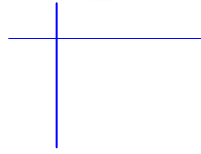




Medical Technology  
Association of Australia



Department of Health and Ageing  
Interdepartmental Committee  
Review of Funding of Diagnostic Imaging

Submission by  
Medical Technology Association of Australia

September 2008

Medical Technology for a Healthier Australia

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## **1. About the Medical Technology Association of Australia and the Medical Technology Industry**

The Medical Technology Association of Australia (MTAA) represents the manufacturers, exporters, importers and distributors 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 items such as bandages and syringes, to high technology items such as cochlear implants and cardiac defibrillators, in vitro diagnostic products and diagnostic imaging equipment such as ultrasound, computed tomography (CT), nuclear medicine, radiography (x-ray), magnetic resonance imaging (MRI), positron emission tomography (PET) and bone densitometry machines.

MTAA believes that there needs to be a fundamental review of the role of medical technology in the healthcare system, in particular the need to ensure equity of access to appropriate medical technology by patients. The system that currently assesses and funds medical technology (to the extent that there is any funding) is out of date, poorly-designed and not sufficiently flexible to keep pace with the rapid development in medical technologies.

The system needs to better value the benefits and potential cost-savings to the healthcare system which are provided by medical technologies. At present there is an ill-equipped mechanism to identify and value these benefits. Medical technology is very much subject to the cost-shifting and silo-ed structure of the healthcare system. Medical technologies frequently are not readily accessible, or accessible without subsidy and at a cost to the patient, or available only after considerable, lengthy and linear processes for regulation, evaluation and assessment for reimbursement. These processes are unnecessarily time-consuming and often lacking in transparency. There is no clear framework and very little evidence base to funding decisions.

Medical technologies are evolving rapidly. We need a system that is robust, flexible, speedy but conscious of safety and efficacy issues, and above all, able to provide positive patient outcomes cost-effectively.

## **2. Current funding arrangements for diagnostic imaging services**

The four Quality and Outlays Memoranda of Understanding (MoUs) between the Australian Government and diagnostic imaging representative groups, commenced on 1 July 2003 and expired 30 June 2008. The MoUs were negotiated between the Australian Government as payer, the professionals who provide the services<sup>1</sup> and, in one of the four MoUs, the diagnostic service providers (represented by the Australian Diagnostic Imaging Association). None of the agreements included the suppliers of diagnostic imaging technology which is an essential component of the supply of services.

Notwithstanding that suppliers of medical imaging equipment have not been included on any of the management committees, the industry participants have a legitimate

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<sup>1</sup> Various the Royal Australian and New Zealand College of Radiologists, the Cardiac Society of Australia and New Zealand, the Australian and New Zealand Association of Physicians in Nuclear Medicine, the Royal Australian and New Zealand College of Gynecologists and Obstetricians

contribution to make through their understanding of emerging technologies and potential for application of those technologies to the benefit of the healthcare system.

The principles and objectives of the MoUs are expressed as promoting<sup>2</sup>:

1. access to quality, affordable radiology services;
2. effective management of outlays by the Commonwealth for the radiology services described in the Diagnostic Imaging Services Table (DIST);
3. improvement in the quality and delivery of radiology services through the development of a quality framework; and
4. co-operative strategies which promote affordability of services for patients.

While there is latitude in the MoUs for an adjustment to be made to funding (including in circumstances where the Medical Services Advisory Committee (MSAC)) approves new procedures or technologies, or new applications of existing procedures or technologies), there is no capacity to undertake a whole of healthcare system assessment of the value derived from, or attributable to, a particular technology.

Furthermore, because of the extensive delays built into the system to approve new procedures by MSAC, many beneficial technologies and procedures are not made available. There are systemic disincentives for the suppliers of medical technology to bring the technology into the Australian market.

MTAA argues that the funding arrangements would be considerably improved by incorporating two assessments which more appropriately value the contributions made by medical technology to the Australian healthcare system:

1. the cost-savings to other parts of the healthcare system delivered by diagnostic imaging through less invasive care, faster recovery times, and fewer complications;
2. the cost-savings derived from improved cost-effectiveness resulting from ongoing health technology assessment under a flexible scheme that reviews older technologies and procedures to make headroom for newer technologies and procedures.

