



Medical Technology
Association of Australia



*NSW Health and Medical Research
Strategic Review:
Response to Issues Paper
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MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

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Introduction

The Medical Technology Association of Australia (MTAA) is pleased to have the opportunity to respond to the range of issues which have been raised in the Issues Paper prepared as part of the NSW Health and Medical Research Strategic Review. Medical technologies provide life-saving assistance to patients in need, deliver long-term sustaining quality of life, and provide aid to improve the day-to-day comfort of patients. Without medical technologies patients would not be able to walk (implantable hips and knees), to hear (cochlear implants and hearing aids), to see (intraocular lenses), or to survive (cardiac pacemakers and implantable defibrillators). Each of these advances has significantly changed the way people with life-threatening or life-challenging conditions are cared for. All developments of medical technologies are research-based, often by companies working in collaboration with healthcare professionals.

MTAA supports the vision for health and medical research expressed in the Issues Paper:

NSW will have a global reputation as a centre of excellence for health and medical research that supports a high quality health system and generates social and economic benefits to the State.

MTAA is attracted to the dual focus of the vision – on the creation of research that supports the health system, and on the generation of economic benefits. Without inclusion of industry as a partner in this endeavor, there cannot be the economic returns to the State. Much of MTAA's response to the Issues Paper examines mechanisms to support collaboration with industry and to encourage the translation of excellent research into products that can be brought to the market, both to benefit the NSW health system and its patients and to deliver flow-on economic benefits from the creation of a robust manufacturing sector that exports globally.

MTAA has addressed the pillars and actions which are most relevant to the encouragement of a viable and robust medical technology sector in NSW.

About the medical technology industry

MTAA represents the manufacturers, exporters and suppliers of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from commonplace, everyday consumable items such as bandages and syringes, to high technology implantable devices such as cochlear implants, cardiac defibrillators and orthopaedic joints, diagnostic imaging equipment, and products which use biological materials.

The medical technology industry had sales in Australia of more than \$7.5 billion in 2009-10 and employed more than 17,500 people. It is strongly research-based with clinical input from healthcare professionals to design and develop products for improved patient benefit. MTAA represents companies supplying approximately 70% of all non-pharmaceutical medical products on the Australian market. About 54% of all medical technology companies in Australia are located in NSW with approximately 79% of all employees in the industry.

Response to the Issues Paper

5.1 Invest strategically

5.1.1 Develop a strategic approach to NSW Government investment in health and medical research

MTAA supports the proposed actions outlined under section 5.1.1 as sensible responses to ensure strategic investment and alignment of government policy resources.

5.1.2 Establish health and medical research priorities for NSW Government

- a. *Develop a health system priority framework of goals to be addressed by research (e.g. improve mental health, prevent chronic and infectious disease, close the gap in Aboriginal health outcomes, cure diabetes) including principles and criteria for priority setting.*

Research communities should work closely with the Australian Institute of Health and Welfare (AIHW) to determine strategic focus areas for research. A recent report by the AIHW shows that the projected leading specific causes of burden of disease and injury in Australia are coronary heart disease, anxiety and depression, Type 2 diabetes, dementia, stroke, lung cancer, chronic obstructive pulmonary disease (COPD), adult-onset hearing loss, colorectal cancer and asthma¹. These conditions should determine NSW research priorities.

At a broad level, other research priorities include:

- Health and medical challenges associated with Australia's ageing population and changing demographics²
- Delivery of cost effective health and medical services
- The drive to deliver medical services in the home, including investments in home healthcare and telehealth
- Rapid growth in chronic diseases, for example, Type 2 diabetes is expected to become the leading cause of disease burden and it is estimated that by 2030 approximately 75% of Australians will be overweight or obese³
- Risk factors associated with poor health, for example, over 30% of Australia's total burden of death, disability and disease can be account for by risk factors (e.g. smoking, obesity)⁴
- Indirect benefits to the healthcare system of the National Broadband Network (NBN).

¹ Australian Institute of Health and Wellbeing (AIHW). (2010). Australia's health 2010. Australia's health series no. 12. Cat. no. AUS 122. Canberra.

² National Health and Hospitals Reform Commission: A Healthier Future For All Australians – final report June 2009. Canberra: Department of Health and Ageing.

³ National Preventative Health Taskforce, 2009, Australia: the healthiest country by 2020 – National Preventative Health Strategy – the roadmap for action.

⁴ AIHW. (2010). Australia's health 2010. Australia's health series no. 12. Cat. no. AUS 122. Canberra.

5.2 Build Globally Relevant Research Capacity

5.2.2. Strengthen health and medical research hubs and networks

The medical technology industry is one of the few manufacturing sectors in Australia demonstrating economic growth. MTAA believes government can support increased growth in the industry and create economic benefits for NSW by putting mechanisms in place to improve translational research capabilities. This includes leveraging the world class research projects at various institutions in NSW and identifying opportunities for commercialisation. Government support should be targeted to commercialisation and manufacturing in Australia.

In NSW, government facilitation to establish better connections between key players in industry and research institutions will encourage the development of a highly skilled workforce.

