. Spending on disease nationally was 87.5 per cent of total recurrent health spending in 2005, and spending on cardiovascular disease was 10.9 per cent of this. This would mean that spending on cardiovascular disease costs the state almost \$2 billion annually. A reduction in costs of treating this disease of only 1 per cent would therefore result in a direct health cost saving of around \$20 million per annum.

2.4 Productivity Benefits

As well as potentially contributing to lower health care costs, or at least, lower quality-adjusted health care costs, the translation of new biomedical knowledge to the health care system has the potential for broader economy-wide cost savings. These take the form of economic benefits that result from the avoidance of production losses as a result of morbidity and lower life span.

These improvements in population health can potentially increase labour force participation rates (increasing economic growth and government receipts), reduce underemployment and improve labour productivity. The magnitude of these effects, of course, depends on the particular research findings and the nature of their application.

There are a number of studies which have attempted to estimate the economic costs to society of morbidity and mortality rates and hence determine the gains in economic activity that would result from a reduction in these. Some of these are discussed later in the chapter.

2.4.1 Estimations of Productivity Benefits

Access Economics estimates a number of productivity benefits that are brought about as the result of biomedical R&D that leads to more effective treatment. These would be a reduction of the indirect economic costs that are attributable to illness. Such as:

- earnings forfeited due to illness causing premature retirement and absenteeism;
- earnings forfeited due to premature mortality;
- earnings forfeited by carers;
- costs of aids and modifications required as a result of illness; and,
- other costs, such as the costs to the criminal justice system that can occur as a result of untreated mental illness.⁵⁸

⁵⁴ National Institutes of Health (2000) *The Benefits of Medical Research & the Role of the NIH*, NIH, May. p14

⁵⁵ Victorian Government Budget Papers, *Statement of Finances 2006-07*, DHS .
<http://www.budget.vic.gov.au>

⁵⁶ <http://www.aihw.gov.au>

⁵⁷ Ibid.

⁵⁸ Access Economics, September 2003, *Exceptional Returns: The Value of Investing in Health R&D in Australia*, prepared for the Australian Society for Medical Research. Canberra. p57

In their book *Biomedical Research: Costs and Benefits*, Mushkin et al attempt to calculate the total value of economic benefits to the USA as a result of all health research. They estimated the total value of the reduction in mortality and morbidity in the USA between 1930 and 1975, determined what share of this was caused by biomedical research and estimated the rate of return of 47 per cent to research.⁵⁹ Other studies have also tried to quantify the economic costs of lost production such as Goetzel who analysed data for 374, 799 employees from six large firms and found that absence and disability losses accounted for 29 per cent of the total health and productivity related expenditures for physical health conditions and 47 per cent for mental health conditions.⁶⁰

According to the ABS national health survey conducted in 2001, a total of 3.7 million work days were lost as a result of illness.⁶¹ Note that this figure does not include the amount of 'days out of role' which result from employees operating in a diminished capacity as a result of illness or injury. Over 17 per cent of employees had spent some time out of their usual role over the two weeks prior to the survey as a result of illness or injury.⁶² A ten percent reduction in days off would result in the equivalent of an additional 1600 full time employees in the labour force. At the mean full time weekly earnings at that time of \$840⁶³, this increase in hours worked would imply an increase in national income of approximately \$70 million dollars for that year.

Effective diffusion of research knowledge into clinical practice may also generate improvements in rates of diagnosis and subsequent treatment. This is a further area where significant benefits – in terms of both health and productivity outcomes – may be able to be obtained. A recent study from the University of Queensland surveyed 98,000 employees at 58 of Australia's largest companies. The study, which is to be released later this year, found that on average workers with untreated depression are \$9,660 less productive per year.⁶⁴ Though the final results have not been determined as yet, researchers suggest that when workers seek help to manage their depression that employers could recoup almost \$7,600 per employee.⁶⁵ Given the prevalence of depression, with around 300,000 Victorian's suffering from major depression in any given year⁶⁶, this suggests that even small research led proportional improvements in rates of diagnosis and subsequent treatment would yield substantial productivity benefits. Each one per cent increase in the rate of diagnosis and subsequent treatment from this affected population base would translate to a productivity increase valued at almost \$25 million per annum.

Another study undertaken for the Victorian Government by Boston Consulting estimated that all mental illnesses combined cost 4.7 million lost days of work in Victoria alone in 2006 –

⁵⁹ Referenced in Buxton et al, 2004. *Estimating the economic value to societies of the impact of health research: a critical review*. World Health Organisation,

⁶⁰ Goetzel, Ron Z. et al. Jan 2003. *The Health and Productivity Cost Burden of the "Top 10" Physical and Mental Health Conditions Affecting Six Large U.S. Employers in 1999*. Journal of Occupational Medicine.

⁶¹ ABS Cat 4364.0 Table 21

⁶² <http://www.abs.gov.au/AUSSTATS>

⁶³ ABS Cat 6301. <http://www.abs.gov.au/AUSSTATS>

⁶⁴ M Sweet and S Price, forthcoming, *Bosses feel the pinch when workers battle depression*.

⁶⁵ Ibid.

⁶⁶ Mental Health Research Institute, 2004, *The Depression Awareness Research Project*, estimated the annual incidence of major depression at over 6 per cent of the Australian population. In Victoria this would translate to around 300,000 people.

which is a much greater estimate than the earlier ABS data.⁶⁷ Boston Consulting estimated that this cost the Victorian economy \$660 million per year.⁶⁸

2.5 Industry Development

There can also be gains to the development of local industry as a result of public funding of biomedical research, and diffusion of the results. This can result from two main mechanisms. Firstly, the funding of research can create a pool of skilled scientists that can be drawn upon by industry. Secondly, the public nature of basic knowledge in this area can provide an intellectual foundation for later commercial applications of biomedical knowledge. A United States study estimates that each \$1 of funding for basic biomedical science stimulates a further \$3.15 in pharmaceutical industry R&D.⁶⁹

Development of local industry is one of the driving motivations behind Victoria's sustained investment in biomedical research. Victoria's Biotechnology Strategic Development Plan 2001 was driven by the vision that 'by 2010 Victoria will be recognised internationally as one of the world's top five biotechnology locations for the vibrancy of its industry and the quality of its research'.⁷⁰ The vision remains the same in its 2004 update to the original plan.

The Victorian Government outlined a number of objectives that related to industry development in the 2001 plan. The development plan called for at least 50 new start-up companies to be based in Victoria by 2005. This objective was met as from 2000 to 2002 68 new core and related biotechnology start-up companies were established in Victoria.⁷¹

The Government also wanted to have attracted at least five new research or investment partnerships with local or international biotechnology related companies by 2005 to a combined value of at least \$25 million. This objective was more than met as combined investment accounted for US \$120 million by 2004.⁷²

The government also aimed to increase clinical trial research investment by 50 per cent by 2005 through its activities in supporting biomedical research and infrastructure provision. Though information of progress against this target is not publicly available, DIIRD argued that substantial progress was being made on this front in its 2004 policy review.⁷³

Finally, the government aims to create three significant manufacturing facilities by 2010. Though it is too early to assess whether this target has been met a number of industry groups have expanded their manufacturing operations since the 2001 policy release.⁷⁴

2.5.1 Estimations of Industry Development Effects

As a result of the complex set of mechanisms by which knowledge is generated by basic research and diffused to industry there is some difficulty in determining the extent to which biomedical research supports the development of industry.

Many estimates of the economic benefits of R&D have been undertaken. For instance, Silverstein et al listed 10 biomedical discoveries that, they claimed, had been applied outside

⁶⁷ D Hughes. *Call for fair division of mental costs. The Australian Financial Review* 7 July 2006, 10.

⁶⁸ Boston Consulting, *Improving mental health outcomes in Victoria: the next wave of reform*, July 2006

⁶⁹ Toole, A., 2002, *Does Public Scientific Research Complement Industry R&D Investment? The Case Of NIH supported Basic And Clinical Research And Pharmaceutical Industry R&D*

⁷⁰ DIIRD, 2004, *Biotechnology: Strategic Development Plan for Victoria 2004*, p7

⁷¹ Ibid. p15

⁷² Ibid. p15

⁷³ Ibid. p15

⁷⁴ Ibid. p16

the health sector and were worth US \$92 billion in sales.⁷⁵ Moreover, Rosenberg suggests that the half a million jobs estimated to reside in the US biopharmaceutical industry ‘would not exist if industry wasn’t standing on the shoulders of public funding and academic performance’.⁷⁶ Other studies have looked at the employment benefits created by public funding of R&D more specifically and have even attempted to quantify these at a sub-national level, but this task is highly speculative.