### **3. Value of medical imaging – its contribution to the healthcare system**

Medical imaging has delivered extraordinary benefits to patient care. It allows physicians to see inside the body, without making an incision. It allows intricate procedures on fragile organs, without surgery. It enables accurate diagnoses, and can treat the condition it diagnoses.<sup>3</sup> The use of diagnostic imaging procedures has become more ubiquitous because its innovations have made imaging faster, more precise, and less invasive. Medical imaging has become essential for virtually all major medical conditions and diseases.

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<sup>2</sup> These objectives are drawn from the Radiology MoU but reflect generally the focus of all MoUs

<sup>3</sup> Poldais LLC for National Electrical Manufacturers Association, *How Medical Imaging has Transformed Health Care in the US*, December 2006, [www.medicalimaging.org/news/final\\_changing\\_the\\_landscape.pdf](http://www.medicalimaging.org/news/final_changing_the_landscape.pdf) accessed 08.09.08 (in this submission, the NEMA Report)

Policy decisions intended to manage growth in imaging utilization must take into account a broader view of imaging value. Policy decisions must recognise that much of the growth in utilization emerges from deep, systemic, patient-centred changes that medical imaging has fostered.

In transforming the delivery of medicine through less-invasive treatment, patients recover more rapidly and with less time spent in hospital. There are multiple examples of how medical imaging delivers these side benefits to the healthcare system and society more broadly by treating patients more effectively and enabling them to return to productive life more quickly:

1. image-guided renal angioplasty opens blocked kidney arteries without surgery, thus reducing the risk of complication. It also allows patients to avoid a two-week hospital stay<sup>4</sup>;
2. physicians use image-guided embolization to correct uterine fibroid tumours without hysterectomy which permits patients to return to work in two weeks, rather than six;
3. in cancer care, physicians use imaging to perform minimally invasive bone biopsies, rather than surgery, thus allowing patients to avoid complications, a long recuperation and a significant scar<sup>5</sup>;
4. during liver cancer surgery, physicians use ultrasound to help them differentiate between diseased and healthy tissue and make adjustments as they operate. This information allows them to improve precision, reduce blood loss, and ultimately speed up healing.

Medical imaging has become the standard of care in a range of chronic diseases that dominate healthcare needs, including heart disease, stroke and cancer. It has also contributed significantly in public health campaigns for the prevention and early detection of disease. For example, earlier detection of breast cancer through mammography has reduced the death rate in Australia and other countries<sup>6</sup>. Further investment in medical imaging for early detection of other conditions, such as cardiac disease, can make a significant contribution to overall health outcomes.

Ultrasound and MRI aid in diagnosis and treatment. CT, MRI and ultrasound scans give physicians vital information about the location and nature of the cancer to aid in treatment planning. Intra-operative ultrasound and MRI during surgery help physicians remove cancerous tissue, while sparing healthy tissue. Minimally invasive imaging procedures allow biopsies of breast, bone, and other tissue without open surgery, dramatically reducing infections, complications, and recovery time. New radiation treatment systems provide targeted radiation therapy that matches the tumour shape, but protects surrounding tissue. The result is better success rates, quicker pain relief, and fewer complications<sup>7</sup>.

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<sup>4</sup> Xue, F et al., "Outcome and Cost-Comparison of Percutaneous Transluminal Renal Angioplasty, Renal Arterial Stent Placement, and Renal Arterial Bypass Grafting", *Radiology*, 1999; 212:378-384, cited in NEMA paper supra at page 8

<sup>5</sup> Jelinek JS, Murphey MD, Welker JA, Henshaw RM, Kransdorf MJ, Shmookler BM, Malawer MM, "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors", *Radiology* 2002; 223; 731-737, cited in NEMA paper supra, page 9

<sup>6</sup> Access Economics Pty Limited for Australian Diagnostic Imaging Association, "The Value of Diagnostic Imaging", 12 March 2008 [http://www.adia.asn.au/objectlibrary/156?filename=FINAL The Value of DI 12 Mar08.pdf](http://www.adia.asn.au/objectlibrary/156?filename=FINAL%20The%20Value%20of%20DI%2012%20Mar08.pdf) accessed 08.09.08

<sup>7</sup> NEMA paper supra, page 16

The former director of the US National Cancer Institute, and now Commissioner of the US Food and Drug Administration, Dr Andrew von Eschenbach, has stated that imaging is one of the primary tools in helping eliminate death and suffering from cancer:

*“Whether it’s as a minimally-invasive screening tool, a surrogate marker for clinical endpoints in clinical trials, or a method of guiding the delivery of treatment, imaging will be an indispensable tool in the march toward the 2015 goal of eliminating the suffering and death due to cancer.”*<sup>8</sup>

Physicians have adopted imaging as a key mechanism to deliver improved patient outcomes. A 2001 study published in the policy journal *Health Affairs* asked 225 leading physicians to rank the relative importance of 30 medical innovations in terms of their value in improving patient care<sup>9</sup>. The physicians overwhelmingly picked two imaging technologies – CT and MRI – as the most significant. The next highest, a heart drug, was rated much lower. Of the top five, three involved imaging – CT and MRI, image-guided balloon angioplasty, and mammography.

