Department of Health and Ageing
Review of Funding for Diagnostic Imaging Services

Submission by
Medical Technology Association of Australia

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Level 12, 54 Miller St, North Sydney NSW 2060 Australia www.mtaa.org.au PO Box 2016 North Sydney NSW 2059 Australia
P (+612) 9900 0650 F (+612) 9900 0655 Medical Technology Association of Australia Limited ABN 61 129 334 354

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 welcomes the opportunity to comment on the review of funding for Diagnostic Imaging Services. There is a particular need to ensure equity of access to appropriate diagnostic imaging technology by patients. Imaging is no longer used only for diagnosis, but also for treating and managing a wide range of medical conditions. Technology is advancing rapidly and any funding system must be sufficiently flexible to keep pace with the rapid development of these technologies. In some cases technological advances may occur faster than the time it takes to assess the technology (e.g. improvements in MRI technology over the course of an investigation)[1].

2. The Review of Diagnostic Imaging

The Review of Diagnostic Imaging was announced as part of the 2009-10 Budget and is being conducted in parallel with the Medical Benefits Schedule (MBS) Quality Framework and will align with the Review of Health Technology Assessment (HTA).

The Review of Diagnostic Imaging is a government request for an evaluation into the way that diagnostic imaging services are funded. Around 70% of diagnostic imaging services are currently covered by Medicare.

The MBS covers[2]:

Modality Group	Relevant items in the Diagnostic Imaging Services Table (DIST) of the Medicare Benefits Schedule (MBS)
Ultrasound	All items in subgroups 1,3,4 & 6 of Group I1
Computed Tomography	All groups in Group I2
General Radiology (X-ray)	All items in subgroups 1,2,4-9 of group I3; & all items in subgroups 11,12 & 14 of Group I3
Mammography	All items in subgroup 10 of Group I3
Angiography	Items 59970 & 59974 – 60078 only in subgroup 13 og Group I3

[1] RANZCR Submission to Review of Health Technology Assessment in Australia – May 2009.
[2] other services covered by the MBS include: nuclear medicine imaging, PET, CT scans rendered on hybrid PET (PET/CT) and hybrid Single Photon Emission Computed Tomography (SPECT)/CT units.

Fluoroscopy	All items in subgroups 15 & 17 of Group I3
Orthopantomography (OPG)	Items 57960, 57963, 57966, & 57969 only in subgroup 3 of Group I3
Magnetic Resonance Imaging (MRI)	All items in Group I5

The scheme **does not cover** the diagnostic imaging services listed below.[3]

- Cardiac Ultrasound (Group I1, Subgroup 2; 55113-55135);
- Cardiac Angiography (Group I3, Subgroup 13; 59903, 59912, 59925, 59971, 59972 and 59973; Subgroup 16; 60918 and 60927);
- Obstetric and Gynaecological Ultrasound (Group I1, Subgroup 5; 55700-55774); and
- Nuclear Medicine Imaging (Group I4; 61302-61650)

There is currently little scope for the funding of new and emerging technologies. MTAA believes that industry participants have a legitimate contribution to make through their understanding of emerging technologies and potential for application of those technologies to the benefit of the healthcare system. Diagnostic imaging technologies are evolving rapidly and have revolutionized healthcare. 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. New technologies and complex hybrid imaging techniques (e.g. PET/CT) will require special consideration.

Novel techniques such as molecular imaging do not have a reimbursement pathway. Molecular imaging provides a noninvasive image of molecular pathways inside an organism. This type of technique has the potential to change the future of diagnostics due to its ability to both detect pre-disease states prior to symptom manifestation and treat disease[4]. Any funding mechanism must be flexible enough to enable reimbursement for emerging imaging techniques that have the potential to change diagnostics (other examples include radiation oncology, functional imaging, diagnostic and interventional radiology). Furthermore any funding model needs to take into account pricing for true innovations (e.g. the introduction of RapidArc™ treatment delivery for Radiation Oncology) versus incremental changes in the use of existing technology (e.g. improving imaging during radiation treatment).