International examples in Denmark, Ireland and Canada indicate the most successful way of improving translational research is through commercial engagement between business, research institutions and hospitals. These examples suggest the most effective way of achieving this formal engagement is through establishing industry clusters.

While there are many examples of successful life science hubs or clusters around the world, there is not one simple formula for success. However it is a combination of supporting infrastructure that is physical, social and commercial that are clear themes central to their competitive advantage.

Although there is limited evidence of successful clustering to date in Australia, there is a concentration of medical technology companies, as well as pharmaceutical and biotechnology companies, in Northern Sydney, primarily in North Ryde and Macquarie Park. Not only are Macquarie University and the new Macquarie University Hospital located in this area, but there is also under development a hearing hub based around Cochlear, the leading medical device company for development of the cochlear implant.

The physical infrastructure for this cluster is in place. What is missing from this vibrant business and research hub is the social and commercialisation infrastructure to make it internationally competitive. Social infrastructure is the critical component of diffusion of knowledge amongst relevant parties. Commercialisation infrastructure is the mechanism to highlight the potential of research projects at the early stages ensuring the right linkages are in place to get the product to market.

Medicon Valley in Denmark is one of Europe's largest life sciences clusters covering eastern Denmark and south-western Sweden and consists of 12 universities, 32 hospitals, more than 300 life science companies and the cluster organisation Medicon Valley Alliance. The formal role of Medicon Valley Alliance is to facilitate the diffusion of knowledge by building networks between all the parties within the cluster as well as with potential investors, service providers and government.

In Ontario Canada the life sciences industry is clustered in a corridor consisting of 60 publicly funded research institutes all with a history of collaboration with the private sector. In April 2010 the Ontario Government announced a Life Sciences

Commercialisation Strategy with three main priorities; to improve collaboration between government, academia and industry, to position Ontario as a destination for advanced health technologies and to grow the industry to rival leading technology centres in the United States.

Part of this plan included establishing the Ontario Network of Excellence which is a group of not-for-profit organisations which are experts in growing knowledge based companies. They have developed programs to facilitate collaborative partnerships between academia and business and they also offer coaching and mentoring for entrepreneurs as well as financing programs.

NSW faces competition from medical technology destinations closer to home in the Asia Pacific region. The Daegu-Gyeongbuk High-tech Medical Cluster is an early stage government led project tasked with creating a centre of excellence in medical technology in Korea. Daegu is home to 5 medical universities, 29 general hospitals and 18,000 medical personnel including over 6,000 doctors. There are many incentives for companies to set up premises in the cluster including monthly subsidies for employees, and corporate tax exemptions.

Singapore has also attracted many large medical technology companies to set up commercial operations, research and development centres and manufacturing operations in recent times. There are many incentives for companies to operate in Singapore including access to a highly skilled workforce and a competitive tax environment with a current headline corporate tax rate of 18%.

MTAA believes NSW to date has missed out on medical device commercialisation opportunities due to insufficient government support and advocates to government to support the development of a life science cluster in Sydney.

MTAA believes NSW can develop a cluster with sufficient scale and scope initially by formally establishing an entity tasked with building proper linkages between all relevant parties in a similar way to the examples provided in Canada and Denmark.

5.2.4. Build state or national shared research assets, including data linkage, bio-banking and informatics

- a. Support and expand data linkage capability, including the Centre for Health Record Linkage*
- b. Facilitate timely access to administrative data sets, including NSW Government agency data, MBS, PBS etc*
- c. Support NSW population cohort studies (e.g. 45 and Up)*
- d. Support the development of shared tissue and bio-banks*
- e. Support shared IT platforms, data management systems and operating procedures*
- f. Train researchers in the use of shared research assets*

The review addresses the need to build state or national shared research assets, including data linkage, bio-banking and informatics. The Australian healthcare system holds within it vast amounts of data that are not uniformly merged.

The 2009 Federal Government review of health technology assessment (HTA) in Australia recommended the creation of registries for high risk implantable items and/or procedures⁵.

⁵ Commonwealth Government of Australia, Review of Health Technology Assessment in Australia, December, 2009.

A 2009 report by the National Health and Hospitals Reform Commission (NHHRC) also recommended that Australia have systems in place to “provide comparative clinical performance data back to health services and hospitals, clinical units and clinicians”⁶. Clinical registries provide real-world data on clinical practice, patient outcomes, safety and the comparative effectiveness of different treatments (e.g. a pharmaceutical versus a device for the treatment of a cardiac condition). There are a number of different types of registries, for example device or procedure specific registries (which collect data on medical devices or surgical procedures), class registers (which collect data on specific interventions) and comparative registers (which look at a range of options for treating a specific disease)⁷.

Australian registries with national coverage collect data on renal dialysis, joint replacements, breast implants and organ transplantation. The National Joint Replacement Registry (NJRR) is funded by industry, collects data on orthopaedic prostheses and is a doctor-led registry which achieved clinical buy-in via the Australian Orthopaedic Association (AOA) encouraging its members to comply.