In March 2005 testimony to the US Congress, a coalition of more than 20 physician speciality groups characterized the importance of imaging as follows:

*“In addition to traditional diagnostics employing medical imaging, we now use imaging to guide minimally invasive treatments and to track ongoing treatment protocols through judicious use of medical imaging. We are enabled as physicians to adjust patient care plans mid-therapy to achieve the best possible outcomes. Several specialist groups intimately integrate medical imaging in the most delicate and intricate aspects of their care. The prudent use of medical imaging in the actual treatment regimen is not only excellent medicine: it also manages short- and long-term costs by minimizing wasteful and ineffective treatment.”*<sup>10</sup>

Diagnostic imaging has revolutionized disease screening in ways that improve clinical outcomes and reduce costs. For example, bone densitometry can identify bone loss early enough to significantly reduce fracture risk. A 2005 study published in *Osteoporosis International* estimated that bone mineral density scanning of an additional one million women in the US in 2001, followed by appropriate osteoporosis therapy, would have averted 35,000 fractures and generated US\$78 million in Medicare savings by 2003<sup>11</sup>.

A similar study has been undertaken in Australia by Access Economics for the Australian Diagnostic Imaging Association<sup>12</sup>. The report examines the cost-benefit of using a Dual Energy X-Ray Absorptiometry (DEXA) scan to diagnose osteoporosis (and treating it with biphosphonate and calcium therapy) versus no scan (and no treatment) in women aged 65-74 years, with the main benefit being the prevention of

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<sup>8</sup> National Cancer Institute, *Director’s Update, Imaging: An Integral Tool on the Path to 2015*, National Cancer Bulletin, Vol. 2, No. 17, April 26 2005

<sup>9</sup> Victor R. Fuchs and Harold C. Sox Jr, “Physicians’ Views of the Relative Importance of Thirty Medical Innovations”, *Health Affairs*, Volume 20, Number 5, September/October 2001

<sup>10</sup> Kim Williams M.D., Testimony before the US House Ways and Means Committee, Subcommittee on Health, March 17, 2005

<sup>11</sup> Cited in National Electrical Manufacturers Association, “The Value of Medical Imaging: improving outcomes and reducing costs”, 2008, page 17

[http://medicalimaging.org/news/value\\_of\\_medical\\_imaging\\_062408.pdf](http://medicalimaging.org/news/value_of_medical_imaging_062408.pdf) accessed 08.09.08

<sup>12</sup> *Supra*, page 12

osteoporotic fractures. The intervention showed a significant cost benefit of \$25,802 per QALY (Quality Adjusted Life Year).

While the utilisation of imaging has increased with the increased incidence of availability, any increase in expenditure should not be assumed as a negative impact on the healthcare budget. Any assessment of expenditure needs to take into account the savings delivered by appropriate use of imaging. Firstly, many imaging procedures are less expensive than alternative procedures. Second, the savings from imaging often come from new efficiencies – fewer complications, less infection, and shorter hospital stays, among others. Third, many savings arise from new productivity gains in patients, such as faster recovery, less surgery, less time off work, less disability, less need for outside care-givers.

MTAA argues that the full cost-effectiveness of a medical imaging procedure should be examined as part of any funding review. Capped funding arrangements lead to selection of procedures that are not clinically optimal, driven by the source of the funding.