3. Review of Funding of Diagnostic Imaging Services Discussion Paper

The review seeks information on a number of areas including funding and relativities, alternative financing arrangements, MRI and PET. The review outlines four key tasks:

1. *To establish appropriate fee relativities for MBS items across and within different diagnostic imaging modalities;*

2. *To develop alternatives to fee-for-service and establish whether there are areas of diagnostic imaging that would be more appropriately funded through a different mechanism;*

[3] http://www.health.gov.au/internet/main/publishing.nsf/Content/diagim-accred1.
[4] Medical Imaging and Technology Alliance: http://www.medicalimaging.org/.

3. *To review current funding arrangements for MRI, particularly restrictions around Medicare eligible/ineligible units; and*

4. *To review current funding arrangements for PET, particularly around what capital arrangements should apply.*

The review paper argues that advances in technology have impacted costs and that cross-subsidisation between modalities has arisen due to the fact that rebates do not reflect actual service costs. MTAA considers the following specifics:

1. FEE RELATIVITIES ACROSS DIAGNOSTIC IMAGING MODALITIES

25. Have technological advances affected the costs of providing services? If so how?

28. What evidence is available about how different diagnostic imaging services contribute to better health outcomes?

4. Technological advances and the costs of service provision

The four Quality and Outlays Memoranda of Understanding (MoUs) between the Australian Government and diagnostic imaging representative groups expired in 2008. The MoUs were negotiated between the Australian Government as payer, the professionals who provide the services[5] and, in one of the four MoUs, the diagnostic service providers (represented by the Australian Diagnostic Imaging Association). These agreements did not include the suppliers of diagnostic imaging technology.

The majority of services are covered by private imaging practices (60% to 65%). Currently there is little competition as the MBS pays fixed rebates to all providers who can meet minimum requirements. The review invites different approaches to funding than fee for service. The review notes that currently MBS items are not adjusted to reflect whether capital investment has recently occurred or whether equipment is fully depreciated. This is not entirely correct. There is a reduced Schedule fee that applies to cardiac angiography and CT services provided on equipment that was manufactued or first installed in Australia at least 10 years ago[6].

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. Because of delays in the MSAC approval procedure, there are systemic disincentives for the suppliers of medical technology to bring the technology into the Australian market and many beneficial technologies and procedures are not made available.

There are a number of cost-savings to other parts of the healthcare system delivered by diagnostic imaging through less invasive care, faster recovery times, and fewer complications. Technological advances have the ability to lower costs. This is the case in Australia, where teleradiology reduces the costs associated with patients travelling large distances for radiological services.

[5] Variously 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 Gynaecologists and Obstetricians.
[6] www.health.gov.au/internet/mbsonline/publishing.nsf/.

Diagnostic imaging has revolutionized disease screening in ways that improve both 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[7].

A similar study has been undertaken in Australia by Access Economics for the Australian Diagnostic Imaging Association[8]. 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 osteoporotic fractures. The intervention showed a significant cost benefit of $25,802 per QALY (Quality Adjusted Life Year).

A funding system must value the benefits and potential cost-savings to the healthcare system which are provided by diagnostic imaging services. For example the cost difference between early and late treatment for MS is high. Early treatment is associated with a cost of $422,271 over ten years, while delaying treatment results in a cost of over $572,018 over ten years[9]. The current systems are not well equipped to value these mechanisms. An additional consideration is the ability of an imaging technology to the enable selection of appropriate treatment (and the avoidance of an inappropriate treatment).

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. There is a shortage of diagnostic imaging facilities and consultant physicians in remote regions of Australia[10]. There are no specific MBS item numbers for remote radiology services. These services are brought under existing service numbers to the extent that the service number is appropriate for the service. The current review of funding does not consider specific funding mechanisms for teleradiology or the cost differences between regular and tele-radiology (the transfer of diagnostic images for review by a radiologist at a site distant from where the images were acquired). These services are increasingly being used to provide services to more remote regions that do not have onsite radiologists[11].

MTAA recognises that the focus will be on the impact that new technologies have on health budgets. 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.

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[7] 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 accessed 08.09.08

[8] Supra, page 12.

[9] The Value of Diagnostic Imaging (2008). Report by Access Economics Pty Limited for Australian Diagnostic Imaging Association.

[10] Australian Association of Consultant Physicians (AACP) (2008). Submission to the Strategic Review of Future Funding Arrangements for Diagnostic Imaging and Pathology Services.

[11] Kenny, L.M. & Lau, L.S. (2008). *Clinical Teleradiology, 188(4),* 197-198.