In the draft report of its current comprehensive study into the returns from public science in Australia, the Productivity Commission reviewed all of the available studies into the issue and concluded that while it is not possible to put a precise number on the economic returns delivered, the available evidence suggests that they are positive and significant.

Though the exact relationship between biomedical research and industrial development is unclear, as other conflicting variables also confound measurement, many governments have recognised it as substantial. Some help support their pharmaceutical industries so that they might capture a range of economic benefits which range from employment, import substitution and reduced drug costs.⁷⁷

The Productivity Commission, when commenting on the effectiveness of the Pharmaceutical Industry Investment Program, notes that the R&D component of the scheme has delivered net benefits to Australia, among other things, through its effect on industry development and suggests that the program concentrates on R&D, and argues that further ‘concentrating (the scheme) on R&D could also make a ‘bigger splash in a smaller pond’.⁷⁸

The size of the pharmaceutical industry in Australia is substantial. Medicines Australia estimates that the turnover of the pharmaceutical industry, including wholesaling, was \$6.99 billion in 1999-2000.⁷⁹ Exports are also significant with \$1.4 billion exported in 1999-2000.⁸⁰ However, only around a third of pharmaceutical products consumed in Australia are wholly manufactured here, with another 18 per cent made overseas but fully finished and packaged here.⁸¹

In addition to pharmaceutical industry development, medical devices and equipment is another sector whose development may benefit from publicly funded biomedical research. The growth of Cochlear is a good illustration of this. Cochlear’s core technology resulted from work undertaken at the University of Melbourne in the 1960s and 1970s. Since Cochlear’s establishment in 1978 it has benefited from a wide range of public R&D linkages and grant support. There has been extensive funding provided to related work through a special research centre and Cochlear is a part of the CRC HEAR, which also includes Australian Hearing, the Bionic Ear Institute and the University of Melbourne. Cochlear is now a large company which has experienced strong revenue growth over the past decade, with revenues now exceeding \$350 million per annum.

⁷⁵ Silverstein S. et al. 1995 *A few basic economic facts about research in the medical and related life sciences*, FASEB Journal

⁷⁶ Rosenberg L. 2002 *Exceptional economic returns on investments in medical research*. Medical Journal of Australia

⁷⁷ Buxton et al, 2004. *Estimating the economic value to societies of the impact of health research: a critical review*. World Health Organisation,

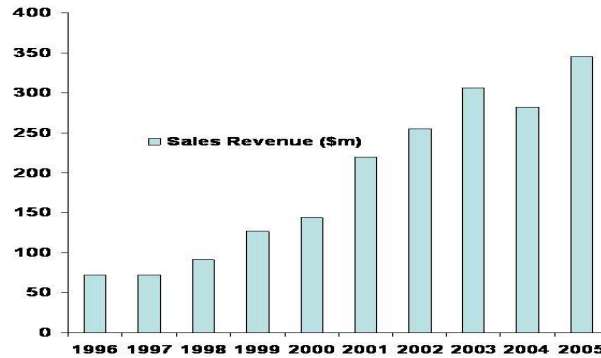
⁷⁸ Productivity Commission, 2003, *Evaluation of the pharmaceutical industry investment program*.
pxiii

⁷⁹ 2002, *Pharmaceutical Fact Sheet*, Medicines Australia, Canberra.

⁸⁰ Ibid.

⁸¹ Ibid.

Cochlear Ltd revenue growth 1996 - 2005



Source: www.cochlear.com

Employment outcomes for cochlear are also strong, with Cochlear employing around 1,000 people worldwide, of whom approximately 60 per cent work in Australia. Cochlear also now contributes funding to a range of research collaborations at CRC HEAR, including projects involving the Bionic Ear Institute, the Cochlear Implant Clinic and Melbourne University's Department of Otolaryngology.

This chapter has predominantly looked at the benefits that can be captured as a result of biomedical R&D rather than looking at the benefits of improving the translation of biomedical R&D into clinical practice more specifically. There are two reasons for this. First, there is a relative paucity of information on the benefits of improved translation of biomedical knowledge relative to the amount of information relating to the benefits of biomedical R&D more generally. Secondly, the nature and scope of benefits that flow from the improved application of knowledge derived from biomedical R&D are often contingent on the particular context. Hence, we will look at some of these benefits more specifically in the next chapter when we look at the current policy settings that are aimed at improving translation of biomedical R&D.

3 Approaches to the Transfer of Biomedical Research Discoveries to the Health Care System

3.1 Channels for Biomedical Research Translation

Though in recent years there has been significant growth in biomedical research a ‘large gulf remains between what we know and what we practice’.⁸² For instance, there is a wide variation in the way drugs are used despite there often being good evidence of their best use.⁸³ This variation is common both internationally and within countries; the gap between evidence and practice can result in sub-optimal diagnosis and treatment, and in some cases can impact negatively on patient safety and health outcomes. At the very least, by not applying the most recent techniques, or using the most recent technology, patients are forgoing potential benefits to their health.

The discrepancy between knowledge and practice is often the result of slow and uneven diffusion of knowledge from R&D. Moreover, it is also often a result of the increasing demedicalisation of biomedical research where researchers are predominantly scientists rather than clinicians, and research can become more a question of scientific curiosity or commercial application rather than an attempt to solve a specific medical problem. Unfortunately, the gap between investigation driven by scientific curiosity and the clinical application of the results of such study may be years or even decades.⁸⁴ By hastening this process, by ensuring that biomedical research focuses more strongly on delivery of health outcomes, and by ensuring that the results are more widely applied, it may be possible to capture additional health benefits for society.

The barriers to quick diffusion of knowledge from research often result from a lack of:

- incentives and opportunities for researchers to interact with clinicians and share their findings;
- input from the health care system into research direction; and,
- time available to medical practitioners to uptake new information and practices.

Moreover, a range of barriers to commercialisation may exist which would mean that translation of research knowledge through this mechanism is also slowed.

⁸² Davis et al, July 2003. *The case for knowledge translation: shortening the journey from evidence to effect*, British Medical Journal, www.bmj.com/cgi/content/full/327/7405/33. p1

⁸³ Ibid.

⁸⁴ UK Evaluation Forum, May 2006, *Medical research: assessing the benefits to society*

Three important channels by which new biomedical knowledge can be utilised within the health sector are:

- Improved knowledge of medical practitioners and of researchers through network effects and training;
- Technological adoption, where new technologies represent the application of new research findings about the nature of the human body; and,
- Systematic or institutional reorganisation, where the processes and conventions of a health institution are changed to reflect increasing knowledge gained from biomedical science (and health science more generally).

Each of these channels for biomedical knowledge translation are considered below.

3.2 International Experience

Though internationally there has been an increasing emphasis on knowledge translation, with a special emphasis on commercialisation, this drive is not entirely new. For instance, in Britain, the National Health Service set up a programme to evaluate different methods of promoting the implementation of research findings in the early nineties.⁸⁵ There is a growing awareness internationally that knowledge diffusion strategies that rely on the passive diffusion of information to the practitioner – such as conferences and courses – have little impact on the behaviour of health professionals.⁸⁶ Instead, removing institutional, social and organisational barriers to diffusion and adoption of new knowledge will have a much greater impact.

Appendix A considers a range of initiatives that have been introduced in the United Kingdom, Canada, Singapore and the United States to improve the translation of research into clinical practice. In addition to the specific initiative outlined in Appendix A, internationally governments have also invested in, or encouraged investments in, biomedical research clusters.

Clustering – A way of maximising network effects?

Clusters, as a result of agglomeration effects, are often thought to be catalysts for regional economic development and have, as a result, been the focus of much government policy making. In some countries clusters have been very effective in maximising spillovers, reducing costs and driving economic growth. In the US for instance, nine biotechnology clusters account for at least 75 per cent of the national industry.⁸⁷ Many clusters in advanced technologies begin as government or university led efforts and then evolve to comprise private firms with strong public linkages.⁸⁸ Devol (2003) suggests that successful clusters share a number of common factors which are:

- Innovation: as knowledge is shared more efficiently in close proximity.
- Human Capital: effective clusters need a pool of well educated people.
- A Globalised Economy: clusters need access to the world economy.
- Dynamism: effective clusters foster an environment where companies can start and flourish.⁸⁹

The development of a successful cluster can be one way of ensuring that the institutional framework increases the potential for effective translation of research knowledge into the health care sector.