#### **4. Improving cost effectiveness**

MTAA identifies as a significant impediment the multiple and duplicative processes that a new medical technology must go through before it reaches the patient. These inefficiencies and disincentives were identified by the Productivity Commission<sup>13</sup> in its research report on *Impacts of Advances in Medical Technology in Australia* and by the Banks Report<sup>14</sup>. The Productivity Commission<sup>15</sup> in its research paper on the impacts of advances in medical technology, noted that:

*“Hypothetical assumptions using reasonable assumptions about the value of additional life expectancy and improved quality of life, and the contributions in medical technology to these observed improvements, suggest that the benefits of technological advances to the Australian community have outweighed the costs”<sup>16</sup>*

MTAA is strongly in favour of a review of the processes for the assessment of health technology, which was a recommendation of the Banks Review and agreed to by the former government in its response to the Banks Report. Banks recommended<sup>17</sup>:

*“The Australian Government should undertake a system-wide, independent and public review of health technology assessment, with the objective of reducing fragmentation, duplication and unnecessary complexity, which can delay the introduction of beneficial new medical technologies. Health technology assessment processes and decisions should also be made more transparent, in line with good regulatory practice.”*

Health technology assessment (HTA) is defined as<sup>18</sup>:

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<sup>13</sup> Productivity Commission, Research Report, *Impacts of Advances in Medical Technology in Australia*, Canberra 31 August 2005

<sup>14</sup> Report of the Taskforce on Reducing Regulatory Burdens on Business, *Rethinking Regulation*, Canberra January 2006

[http://www.regulationtaskforce.gov.au/\\_data/assets/pdf\\_file/0007/69721/regulationtaskforce.pdf](http://www.regulationtaskforce.gov.au/_data/assets/pdf_file/0007/69721/regulationtaskforce.pdf)

<sup>15</sup> Productivity Commission, Research Report, *Impacts of Advances in Medical Technology in Australia*, 31 August 2005

<sup>16</sup> Ibid page XLIV

<sup>17</sup> Ibid page 33, recommendation 4.22

<sup>18</sup> International Network of Agencies for Health Technology Assessment (INAHTA)

*“Systematic evaluation of properties, effects, and/or impacts of healthcare technology...Its main purpose is to inform technology-related policymaking in healthcare”.*

It is MTAA’s position that HTA should be used to support patient access to innovative technologies by promoting the use of technologies that are clinically and cost effective. Conversely, HTA should be used as a mechanism to support disinvestment in current services and technologies which are cost ineffective, thereby creating ‘headroom’ for new technologies when they become available. HTA should not be used as a rationing mechanism.

MTAA favours a system that supports a national Medical Technology Policy that provides:

- a streamlined process for the registration, assessment and reimbursement of new medical technologies
- a transparent process so that requirements are clearly understood and articulated and applied in a uniform manner across all areas of registration, assessment and reimbursement
- an accountable process for funding medical technology that is open to review; and
- evidence-based decision-making for funding arrangements for medical technologies.

There should be no barriers to access critical medical technologies on the basis of affordability. The test should be cost-effectiveness of the product within the framework of the healthcare system, with equity of access, regardless of public or private status, a fundamental principle. HTA should adopt a broad perspective, capturing the impact of newer technologies on patients, carers, the health system and society as a whole.

MTAA recognises that the focus will be on the impact that new technologies have on health budgets. However HTA bodies need to adopt a societal perspective, considering the impact of technologies on broader societal costs such as productivity and social care costs.

An HTA system should include as essential elements:

- a transparent process
- stakeholder involvement –
  - healthcare professionals
  - healthcare payers (public and private)
  - patients/consumers
  - technology manufacturers
- evidence-based assessment; and
- an opportunity to review decisions.

There needs to be a clear process including timelines, appraisal criteria, and consideration of evidence. The development of recommendations must be transparent and supported by a clear audit trail. There needs to be an opportunity to review by any of the stakeholders with a right of appeal against a recommendation. The appeal body must be independent of the original assessment body.

In determining the optimal timing of when to review new technologies, decisions need to be informed by available evidence, in particular where a technology is used in a

surgical procedure because of the learning curve effect of a surgeon understanding the procedure in which the technology is used. HTA is an iterative process and should be revisited at relevant points in the life-cycle of the technology to take into account new evidence.

MTAA does not support the inappropriate or excessive use of medical imaging or indeed, any medical technologies. However, simply applying a cap on expenditure on imaging without analysis of the benefits across the healthcare system, and to the economy as a whole, is a very short-sighted position.

## **5. Conclusion**

MTAA welcomes the opportunity to contribute to the review of provision and funding of diagnostic imaging services. A fresh approach to assessment and funding of diagnostic imaging technologies and services is long overdue and desperately needed. We need to take a fresh look at the interface between medical technologies and the healthcare system and the assessment of, access to, and funding for, medical technologies.

Medical technologies are evolving rapidly. We need a system that is robust, flexible, speedy but conscious of safety and efficacy issues, and above all, able to provide positive patient outcomes cost-effectively.