5. Technological advances and upgrading of equipment

MTAA has previously provided information to the Department to assist its investigation of length of life for a range of diagnostic imaging devices. The table below provides a composite overview of the timeline of quality life for different imaging modalities. The table suggests times (number of years) at which equipment must be upgraded and may be used to determine price.

Modality	Quality life
Computed Tomography	10 years[12]
Ultrasound	5 years
Magnetic Resonance Imaging	8 – 10 years (electronics); ≥ 15 years (magnet)
X-Ray	15 years (analogue); 7 years (digital)
OPG	15 years (analogue); 7 years (digital)
Mammography	10 years (analogue); 7 years (digital)
Fluoroscopy	10 years
Nuclear Medicine	≥10 years
Positron Emission Tomography	10 years[13]

In general industry accepts that the current rules are suitable to other diagnostic modalities, with adjustment to the life years as detailed above. It should also be noted that since age only is not a guarantee of quality, these quality life years apply to systems properly maintained and serviced in such a way that they perform according to their specifications. Taking fluoroscopy as an example, 10 years may be appropriate for the equipment in general but not for all parts which include a vacuum tube (such as an image intensifier). An old image intensifier will impact negatively on the image quality and the patient dose. Additionally, funding models need to consider the management of outmoded technologies.

Any model of funding would need to consider upgrades to imaging equipment so as to bring it to 'the equivalent of new' where technically feasible. The manufacturer would then certify the upgrade as equivalent to current technology available for sale by that manufacturer. There would need to be caveats on the certification to ensure that it did not act as a 'warranty' by the manufacturer and that the upgrade resulted in a product that was equivalent to current technology. Clearly an upgrade is not the same as a new product as it may rely on, or be interdependent with, elements which have not been upgraded. The certification would have to be for the narrow purpose of the *Health Insurance (Diagnostic Imaging Services Table) Regulations* or replacement.

6. The contribution of diagnostic imaging services to health outcomes

Medical imaging can be used to detect diseases early (often at their most curable and less costly stages). Medical imaging has delivered extraordinary benefits to patient care. It allows physicians to see inside the body, without making an incision.

[12] There is evidence of earlier upgrading in both the public (7 years) and private (5 years) health systems.
[13] There is no market for PET systems in ANZ, only PET/CT. The market is not yet advanced enough to determine quality life.

It allows intricate procedures on fragile organs, without surgery. It enables accurate diagnoses, and can treat the condition it diagnoses.[14] 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.

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[15]. 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 both 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[16].

There are a number of disorders where early detection and early intervention can delay the severity of the illness. In MS, damage to myelinated pathways occurs prior to the onset of the first symptoms. Early detection means that the disorder can be treated at the beginning of the disease trajectory, slowing the progression of the disease[17].

In transforming the delivery of medicine through less-invasive treatment, patients recover faster. 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:

- 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[18];

- 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;

[14] Polidais, L.L.C. 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 accessed 08.09.08 (in this submission, the NEMA Report).
[15] 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 accessed 08.09.08.
[16] NEMA paper supra, page 16.
[17] Fould, P. (2010). Advanced MRI may speed diagnosis of multiple sclerosis. *Diagnostic Imaging, March 5,* 1-3.
[18] Xue, F. et al. (1999). Outcome and Cost-Comparison of Percutaneous Transluminal Renal Angioplasty, Renal Arterial Stent Placement, and Renal Arterial Bypass Grafting, *Radiology*, *212,* 378-384, cited in NEMA paper supra at page 8.

- 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[19];

- 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.

- Pain can be minisimsed in liver biopsies when ultrasound is used to guide the biopsy. A study found that 62% of patients who received ultrasound experienced no complications at all, versus 48% whose biopsy was done without ultrasound. There was also a decrease in the rates of hospitalization in those patients who had received ultrasound guided biopsies[20].

- Diagnosis no longer requires multiple tests Wilson and Islam (2007) note that "usually, MRI is the only imaging modality needed for diagnosing multiple sclerosis (MS), and it far surpasses all other tests with respect to its positive predictive value"[21].

- It has been traditionally been difficult to image the lungs. Previously the lungs were assessed using numerous tests (e.g. a pulmonary lung function test, bronchoscopy, chest X-ray, and CT). These days a single MRI can be used to assess a number of conditions including pneumonia, pulmonary embolism, chronic airway disease and lesions[22]. (MRI is not used to assess lung function in Australia or covered by the MBS).