⁸⁵ Advisory group to the NHS Central Research and Development Committee, 1995, *Methods for the implementation of the findings of research: priorities for evaluation*, Leeds: Department of Health,

⁸⁶ Davis, DA, 1995, *Changing physician performance: A systematic review of continuing medical education strategies*, JAMA.

⁸⁷ Ibid.

⁸⁸ Ibid.

⁸⁹ Ibid.

Many examples of successful clusters exist in the USA such as clusters based in Boston, Delaware and around Stanford University. Canada also has clusters in Toronto and Montreal. Biomedical clusters also exist in Munich, Zurich, Oxford, Singapore, Jerusalem, and in many other countries. The Discovery District in Toronto is seen by many as a good example of an effective translational cluster.

The Toronto Discovery District

Toronto Discovery District is the fourth largest medical and biotech cluster of any metropolitan area in North America, with more than one billion dollars directed annually to research activities within it. The Discovery District is a 2.5 square kilometre research park that is integrated into Toronto's downtown core. More than \$500 million has recently been invested in new infrastructure that supports basic research and the commercialisation of new scientific discoveries in the Toronto area.

Key facilities within the Discovery District include: the MaRS centre which has 750,000 square feet of research labs, business incubator facilities and business services (and next year is expected to announce an additional one million square feet of research and commercial space); the new Donnelly Centre for Cellular and Bio-Molecular Research, a multi-story, \$110 million research centre; and, the new Leslie Dan Faculty of Pharmacy.

Overall, there are 3 Universities (including the University of Toronto), 9 Teaching Hospitals and more than 30 specialised Medical and Related Sciences Research Centres located within the Discovery District. More than 22,000 people are employed within the district in medical care and research related jobs.

3.3 The Australian Experience

3.3.1 Improved Knowledge of Medical Practitioners/Researchers

Knowledge transfer involves an active exchange between the researchers who create the new knowledge and those who use it, with biomedical knowledge diffused either formally or informally. Medical practitioners undertake continued professional development so as to keep abreast of new trends in biomedical thought, new diagnostic tools, and new treatments.⁹⁰ Traditionally this has meant formal, passive learning, centred round the medical conference. Newer types of career development, however, focus on aiding behavioural change in medical practitioners through interventionist approaches such as computer diagnostic tools, and patient-mediated interventions.⁹¹ Moreover, formal links are often created between teaching and research institutions so as to communicate research findings between different research bodies as well as between researchers and clinicians. Clinical research is another important way that research findings are tested before they are applied as new treatments.

Translating biomedical innovation into clinical practice involves undertaking, and diffusing the results of, clinical research to inform clinicians of related diagnostic and delivery techniques for new technologies, as well as new patient management strategies. More informal modes of transmission include the human capital that individuals acquire – and diffuse – when they move between different research bodies, and medical institutions.

⁹⁰ Bero, L. et al, 15 August 1998, *Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings*, BMJ

⁹¹ Haines, A. et al, 4 July 1998, *Getting research findings into practice*, BMJ

One important mechanism by which medical practitioners gain improved knowledge is through undertaking clinical research. This means that they will be better placed to understand the value of research and to stay abreast with the most recent research findings. It also means that they will be able to undertake research that is aimed at a particular medical problem and hence has a direct clinical application. One recent example of support for this type of initiative is the proposed clinician research fellowship program sponsored via Bio21 Australia.

The University medical school Departments of Medicine and Surgery activities that are located within hospitals can also play a potentially important role in the translation of research generated knowledge into the training of clinicians. This knowledge can then be carried through into future clinical practice.

Knowledge transmission through increased human capital can have two different effects:

- The immediate – which means that medical practitioners are able to put the newest knowledge into effect so as to directly benefit their patients.
- The indirect – where this type of diffused knowledge begets other research that builds upon the original findings, and which may one day have a medical application.

The National Health and Medical Research Council aims to ‘improve health care practice through the provision of authoritative and timely advice, and the dissemination of evidence based guidelines and information’.⁹² The NHMRC provides a range of evidence based advice, guidelines and products to medical practitioners and to the broader community – in the form of pamphlets, posters, pocket cards and publications. The NHMRC has developed guidelines in relation to conserving Australia’s blood supply, colorectal cancer guidelines, Vitamin K deficiency guidelines and in a wide range of other areas.⁹³

The NHMRC also works to identify gaps in Australia’s health evidence base. It then sponsors workshops into these areas to identify potential directions to take from there. It also works with other health organisations to facilitate knowledge sharing and identify opportunities for collaboration. The NHMRC also supplies funding for work on translational research through the Centres for Clinical Research Excellence (CCRE). Currently the NHMRC is funding 23 of these centres, which includes two dedicated to Aboriginal and Torres Strait Islander health. These centres aim to support clinical research (translational research) to improve health outcomes for the community, foster training of clinical researchers, and ensure the effective translation of research outcomes into clinical practice.⁹⁴ The most recent round of grants provide \$400,000 per year for 5 years – up from the initial offer of \$250,000 per year for 3 years.⁹⁵ This followed the adoption of an evaluation report of the initial program which suggested that the three year period was too short.⁹⁶

This evaluation report suggested that while the CCREs have generally been very successful in initiating the translation of research into clinical practice, the extent to which this is actually carried out is variable. At that time, most of the translation that had been achieved was at a local level. Many of the centres went beyond the traditional modes of diffusion such as publication in scientific journals and presentations at scientific meetings to, for example, set up web based education programs. While some groups were in a position to influence

⁹² NHMRC, December 2002, *Review of the implementation of the National Health and Medical Research Council’s Strategic plan 2000-2003*, p21

⁹³ Ibid.

⁹⁴ Ibid.

⁹⁵ http://www.nhmrc.gov.au/publications/_files/ccrepres.pdf

⁹⁶ NHMRC, 2001, *Centres of Clinical Excellence in Hospital-Based Research: Evaluation Report*, p5

policy the NHMRC recommended more meetings with state and territory health departments to help influence policy.⁹⁷

Currently, the NHMRC is also providing support for translational research into dementia through the Dementia Research Grants.⁹⁸ These are part of a collaborative research initiative into dementia which is being conducted with the aid of the Department of Health and Aging.⁹⁹

The CCREs have been very successful, though support in this area could be greater given the substantial amount of interest in it. Moreover, while clinical research is important, it is also desirable that hospitals support research clinicians – researchers who are not primarily scientists so as to bring a medical perspective to the research needed and to aid the diffusion of knowledge within the hospital.

There is little evidence of significant focus on providing support for clinician researchers within hospitals besides the Bio21 Australia Clinician Researcher Fellowship, which will be outlined later and is only in its preliminary stages.

3.3.2 Technological Adoption/Creation

Another process by which biomedical discoveries are translated to the health system is by becoming embodied in new technologies. The most obvious example of this is the creation of new drugs to treat disease – where new drugs are the embodiment of a variety of past research findings across a range of disciplines. It is important to note that this type of translation of biomedical knowledge is complex, and may have a substantial lag time. It is often very difficult to determine the range of discoveries that contributed to the creation of a new breakthrough technology. Other types of technology creation might include diagnostic tools, or new invasive instruments and procedures. These types of translation of research findings are often closely linked to commercialisation and knowledge transfer to industry.