The Australian Society of Plastic Surgeons (ASPS) maintains the Breast Implant Registry (BIR) to collect information relating to the patient, surgeon, procedural and implant data relating to breast implants.

There have been attempts to set up registries for cardiac and obesity procedures. The Australian Cardiac Procedures Registry (ACPR) was developed through a pilot project sponsored by the Australian Commission on Safety and Quality in Healthcare (ACSQHC), however a sustainable funding source has not yet been identified for future development.

The Centre for Health Record Linkage (CHeReL) provides a capacity within NSW for linking existing statewide datasets. The centre creates and maintains record linkages for health and human services in NSW and the ACT and could potentially include data from registries. Data from the centre are used for projects that benefit the public. The system is hosted at the Cancer Institute NSW and is a collaboration between the Cancer Institute, NSW Health, ACT Health, Clinical Excellence Commission, University of New South Wales, University of Sydney, University of Newcastle and University of Western Sydney. The aim is to facilitate research that contributes to public health, facilitates evaluation and delivery of health services, and contributes to health research methods. Core data sets include admitted patients, births, deaths, mortality, perinatal reviews, emergency department data collection and a central cancer registry.

Data from clinical registries could be linked with other large cohort databases, for example, ‘The 45 and Up Study’. This study includes 265,000 individuals from NSW over the age of 45 and is one of the largest studies of healthy ageing in the world. The study is owned by the Sax Institute which aims to build partnerships between research, service delivery and policy development.

There are a range of biobanks in Australia including 17 formalised tissue banks in NSW. The aim of tissue banking and linkage platforms is to ensure consistent management of research studies that include tissue. The Australasian Biospecimen

⁶ National Health and Hospitals Reform Commission: A Healthier Future For All Australians – final report June 2009. Canberra: Department of Health and Ageing.

⁷ Review of health Technology Assessment in Australia. Submission 39. Medical Technology Association of Australia. 22 May 2009.

Network (ABN) is a good example of a network that enables researchers to use an online system to search multiple biobanks to locate biospecimens. The introduction of electronic medical records and individual healthcare identifiers in Australia may increase data linkage efficiency and enable researchers access to data from clinical registries, biobanks and other databases.

Clinical trials are worth around \$1 billion to the Australian economy each year⁸. There was rapid growth in the number of clinical trials being conducted in Australia from the early 1990s, however this growth hit a plateau and has started a downward trend in the last few years. Information on clinical trials in Australia is available from an online register. The Australian New Zealand Clinical Trials Registry (ANZCTR) includes trials covering pharmaceuticals, medical devices, and treatment and rehabilitation therapies. This register could be used to support and expand data linkage capacity. The majority of clinical trials are sponsored by industry, which could play a key role in assuring shared research assets.

5.3 Build an Innovative Research Culture

5.3.3 Support knowledge-led innovation in clinical practice, health service delivery and population health programs

MTAA proposes the establishment of an entity similar to NHS London Innovations (NHSLI) which was established to work with the NHS Trusts in the London area to provide financial returns to the Trusts and while doing so, to address the physical and emotional health of patients and the prosperity of innovation driven economies. NHSLI identifies potential licensing opportunities for new devices, therapeutics, diagnostics and software developed within the health system. It then fast-tracks to market those innovations that are identified as having commercial potential. It bridges the gap between the NHS, industry, government and public bodies with the aim of making healthcare better through innovation.

Subsidiary businesses have been established for specific purposes such as Xpedite Innovations Management which applies principles of efficient medical innovation and de-risking the product pipeline. It has recently received priming funds from government to provide initial seed and early-stage investment funding for medical start-up companies with a cap of £500,000 per company.

Another business unit is Xcelerate Health Outcomes which provides access to NHS clinical pathways and anonymised patient data to undertake meaningful health economic assessments.

5.3.4 Build expertise in developing commercial-ready Intellectual Property

MTAA identifies a need to establish mechanisms to ensure research ideas that have potential for rapid health benefits are captured at the critical early commercialisation stage. This means providing appropriate assistance to entrepreneurs to translate an idea into a product that can be developed for use across the health system for wide community benefit.

⁸ Australian Government. Clinically competitive: Boosting the business of clinical trials in Australia. Clinical Trials Action Group Report, 2011.

MTAA believes government should invest in a Medical Device Fund to take on this function. The fund would be tasked with linking people, processes and investments, particularly targeted at small and emerging companies in the industry. The fund would operate by supporting innovations which respond to priority health needs. It can provide key financial and expert technical assistance to companies when a working prototype is being developed.

Areas of assistance should be designed to ensure companies are well versed in regulatory affairs, quality management, and reimbursement and that they have access to clinical investigations and access to local manufacturing. The fund could also offer training on customer needs before the product gets to the design and investor stage which should achieve a higher success rate of commercial product than we have seen in NSW and Australia to date.

The Medical Device Fund would work closely with government by leveraging off existing government programmes as appropriate such as the ones currently offered by Commercialisation Australia, in particular the Skills and Knowledge grant.