- PET scans may reduce unnessesary operations for lung cancer. In a group of patients receiving PET scans 21% received futile operations. This was in contrast to 41% of patients who had futile operations after receiving conventional diagnostic work-ups. The use of PET scans led to large cost savings[23].

- Mammograms can detect breast cancer between one to three years before a lump can be felt. It is estimated that early detection of breast cancer can reduce the risk of death by 30% in women aged 50 to 69 years and by 17% for women in their 40's[24].

- Imaging technologies are also used for treatment. For example, targeted radiation therapy is able to protect surrounding tissue due to detection and matching to the shape of the tumour. Intensity modulated radiation therapy (IMRT) thus maps the tumor and then radiates it.

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[19] Jelinek, J.S. et al. (2002). Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors, *Radiology*, *223,* 731-737, cited in NEMA paper supra, page 9.
[20] Lindor, K.D. et al. (1996). The Role of Ultrasonography and Automatic-Needle Biopsy in Outpatient Percutaneous Liver Biopsy. *Hepatology, 23*(5), 1079.
[21] Wilson, J.A., & Islam, O. (2007). Brain, Multiple Sclerosis. *EMed WebMD* available at www.emedicine.com/RADIO/topic461.
[22] Puderbach, M. et al. (2007). MR imaging of the chest: a practical approach at 1.5T. *European Journal of Radiology, 64(3),* 345-55.
[23] Verboom, P. et al. (2003). Cost-Effectiveness of FDG-PET in Staging Non-Small Cell Lung Cancer: The PLUS Study., *The European Journal of Nuclear Medicine and Molecular Imaging*, *30*(11), 1444-1449.
[24] Weir, H.K. (2003). Annual Report to the Nation on the Status of Cancer, 1975-2000, Featuring the Uses of Surveillance Data for Cancer Prevention and Control. *Journal of the National Cancer Institute*, *95*(17), 1293.

- Advances in medical imaging are likely to change the way that clinical research is conducted. The I SPY 2 TRIAL (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis 2) is a multicenter trial that began last week in the United States. The trial will use MRI images to map the response of breast cancer tumours to drugs. This type of technique has the potential to revolutionalize personalised medicine as biological markers may determine which individuals respond to specific treatments[25].

The former director of the US National Cancer Institute, and former 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."[26]

Diagnostic imaging is included in 11 of the top 100 research projects for comparative effectiveness that were identified by the Institute of Medicine (IOM) in the United States[27]. Imaging technologies are advancing rapidly and one of the priorities is to compare the effectiveness of traditional and new imaging modalities. 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[28]. 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 specialty 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."[29]

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[25] http://www.ispy2.org/

[26] National Cancer Institute, *Director's Update, Imaging: An Integral Tool on the Path to 2015"*, National Cancer Bulleting, Vol. 2, No. 17, April 26 2005.

[27] http://www.iom.edu/~/media/

[28] Fuchs, V. R. et al. (2001). Physicians' Views of the Relative Importance of Thirty Medical Innovations, *Health Affairs, 20, 5, September/October,* 30-42.

[29] Kim Williams M.D., Testimony before the US House Ways and Means Committee, Subcommittee on Health, March 17, 2005.

7. Conclusion

Medical technologies are evolving rapidly. For example, emerging diagnostic imaging techniques for breast cancer include breast thermography, bioelectrical imaging, scintimammography, and contrast mammography[30]. Any model of funding needs to ensure that new technologies have rapid access to market and are reimbursed appropriately. 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. Funding must take into account payment for services and capital equipment (and depreciation of the latter).

Scientific and technical advances, driven by computing power that doubles every 18 months, have allowed doctors to provide new kinds of care and in new ways, such as PET scans that reduce guesswork in judging the effect of cancer drugs on a tumor. Imaging has also given doctors vast amounts of new information to better diagnose and treat patients, such as the ability of CT and MRI to visualize and pinpoint brain tumors and aneurysms.

MTAA welcomes the opportunity to contribute to the funding for diagnostic imaging review. 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.

[30] Smith, A.P. et al. (2004). Emerging technologies in breast cancer detection. *Radiology Management, 26(4),* 16-24.