Although much Australian medical research has been successfully translated into useful treatments – a number of examples of this were provided in chapter 2 – most of the industry development activity involved in bringing the research through to a commercial product has occurred overseas.¹⁰⁰

At a national level there has been a push to improve knowledge transfer in general with a particular emphasis on capturing the economic benefits of research. The Minister for Education, Science and Training, Julie Bishop, emphasised the importance of knowledge transfer and defined the term as “the process of engaging with government, business and the wider community to generate, acquire, apply and make accessible knowledge for quantifiable economic benefit for the community.”¹⁰¹

There are significant strengths to Australia’s knowledge transfer system. Large, sophisticated, innovation-intensive business, in particular, are able ‘to maintain ‘strong links to multiple Higher Education Institutions (HEIs) and Publicly Funded Research Agencies (PFRAs)’ and, as a result effectively access the major knowledge transfer supporting

⁹⁷ Ibid. p14

⁹⁸ <http://www.nhmrc.gov.au/funding/types/list.htm>

⁹⁹ <http://www.nhmrc.gov.au/funding/types/granttype/strategic/dementia.htm>

¹⁰⁰ Kingwell, B. et al, MJA, 20 March 2006, *Evaluation of NHMRC funded research completed in 1992, 1997 and 2003: gains in knowledge, health and wealth.*

¹⁰¹ Julie Bishop, Minister for Education and Science, in her keynote address to the *Knowledge Transfer and Engagement Forum*, 16 June 2006.

research funding programs provided by the Commonwealth Government through the ARC Linkage Grants and the CRC Programme.¹⁰²

According to a forthcoming report by Insight Economics *'The business case for knowledge transfer'* the system has two major weaknesses. These are:

- problems with lack of interaction between Small and Medium Enterprises (SMEs) and HEIs/PRFAs and;
- suboptimal HEI/PFRA intellectual property commercialisation practices and outcomes.¹⁰³

The situation is summed up in a recent report by the Business Council of Australia (BCA), in its recent report, *New Pathways to Prosperity: A National Innovation Framework for Australia*:

“Australia’s national innovation system has pockets of excellence, such as the CSIRO and its National Flagships Program, the various Cooperative Research Centres, and sector specific R&D institutions such as the Australian Centre for Minerals Extension and Research (ACMER)...While Australia has benefited from examples of highly effective collaboration, there continues to be considerable scope to improve the level and quality in all sectors – in particular between industry and public sector research institutions and universities. The 2003 ABS Innovation Survey found that only 27 per cent of innovating businesses in Australia were involved in any form of collaboration or alliance. Furthermore, only 6.5 per cent of innovating businesses had collaborative links to universities, governments or research institutions.”¹⁰⁴

While this may be the case, the difficulty lies in determining to what extent the government is responsible for improving on this outcome or whether significant action would yield a marked improvement as it appears that there has already been considerable government action in this area. We look at different options for action in the final chapter of the report.

3.3.3 Systematic/Institutional Reorganisation

Translation of knowledge through this channel includes the reorganisation of methods of treatment, of institutional conventions, and of the built environment to reflect new knowledge. This may occur at a local level as doctors use their improved knowledge to create new processes that maximise patient well being and treatment efficiency. At a broader level, public policy makers may be able to use new biomedical knowledge to design better medical environments and to improve formal institutional arrangements.

The development of organisations such as the Bio21 Australia project and the broad range of CRCs are examples of institutional reorganisation so as to better facilitate the creation of biomedical knowledge and the translation of that knowledge. The increasing focus on translational research as a result of CCREs is also another example of this institutional reorganisation so as to improve the translation of biomedical knowledge.

Another potential systematic reorganisation would be designing institutional arrangements that researchers and medical practitioners share a physical space. This can potentially improve the knowledge of both researchers and medical practitioners though improved communication. This type of transmission can also be facilitated by the clustering of research and medical institutions and providing for movement of staff between these different institutions. It can also be aided by designing hospitals with expanded research

¹⁰² Forthcoming Insight Economics report, *The business case for knowledge transfer*

¹⁰³ Ibid.

¹⁰⁴ BCA, 2006, *New Pathways to Prosperity: A National Innovation Framework for Australia*

capacity, situating research institutes within them to provide clinician researchers, medical practitioners and scientist interaction.

The new \$60 million Centre for Clinical Research (CCR), planned to open in late 2007, is currently under construction at the Royal Brisbane and Women's Hospital (RBWH) campus. It provides a current example of a significant structural initiative aimed specifically at bridging the gap between research and clinical practice. The CCR is jointly funded by

- The Queensland Government's Smart State Research Facilities fund (\$20 million)
- The University of Queensland (\$20 million)
- Atlantic Philanthropies (\$20 million)

The RBWH is one of the largest patient care facilities in Australia, with a statewide referral base. It is intended that the CCR's focus on "issues that arise at the bedside" will complement research conducted at other UQ research institutes such as the Queensland Brain Institute. Providing a setting where discoveries in basic research can be translated to a clinical setting, and where clinical questions can inform and shape curiosity-driven scientific research, is seen as an important step in achieving improved patient outcomes.

The CCR is expected to house 320 scientists from a wide range of backgrounds. The four core areas of research at the CCR will be clinical outcomes and trials; molecular and cellular pathology; clinical neuroscience; and tissue inflammation and injury repair.

The clinical outcomes and trials dimension of research will focus particularly on ambulatory Phase Two to early Phase Three trials of new therapies, as well as developing data tools to track patient outcomes and evaluate new treatments. The molecular and cellular pathology program will draw on the data resources of the Queensland Health Pathology Service as well as the molecular biology capabilities at UQ. It aims to increase understanding of the links between molecular and cellular processes and the clinical expression of disease, in fields such as breast, bowel and prostate cancer. The clinical neuroscience program will build on fundamental brain and nervous system research at the QBI, focusing particularly on the development and evaluation of new methods of diagnosis and treatment of dementia, stroke, movement disorders and brain injury. Finally, the tissue inflammation and repair area will link basic research on inflammation with therapeutic clinical interventions, aiming to develop new approaches to treating inflammation and promoting repair.

3.4 The Victorian and Bio21 Australia Experience

The Victorian Government provided funding for the establishment of Bio21 Australia under the STI Initiative which provides funding to priority sectors working on activities that are directed at building Victoria's science, technology and innovation base, encouraging collaboration, and attracting investment from other sources.¹⁰⁵ The cluster is intended to build depth of infrastructure capacity and human capital. A focus on the creation, sharing and communication of knowledge will help Victoria to develop a comparative advantage in biomedical research and knowledge production and application. The project was formally launched in 2001 and restructured in 2002, when new fee-paying member institutions were recruited.

The Victorian Government has set up a range of other projects which were outlined in Chapter 1. Another collaborative group that it helped establish is the Nucleus Network, which emerged from Clinical Trials Victoria, the Centre for Clinical Studies and its member

¹⁰⁵ Howard Partners, April 2006, *Review of the Bio21 project: volume 1*.

bodies. This network is intended to provide a world-class clinical research services for the Australian biotech industry. Initially, CTV received STI funding of \$8 million in October 2002.¹⁰⁶ Clinical Trials Victoria and CCS were subsequently rolled in together into the Nucleus Network which, as of 2005, is a wholly owned subsidiary of the Baker Heart Institute.¹⁰⁷ The network comprises over forty-five research organisations to provide research services for the biotechnology industry.¹⁰⁸

Throughout 2003-05 a number of reports were released, both in Australia, and internationally, which recognised the long lead time from research to commercial outcomes.¹⁰⁹ They also emphasised that government should focus on the diverse important tracks for knowledge transfer, rather than early preoccupation with start-up companies.¹¹⁰ These reports argued that governments should take a more long term approach when setting up the capacity to translate knowledge more effectively into practice.

Over the period 2000-01 to 2005-06 Bio21 Australia received \$50 million from the Victorian government which went to the building of the Bio21 Institute at the University of Melbourne and the Joint Proteomics Facility (WEHI/Ludwig), and the funding of six collaborative infrastructure projects.¹¹¹ STI funding contributed up to 50 per cent of the cost of each project.

Bio21 Australia's key areas of responsibility are:

- collaborative project development;
- networking and representation;
- ensuring access to Bio21 Australia facilities and services;
- communication and educational services;
- policy and advocacy; and,
- monitoring and reporting.

The Howard Partners 2006 assessment of the Bio21 project, suggest that closer relationships between the health services industry are quite strong and have been strengthened through the Bio21 project.¹¹² This said, the Bio21 precinct is still only at its developmental stage and unlike many biomedical clusters *its primary links are not to the bio-pharmaceutical sector but rather to the health services industry.*

The Bio21 cluster had a number of objectives under the *Bio21 Agreement*. So far the group has been relatively successful in creating the necessary infrastructure to support the further development of the research precinct. This includes the creation of the centrepiece facility, the Bio21 Institute, as well as the construction of the Proteomics facility. Other objectives included the creation of a clinical informatics cluster, the development and enhancement of the medical research cluster, the facilitation of the commercialisation of IP, collaboration with Royal Melbourne Hospital for the purposes of clinical research and trials, the procurement of further funding and the expansion of the membership group.

¹⁰⁶ http://www.business.vic.gov.au/BUSVIC/STANDARD/1001/PC_60333.html

¹⁰⁷ <http://www.nucleusnetwork.com.au/page.aspx?30>.

¹⁰⁸ Ibid.

¹⁰⁹ Howard Partners, April 2006, *Review of the Bio21 project: volume 1*.

¹¹⁰ Howard Partners, April 2006, *Review of the Bio21 project: volume 1*.

¹¹¹ Additional funding for the Bio21 Institute was provided by the Federal Government (\$9 million) University of Melbourne (\$50million) and by Atlantic Philanthropies (\$30 million).

¹¹² Howard Partners, April 2006, *Review of the Bio21 project: volume 1*.

The success rate for these other objectives is mixed. For some of the objectives it is still too early to adequately assess the performance of Bio21 Australia as much of the infrastructure has been in place for only a short time. For instance, further development of the medical research cluster has only been partly achieved so far but as the design of the projects is already underway, and the governance mechanisms for the use of the infrastructure have already been developed, there is a high degree of confidence that important research results will soon be achieved.¹¹³

Other objectives have been met very successfully. The Bio21 Australia project supported the establishment of the Molecular Medicine Informatics Model (MMIM) which provides clinical researchers access to data from a range of databases. In August 2005 the Department of Education Science and Training awarded MMIM \$4.37 million to build on the infrastructure so as to extend the program. A further \$11 million has been allocated from the Health Futures initiative to support the development of the Australian Cancer Grid. This initiative is a very effective way of linking the interests of researchers and clinicians.¹¹⁴

Less successful has been the facilitation of commercialisation which was originally intended to be carried out through Bio21 International. However, individual institutes within the cluster have generally preferred to undertake this activity themselves. This said, in 2004-05 commercialisation activity was still reported at over \$140 million among Bio21 Australia member organisations – representing growing activity in spin out companies, patent applications and research contracts.¹¹⁵

The important objective of collaboration between research institutes and the hospitals in clinical research and clinical trials has so far only been partly addressed. Building capacity for collaboration in this way could form the basis of the next phase of the project, according to internal documents. This is because the current investment in capacity creates a comparative advantage in biomedical research collaboration, which could be improved upon by developing both social and human capital.

Recently the Scientific Advisory Council, Bio21 Australia's discussion and strategy group, established the Clinical Scientists Working Group so as 'to examine issues of relevance to clinician scientists.'¹¹⁶ So far an issues paper has been produced that has led to the concept of a Clinician Researcher Fellowship, a proposal which is currently being developed and will require funding.¹¹⁷

3.4.1 Comparing the Mechanisms for Translation

This chapter has looked at a number of the mechanisms commonly used to generate benefits from biomedical research. It outlined a number of ways which this is done, including commercialisation, which is the most commonly government supported way of capturing outcomes as a result of its potential to deliver both long term health benefits, as a result of technological uptake in the health care system, as well as economic benefits through industry development and direct benefits to research institutes as a result of the commercialisation of IP. This mechanism however, is risky and the commercialisation process takes considerable time to yield results.

The other two mechanisms are improving medical practitioner knowledge, and institutional/systematic reorganisation. Some initiatives have been undertaken to improve these mechanisms such as improving network effects and reorganising including the Bio21

¹¹³ Howard Partners, April 2006, *Review of the Bio21 project: volume 1*.

¹¹⁴ Ibid

¹¹⁵ Ibid

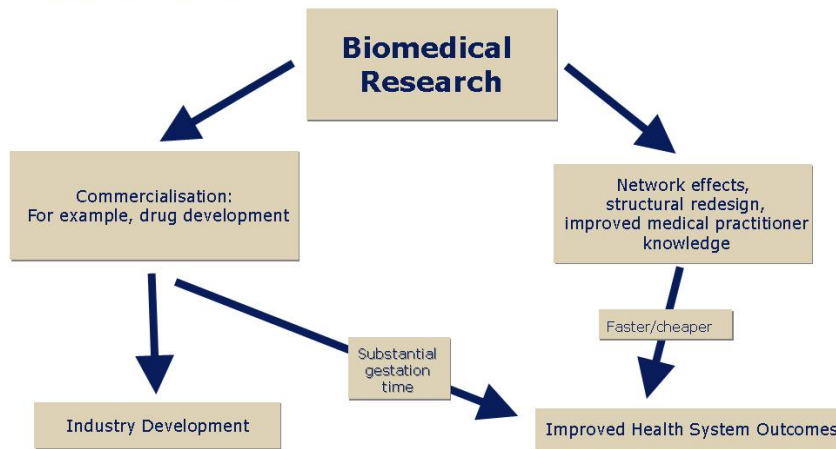
¹¹⁶ Bio21 Australia Ltd, *Annual Report: Scientific Advisory Council Report*. p17

¹¹⁷ Ibid. p17

Australia initiative, Neurosciences Victoria or the Queensland CCR initiative. These mechanisms have the potential to yield faster results for population health and health system costs than purely commercialisation outcome oriented strategies.

Benefits from biomedical research

Comparing the various streams by which benefits are conferred



In Victoria the current arrangement of health research funding is a competitive research model where research institutes are separate (or to a great degree separate) from hospitals and are considerably de-medicalised, in that they are predominantly staffed by scientists rather than clinicians undertaking research. This model has been very effective in generating medical research outcomes such as articles and patents but has been less effective in generating direct health outcomes in the short term.

Importantly, State Government funding for research is now primarily provided by industry departments rather than by the health departments and as a result research is often aimed at generating a commercial product rather than delivery of immediate health care benefits. Reduced allocation of health department resources to research means that hospitals, in particular, give less and less of their time to research. This results in ‘silos of knowledge’ where medical practitioners are not well equipped to take up new research findings, and medical scientists – as a result of their lack of interface with the health care system - are less likely to understand the health needs and problems faced by the health care system.

What is needed to overcome these problems is improved contact between research based scientists and the health sector. This is so that scientists can see what practitioners do and so that medical practitioners have a better understanding of the benefits of research. Moreover, it is important that the hospital system rebuilds its capacity in clinical researchers, as medical practitioners are more likely to focus their research on solutions to problems presented by clinical cases. Moreover, this type of practitioner has the capacity to understand the benefit of research and diffuse new findings within the hospital and, if opportunities for collaboration arise, will be more able to effectively communicate health system research needs to biomedical scientists.

This would entail a paradigm shift in how research is funded, as well as in the reasons which medical research is funded. It is important that clinicians have input into the type of research that is undertaken, as they have a strong knowledge of the needs of the health system. It is also important that hospitals are given adequate funding to conduct their own research so as to train up ‘clinician researchers’ with the capacity to take up and diffuse the newest medical

Deloitte: The benefits from translating biomedical research into the health care system

research findings as well as drive their own important research. Improving the translation of biomedical research into clinical practice so as to generate health benefits cannot be achieved by minor actions such as giving medical practitioners more time to go to conferences to take up new knowledge and to network with their colleges. It requires institutional reorganisation, and funding, which will allow hospitals to play a larger role in driving research, and give them adequate funding so that they can allocate staff time to knowledge uptake.

This chapter has looked at the range of approaches to facilitating the transfer of knowledge from biomedical research both within Australia and internationally. We identified three key channels by which this has occurred these are:

- Improving the knowledge of medical practitioners;
- Technological creation and/or adoption; and,
- Systematic or institutional reorganisation.

In the case of most of the initiatives, both international and Australian, it is still too early to assess whether these have been effective. Generally though, Australian governments have more heavily emphasised the importance of commercialisation as delivering benefits rather than the other two mechanisms of improving medical practitioner knowledge and institutional/systematic reorganisation.

However, there is some evidence of systematic reorganisation such as the case of the Queensland Brain Institute. There is the potential to capture further benefits by adopting this model to improve collaboration between the health care sector and researchers. Finally, this chapter found that there was not a great deal of emphasis or initiatives aimed at improving the knowledge of medical practitioners – either through support for clinical researchers, or through funding hospital based research.

With its industry and innovation focus, DIIRD, who supplied funding for Bio21 Australia, must report against industry development and commercialisation objectives rather than health outcome objectives. This situation likely reinforces the trend towards a growing gap between medical research and health outcomes focus.

4 Assessment of the Need for Further Action in Translation of Research

4.1 Overview

Chapters 2 and 3 outlined the potential benefits of improved translation of biomedical research into the health care system, and the current approaches to biomedical R&D funding and knowledge transfer. This chapter considers a range of actions that might be taken to improve the situation in Victoria. In assessing potential actions we consider questions such as:

- Is there a need for action? That is, is there a sub-optimal outcome that could be improved as a result of action in this area? In the case of improved translation of biomedical knowledge, do market failures exist that could be corrected? Is there a public good in operation that should be strengthened by further action in this area?
- Who should act? What is the best placed institution to act on this matter?
- Is this type of action the most effective way of meeting the desired goals?
- Will this intervention be efficient in meeting these goals? Will intervening in this way produce a positive net benefit that is larger than what could be achieved by another use of resources?

We assess the situation within Victoria, and in particular, within the Bio21 cluster, to determine whether there is a need for further action and whether Bio21 Australia is best positioned to take such action.

4.2 The Need for Action

4.2.1 Medical Practitioner/Researcher Knowledge

There has been an increasing emphasis on translational funding through the Centres of Clinical Research Excellence at a national level. Within the Bio21 project there has also been an emphasis on translational research, and on collaborations between research institutions and the hospitals.

To date Bio21 Australia has facilitated formal and informal collaboration in the area of translational research through the Scientific Advisory Council which shares knowledge and engages in collective planning so as to apply for funding for collaborative research projects and to educate its members. Bio21 Australia has aided the translation of up to date research knowledge within its membership. It has also held a symposium on ‘informatics in medicine and biology’ which attracted 130 registrants, and successfully implemented the MMIM. Moreover, Bio21 Australia has utilised its STI funds to as to enhance Victoria’s capacity in cellular therapy – and has supported the creation of facilities at Melbourne Health, and has supported equipment purchase in this area at the Royal Children’s Hospital and the Centre

for Blood Cell Therapy.¹¹⁸ The idea of introducing a Clinician Researcher Fellowship program in Victoria has also recently been developed though it is yet to be implemented.

This said, much of the action taken so far by Bio21 Australia has been aimed at improving the shared infrastructure that underpins the application of research findings. This is a result of an explicit government emphasis on developing a local biomedical research industry. Moreover, as already noted, there is a ‘silos of knowledge’ effect in operation as a result of the current way that biomedical research is undertaken. Stakeholder discussions indicate that both researchers and medical practitioners would benefit from increased collaboration, and a more effective organisation of institutional relationships. Currently, it was suggested, there are substantial missed opportunities and barriers to communication between these groups. For instance, regular meetings between clinical researchers and basic researchers every second month would create a forum where faster exchange of knowledge could take place.

Much of the Bio21 Australia collaboration to date has been between various research institutes and focused around shared infrastructure. Expanding the range and level of collaboration to better engage the member hospitals could improve health sector outcomes. Moreover, if there is to be adequate collaboration with hospitals then these have to have adequate capacity to uptake new knowledge and to seriously engage with research institutes so as to help direct biomedical research towards more immediate outcomes. There is some indication that, as a result of the increasing emphasis placed on short term service delivery in the health care system, there has been a reduction in the capacity of hospitals to engage in clinical research and for the development of medical practitioners who also have experience in clinical research.

In the case translating knowledge between medical practitioners and researchers it would appear that clusters like the Bio21 project are best placed to implement both formal, and informal, links between researchers and medical professionals. This said, in order for this to be effective, action by government is needed to supply Bio21 Australia with the requisite funds to assist collaboration and to provide hospitals with adequate resources to undertake research, and uptake the results of research.

Providing funding for these types of activities would allow for an improved usage of new research – the MMIM initiative is one example of an initiative that has given translational researchers more immediate access to up to date research. The NHMRC provides a significant amount of guidelines for medical practitioners – government is best placed to ensure that additional resources are allocated to give these individuals time to take up new knowledge, and to utilise the formal and informal linkages created by the cluster.

There is a strong need for action to improve collaboration between institutions in order to increase the knowledge base of medical practitioners, clinical researchers and basic researchers. This would aid the communication of health care needs to research institutes and to aid the translation of research findings to the health care system. Bio21 Australia is well placed to lead initiatives in this area.

4.2.2 Technological Adoption/Creation

As already mentioned, Australia has a wide range of initiatives in place which are designed to support the transfer of knowledge from R&D to the commercial sector. At a federal level there has been an increased push to commercialise the results of R&D. As outlined, the two main areas where some improvement could be made are in facilitating the use of public sector R&D by SMEs and by improving the commercial practices of HEI/PFRA. Currently ARC grants, the CRC sector programs, and the development grants administered by the NHMRC give substantial incentives for research bodies to undertake commercial development. Given this, there needs to be clear evidence of unaddressed market failure

¹¹⁸ Bio21 Australia Ltd, 2005-06 Annual Report

before government supports additional programs directed at improving commercialisation outcomes.

In the case of Bio21 Australia, it was initially intended that the group aid the commercialisation of the research being undertaken by its member organisations. In particular, the commercialisation of interdisciplinary and collaborative projects will be serviced by the application for grant money by Bio21 Australia Ltd and through the workings of the Bio21 International, a separate company set up to either wholly, or partly, carry out commercialisation. However, most groups preferred to undertake their commercialisation on their own. This suggested that many of the research institutes had developed their own capabilities in commercialisation. As a result, a decision was taken by Bio21 Australia for Bio21 International to be wound up. Cooperation in commercialisation is now being fostered by Bio21 Australia through initiatives such as the Shared Intellectual Property register and the Opportunity Tree.

There does not appear to be a compelling case for further action by Bio21 Australia to aid commercialisation processes at this time.

4.2.3 Systematic/Institutional Reorganisation

The current institutional arrangements in Victoria are heavily geared towards pursuing commercial outcomes, or towards investigating basic scientific questions. Moreover, there has been a de-medicalisation of medical research as much research is undertaken for commercial application or scientific curiosity without adequate support given to translational research or research primarily driven by clinical needs. There are a number of reasons for this including:

- that at a state level research has predominantly been funded by DIIRD and as a result industry development through commercial application has been heavily prioritised;
- most biomedical grants do not adequately give incentive for collaboration except in commercial context – such as the CRC grant system;
- that hospitals have become increasingly service delivery focused, and as a result less and less funding and time has been made available for clinical research – which has resulted in a reduction of medical practitioners with clinical research capability and experience, leading in turn to a reduction in the capacity of hospitals to drive, influence or uptake research;
- many medical research institutes have been physically separated from hospitals and hence have little understanding of the needs of the health system;
- medical research institutes are predominantly staffed by scientists and input by medical practitioners is limited.

There have been some attempts to address these problems and to encourage collaboration and to promote translational research. For instance, the creation of Bio21 Australia and its shared infrastructure has allowed increasing collaboration between different institutions and hospitals. The creation of the Centres for Clinical Research Excellence has also improved the focus on translational research.

While some institutional reorganisation has been undertaken within Australia, of which the Queensland CCR is one encouraging example, there is still significant scope for action in this area so as to ensure that biomedical knowledge is effectively diffused, and that research undertaken is in the interest of the community. Bio21 Australia is well placed to lead the debate on this area and look into potential alternative institutional arrangements because Bio21 Australia has a diverse membership and has already heavily emphasised collaboration, as well as attempting to improve translational research.

Deloitte: The benefits from translating biomedical research into the health care system

Also, transmission of information will be quicker and more effective when mediated through a peak body like Bio21 Australia rather than governments having to deal with a range of research institutes.

Given the current institutional arrangements, there is merit in Bio21 Australia taking a thought leadership role in investigating options for restructuring aspects of the health care system, grant system and reconsidering which government departments fund biomedical research.

4.3 Potential Actions

A range of initiatives have been introduced in recent years, both international and Australian, to address each of the above channels. However, it is still too early to assess how effective such initiatives have been. Generally though, it can be observed that Australian governments have more heavily emphasised the importance of commercialisation as delivering benefits rather than the other two mechanisms of improving medical practitioner knowledge and institutional/systematic reorganisation.

This report suggests that, at a fundamental level, a rebalancing needs to occur within the health research sector, with a renewal of focus on directly linking research to current clinical issues of high priority.

To this end, two immediate actions and one longer term action are recommended to improve knowledge flows between researchers and practitioners:

- Building up the clinician researcher base within hospitals.
- Increasing Bio21 Australia activities so as to strengthen formal and informal connections between researchers and clinicians in the cluster.
- Consideration of structural reform to the funding and conduct of health research.

4.3.1 Build up the Clinician Researcher Base within Hospitals

This option would see an increased emphasis by the government on providing grants and funding so as to develop a clinician researcher base within hospitals. While this may involve providing more funding for clinical research broadly, it is important that the types of grants provided are targeted to ensuring that more clinicians have the opportunity to undertake research.

Possible ways of achieving this might included the adoption of a scheme close to that being discussed by Bio21 Australia – the Clinician Researcher Fellowship. Other ways that this might be achieved, or built on, is through making certain grant funding contingent on a hospital working in partnership with a research institute to look at a problem that faces the health system. This would also have the added benefit that the hospital and institute would share knowledge on the problems facing the health care system and the newest research.

Most importantly, hospitals need to have specific funding so they can allocate staff time to research and knowledge uptake – otherwise they will not be well placed to make use of new biomedical discoveries, nor will they be able to effectively input into any collaborative projects.

4.3.2 Use Bio21 Australia to Improve Collaboration between Research Institutes and the Health Care System

Bio21 Australia already emphasises collaboration between research institutions and hospitals, and helps manage collaborative research projects between its members. This role could be expanded so as to gain more substantial benefits.

More emphasis needs to be placed on collaboration between research institutes and hospitals – although as already mentioned capacity building within hospitals needs to be undertaken to make this viable. This would ensure that researchers have a greater understanding of health system needs when designing research projects. However, this is not to suggest that basic biomedical research should not be undertaken but rather that some additional focus is needed to ensure that more research is targeted at addressing health sector problems through a more immediate mechanism for example, a focus on treatment strategies rather than through the technological creation process.

Increasing Bio21 Australia activities so as to strengthen formal and informal connections within its group and between it and government would help:

- increase practitioner knowledge of basic research where useful to improve treatment;
- where possible, increase responsiveness of biomedical research to Health System needs.

A financial incentive for collaboration may be worthwhile to ensure that it is not just a marginal activity for institutions. For instance, increasing collaborative grant funding would encourage a range of clinical researchers to come together to solve a particular health problem.

4.3.3 Consideration of structural reform to the funding and conduct of health research

This report has outlined a number of problems in the current institutional arrangements that mean that knowledge transfer of biomedical research is suboptimal. There is a substantial potential to improve health system outcomes by restructuring the system to support closer collaboration of institutes and hospitals – perhaps by putting medical practitioners and some researchers in close physical proximity to each other such as in the case of QBI.

There are many ways which the problems that this report has outlined could be addressed. A shift in who funds biomedical research might yield dividends, or giving higher priority for funding of medical research within hospitals as part of the biomedical research budget. A paradigm shift in the reasons that the state funds biomedical research could also prove useful. These types of questions would all have to be fully considered if we are to move forward. Bio21 Australia is perfectly positioned to lead this debate and should examine:

- who should fund biomedical research;
- the reasons for funding biomedical research, should we prioritise health system outcomes or industry development more highly?
- the potential benefits of a physical overhaul of the system – increasing space for research within hospitals; and,
- the potential benefits from increasing funding for collaborative projects which are directed at immediate health system benefits.

4.4 Next Steps for Bio21 Australia

The next steps for Bio21 Australia in this process would be to:

- Establish a detailed case for a range of discrete actions focused on improving collaboration between its member organisations so as to capture the benefits available from increased knowledge flows. The case for each action should articulate the need for action, consider the costs and benefits of the action, identify appropriate funders of the action and detail an implementation plan for the action. The case for each action may form the basis for submissions to appropriate funding bodies.
- Continue its efforts to seek increased government funding for the support of the Clinician Researchers Fellowship program and also advocate the allocation of more grant funding to projects involving strong research/practitioner collaboration.
- Take a “thought leadership” role in investigating structural issues around how biomedical research is funded and conducted. It could establish a working group to focus on the long term structural issues that we have outlined in this report and play a leading role in informing future health and health research policy.

Appendix A: Additional evidence of available benefits from effective translation of biomedical research

Additional examples of benefits from research translation

Health benefits

Applied research was undertaken in The Alfred Hospital in Melbourne where medical researchers have developed a heart health program for survivors of heart attacks. The program means that patients can reduce the likelihood of hospital admission by 80 per cent.¹¹⁹ The program comprises of drug therapy, patient education, lifestyle modification and exercise therapy.¹²⁰ The program is expected to reduce the cost burden on the medical system by minimising the chance of hospitalisation, and is expected to have strong quality of life benefits for many patients.

The heart health program is linked to the discovery that exercise programs have effects in the heart similar to those of beta blockers and led to a paradigm shift in rehabilitation programs in Australia and internationally.¹²¹ This discovery has led to significant reductions in patient mortality. According to the Baker Heart Research Institute, the work of Prof. David Kaye, Murray Esler and Garry Jennings has underpinned these developments.¹²²

The ORYGEN collaboration is made up of a youth mental health service and a research centre, and undertakes a range of education, advocacy and health promotion activities. The overall goal of ORYGEN is to integrate knowledge gained from clinical practice and research activities to implement, and advocate for, high quality mental health services for young people. The Clinical Program provides mental health assessment and treatment for young people aged 15 to 24 years from the western and northwestern suburbs of Melbourne. The research centre is affiliated with the University of Melbourne's Neuropsychiatry Centre, Melbourne Health and the Colonial Foundation. The ORYGEN Research Centre's research on the early phases of psychotic illness is well recognised internationally, for its work in conjunction with the University's Melbourne Neuropsychiatry Centre (MNC). A recent study found that brain scans can be used to predict how well young people will recover from early

¹¹⁹ Australian Society for Medical Research, *Australian Case Studies 1*. 2002.

¹²⁰ Ibid.

¹²¹ Ibid.

¹²² Ibid.

psychotic episodes that occur in mental illnesses such as schizophrenia – a discovery with substantial potential diagnostic and treatment benefits¹²³.

Health system value for money outcomes

A recent Australian discovery also looks likely to have large implications for quality of life as well as health care costs. A preventative vaccine and a treatment vaccine for cervical cancer has resulted from the work of Dr Jian Zhou and Professor Ian Frazer of the Centre for Immunology and Cancer Research, University of Queensland.¹²⁴ The vaccine has the potential to save hundreds of thousands of lives world wide, as over 500,000 women are diagnosed with cervical cancer each year, and it is the second most commonly occurring deadly type of cancer among women.¹²⁵ It is expected that the discovery will deliver \$100 million of revenue per year for the team, and that it will save up to \$500 million a year in direct health care costs in Australia alone.¹²⁶ The vaccine, Gardasil, has now been approved by the FDA for use in the USA in girls and women aged 9 to 26.¹²⁷ The vaccine will soon be provided free to young Australians – in Queensland girls of secondary school age will receive a first dose of the vaccine in April.¹²⁸

International research translation initiatives

United Kingdom

The current UK system of publicly-funded medical research includes several measures designed to improve the translation of research outcomes into health sector outcomes. Some of these are:

- The UK Clinical Research Collaboration (UKCRC), involving a range of health research partners. These include the main UK research funding bodies; academia; the NHS; regulatory bodies; the bioscience, healthcare and pharmaceutical industries; and patients. The project was established to enhance the development of research infrastructure – including facilities, expertise, and funding mechanisms – while taking into account the needs of all these stakeholders. The UKCRC was established following the recommendations of the Bioscience and Innovation Growth Team, which noted that enhancing the interaction of researchers, funding structures and industry would be key to the future of a sustainable biomedical research sector, and the improved patient outcomes this promises.¹²⁹
- Following the publication of the 10 year Science and Innovation Investment Framework in 2004, the joint Medical Research Council/NHS Health Research Delivery Group was established, to increase coordination between the various Government programs funding medical and clinical research.¹³⁰

¹²³ http://uninews.unimelb.edu.au/articleid_3665.html

¹²⁴ Australian Society for Medical Research, 2003, *Australian Case Studies 2*.
<http://www.asmr.org.au/news/newsletters/pubi.html>. 5/02/2006

¹²⁵ Ibid.

¹²⁶ Ibid.

¹²⁷ <http://www.uq.edu.au/news/index.html?article=9829>

¹²⁸ Albert and Logan News, *Vaccine for girls welcome*, 14 February 2007,

¹²⁹ http://www.bioindustry.org/bigtreport/downloads/exec_summary.pdf

¹³⁰ Cooksey, 2006, *Review of UK Health Funding*, <http://www.hm-treasury.gov.uk>

- The Medical Research Council, in 2000, established MRC Technology, which has managed the commercial development of intellectual property generated by MRC-funded scientists.

In addition to this, there are a number of initiatives funded by the MRC and training hospitals such as Guys' and St Thomas,' in which "research translators" will work at universities to bridge the gap between pre-clinical and clinical science, enhancing communication and knowledge sharing between these groups.

In December 2006, David Cooksey released the final report of his *Review of UK Health Funding* for the UK Treasury, and the departments of Health and of Trade and Industry. The Review identifies some gaps in the current UK system of translation, categorising these gaps as occurring, on one hand, in the conversion of research into ideas and products, and on the other, in the introduction of these ideas and products into clinical practice.¹³¹

Its recommended strategies included the establishment of a Translational Medicine Funding Board, which would specifically target initiatives aimed at improving processes of knowledge transfer. It also supported the founding of the National Institute of Health Research, a coordinating body which would, by integrating health research across the country, enhance translation of research into health outcomes.

Programs such as the development of specialist "research translators" at Guys' and St Thomas' were commended by the Review team, who noted that it had been suggested by many contributors that this model would significantly help to close current gaps between the laboratory and clinical research.

Canada

In Canada there has also been a strong emphasis on the translation of health research. The Canadian Institutes of Health Research (CIHR) was created in June 2000 to 'excel in the creation of new knowledge and to translate that knowledge from the research setting to real – world applications in order to improve the health of Canadians, provide more effective health services and products and strengthen the health care system'.¹³² Through knowledge translation (KT) the CIHR aims to significantly increase and accelerate the benefits flowing to Canadians from the nation's health research, and to 'establish Canada as an innovative and authoritative contributor to health-related knowledge translation'.¹³³

Various Canadian initiatives include:

- Using CIHR to create partnerships between researchers, policy makers, health care providers, patient groups and the general public and the private sector in the form of KT networks.
- Supporting research into the science of KT, the running of pilot programs
- CHIR will financially support KT activities both internally and externally.
- CHIR will, through its relationships between researchers and medical professionals, attempt to foster a culture of KT within its group.¹³⁴

¹³¹ http://www.hm-treasury.gov.uk/media/56F/62/pbr06_cooksey_final_report_636.pdf

¹³² Canadian Institutes of Health Research, 2004, *Knowledge Translation Strategy 2004-2009: Innovation in Action*. www.irsc.gc.ca/cgi-bin/print-imprinter.p2

¹³³ Ibid. p2

¹³⁴ Ibid.

Singapore

In Singapore, biomedical research is being heavily emphasised, with the country recently announcing that it will commit a further \$7.5 billion over the next five years to sustain innovation-driven growth through technology clusters.¹³⁵ This comes on top of already substantial commitments and Singapore aims to have R&D funding at 3 per cent of GDP by 2010.¹³⁶ The Biomedical Science initiative phase 1 (2001-05) comprised of a large amount of capacity building in basic research, and establishing an international presence in biomedical science.¹³⁷ For the BMS phase two the Biomedical Research Council will focus on strengthening translational research to help bridge the gap between basic science and clinical practice.¹³⁸

In particular, these goals will be met through the action of the Singapore Institute for Clinical Sciences (SICS) which will focus on developing a clinical science program. Through the establishment of the Experimental Therapeutics Centre (ETC) which will ‘aim to build up the required capabilities and resources in this spectrum of the drug discovery and development value chain. It will also play the role of training young scientists to provide them with the skill set for product development.’¹³⁹ Singapore is also repositioning its Centre for Molecular Medicine (CMM) to increase its focus on human disease, renaming it the Institute of Medical Biology, and charging it with operating in the space between medicine and biology. This will work with the other research groups that form part of the biomedical council.

An important part of the Singapore government’s promotion of biomedical science as the fourth pillar of the economy is the development of the Biopolis precinct which will operate as a cluster of public and private research groups and which aims to attract significant international commercial investment.

United States

In the US, there has been a relatively recent increase in expenditure on biomedical research followed by a stage of stagnation and slight decline in expenditure in real terms. The National Institutes of Health experienced a doubling of their funding between 1998 and 2003 when medically related research was highly prioritised.¹⁴⁰ Since then however, investment in this area has declined slightly in real terms.¹⁴¹ Total spending is still large; in 2003 the United States spent an estimated 5.6 per cent of its total health expenditures on biomedical research, more than any other country.¹⁴²

Knowledge translation has also been heavily prioritised in recent years. The primary federal agency funding health research in the US is the Department of Health and Human Services, through the National Institutes of Health (NIH). The NIH contains 27 institutes, each of which focuses on a specific area of research. The NIH budget is currently approximately US \$29 billion per year.

¹³⁵ BioSpectrum: Asia Edition, Feb 2007, *Singapore releases science and technology plan for 2010*

¹³⁶ Ibid.

¹³⁷ Singapore Government, Media Release 7 December 2006, *Biomedical Sciences International Advisory Council Endorses Two New Initiatives*

¹³⁸ Ibid.

¹³⁹ Ibid.

¹⁴⁰ Loscalzo, J. *The NIH Budget and the Future of Biomedical Research*, www.nejm.org, p1665

¹⁴¹ Ibid.

¹⁴² <http://www.reason.com/news/show/36942.html>, Quoting the 2005 Journal of the American Medical Association Report

The NIH roadmap represents an attempt to address the emerging importance of translational research. This cross-Institute initiative aims to enhance the processes of converting fundamental science into improved health outcomes.

The three broad aims of the roadmap are:

1. to develop the information, technologies, and other scientific resources needed to support advanced biomedical knowledge;
2. to reduce the barriers to interdisciplinary, inter-sectoral collaboration; and
3. to develop research networks which connect academic laboratories with health care providers and clinicians, to facilitate the development, testing and adoption of new treatments.¹⁴³

Programs associated with the Roadmap include:

- Director's Pioneer Awards, for highly speculative research unlikely to receive private sector funding, which is very risky but also potentially may deliver breakthrough discoveries.
- The Interdisciplinary Research Training Initiative which aims to train researchers in three ways - through long-term interdisciplinary research training; short-term courses and research experiences; and curriculum development.
- The National Clinical Research Associates scheme, aiming to create a group of professionals with training both in healthcare provision and in research. This is intended both to enhance the conduct of clinical research, and to encourage communication between clinicians and the researchers who develop treatments.
- Clinical and Translational Science Awards. These focus on the funding of clinical and translational research. These awards fund a consortium led by National Centre for Research Resources. The consortium began with 12 academic health centres and a further 52 awardees have received planning grants to aid them to join the consortium. This program will be fully implemented by 2012 and when completed aims to 'energize the discipline of clinical and translational science'.¹⁴⁴

¹⁴³ www.nihroadmap.nih.gov

¹⁴⁴ <http://www.ncrr.nih.gov/clinicaldiscipline.asp>

The United States also has a number of large medical research clusters. The Dana-Farber/Harvard Cancer Centre Cluster is one of the largest clusters in the US.

*The Dana-Farber/Harvard Cancer Centre Cluster*¹⁴⁵

Founded in 1997, Dana-Farber/Harvard Cancer Centre (DF/HCC) was spawned by the vision of creating the most productive cancer research centre in the world. For five decades, Dana-Farber Cancer Institute (DFCI) had built a reputation as a centre of excellence, culminating in it being named by the National Cancer Institute as one of the nation's premier Comprehensive Cancer Centres.

However, other institutions in the Harvard medical community also had exceptional programs in cancer care, research, education and the basic sciences. In fact, several of the seven institutions that eventually launched the DF/HCC consortium — Harvard Medical School, Harvard School of Public Health, Dana-Farber Cancer Institute, Brigham and Women's Hospital, Children's Hospital Boston, Beth Israel Deaconess Medical Centre, and Massachusetts General Hospital — had already begun to work together in adult and paediatric cancer care. All these hospitals' physicians and scientists held Harvard faculty positions. And laboratory researchers delving into the genetics and molecular biology of cells were finding it critical to share vast amounts of knowledge and state-of-the-art facilities. It only made sense to organize the Harvard cancer research effort into one powerful enterprise.

Since its inception, DF/HCC's growth has been enormous. In addition to its Comprehensive Cancer Centre funding, annual cancer-related grants to member institutions have risen from A\$295 million in 1999 to more than A\$500 million in 2004. The greatest increase in grants has been in the multi-institutional category — a testament to the intense activity created by the DF/HCC consortium.

¹⁴⁵ The Allen Consulting Group, May 2006. *Cancer and Biobank Infrastructure in NSW*, Originally sourced from www.dfhcc.harvard.edu

