Medical Technology
Association of Australia

Department of Health and Ageing
Interdepartmental Committee
Review of Funding of Pathology Services

Submission by
Medical Technology Association of 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 for ultrasound, computed tomography (CT), nuclear medicine, radiography (x-ray), magnetic resonance imaging (MRI), positron emission tomography (PET) and bone densitometry.

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 The system that currently assesses and funds medical technology (to the extent that there is any funding) is out of date, poorly-designed and not sufficiently flexible to keep pace with the rapid development in medical technologies.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 pathology services

The Pathology Quality and Outlays Memorandum of Understanding (MOU) between the Australian Government and pathology service representative groups commenced on 1 July 2004 and will expire on 30 June 2009. The MOU was negotiated between the Australian Government as payer and the professionals who provide the services namely the Australian Association of Pathology Practices, Royal College of Pathologists of Australasia and National Coalition of Public Pathology. When the first capped pathology MOU was introduced in 1996 the AAPP represented many smaller independent pathology service providers. Consolidation within the pathology service providers has meant the AAPP now represents two large major multinational healthcare companies listed on the ASX. The suppliers of in vitro diagnostic kits and reagents necessary to perform the pathology tests were not included in the negotiations.

The principles and objectives of the MOU are expressed as promoting:

1. access to quality and affordable pathology services

2. effective management of Government outlays relating to relating to the services described in the pathology services table (PST) of the MBS and applicable to the MOU

3. improved patient care through the enhancing the quality of pathology services and the appropriate use of services; and

4. co operative strategies which promote affordability of services for patients

While there is latitude in the MOU for an adjustment to be made to funding either via a submission to Medical Services Advisory Committee (MSAC) or by application to the Pathology Services Table Committee (PSTC), 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. A good example of this is Her 2 neu testing for herceptin indication. 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 pathology services. Effectively diagnosing disease often enables doctors to prescribe safer less invasive and more effective treatment options. Preventative screening assays lead to earlier diagnosis and savings to the healthcare system from a developing burden of chronic disease such as diabetes and heart disease. The growth of chronic illness is outpacing the healthcare system ability to pay for treatment;

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. The science behind personalised medicine is advancing rapidly, and will necessitate the reinvention of business models across the healthcare spectrum. The developing trends in personalised medicine means a diagnostic test will determine if a pharmaceutical will be effective.

The Australian reimbursement system should encourage appropriate investment in new tests and technology. Pathology rebates have not increased for 20 years. The increased cost to government of pathology services has been through an increase in volume. These costs have been contained by the pathology providers through technological advances from the suppliers of pathology instrumentation.

3. The value of diagnostic pathology – its contribution to the healthcare system

In Vitro Diagnostics or diagnostic pathology have an undeniable and not always recognised contribution to make in protecting health and ensuring appropriate and effective care. It is estimated that 70-80% of all healthcare decisions affecting diagnosis and treatment involve a pathology investigation, with individual treatment decisions – and the monitoring of their response to treatment – often dependent on a range of pathology based tests and investigations[1].

The core of the pathology service lies in ensuring that the appropriate test is requested, that the right result is produced, and that the result is understood and used correctly for the benefit of the patient. Diagnostic pathology is a key area for initiating care pathways leading to better patient outcomes.

Pathology services in Australia have been managed quite independently of their clinical users and patient outcomes, with a greater emphasis on the number of tests provided, the analytical quality of those results, and the cost of provision. The trend of patient-centered care therefore represents a significant challenge to the healthcare system and pathology providers.

The objective of the diagnostic pathology service is to improve patient outcome. Some examples include:

- Screening for chlamydia infection in young women has been shown to be very cost-effective by reducing the prevalence of the infection, and the complications associated with that infection, such as ectopic pregnancy, infertility and pelvic inflammatory disease[2].

- The assessment of tissue HER-2/neu status is essential to determine whether the drug Herceptin® will be effective in a woman with breast cancer[3].

- There is recent evidence to show that measuring the plasma brain natriuretic peptide level in patients with heart failure to guide and monitor therapy is a more effective way of managing the treatment of heart failure than the current practice based on clinical observation.[4]

- Point of Care Testing (POCT) will enable results to be delivered more quickly to the clinical decision maker. It has been shown that POCT in the emergency room reduces the patient's length of stay, enabling more efficient triage, while POCT in acute crises can enable treatment to be given sooner with better patient outcomes. POCT can also be helpful in the management of long-term conditions, providing the monitoring of tests that reflect disease

[1] Lord Carter of Coles Report - Report of the review of NHS pathology services in England

[2] Francis J Bowden, Marian J Currie, Helen Toyne, Clare McGuiness, Lynette L Lim, James R Butler and Nicholas J Glasgow 2008

[3] Ferretti G, Felici A, Papaldo P, Fabi A, and Cognetti F, (2007) 'HER2/neu role in breast cancer: From a prognostic foe to a predictive friend',

[4] Jourdain P, Jondeau G, Funck F, Gueffet P, Le Helloco A, Donal E, Aupetit J F, Aumont M C, Galinier M, Eicher J C, Cohan-Solal A, and Julliere Y, (2007) 'Plasma brain natriuretic peptide-guided therapy to improve outcome in heart failure: The STARS BNP Multicenter Study"

status at the time of the clinic visit, reducing the number of clinic visits, as well as improving the clinical outcome[5].

Currently in Australia none of the above services are adequately reimbursed by the Medical Benefits Scheme. MTAA argues that the full cost-effectiveness of a diagnostic pathology service 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. A key challenge from the IVD industry perspective is that there is an urgent need to reform the business model in pathology services in Australia away from the "production-centric" pathology organisations towards a "patient centric" diagnostic service.

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[6] in its research report on *Impacts of Advances in Medical Technology in Australia* and by the Banks Report[7]. The Productivity Commission[8] 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"[9]

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[10]:

"*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[11]:

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[5] Price C P, St John A, and Hicks J M, (eds) (2004) *Point-of-Care Testing* (2nd edn), AACC Press, Washington, DC.
[6] Productivity Commission, Research Report, *Impacts of Advances in Medical Technology in Australia*, Canberra 31 August 2005
[7] 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
[8] Productivity Commission, Research Report, *Impacts of Advances in Medical Technology in Australia*, 31 August 2005
[9] Ibid page XLIV
[10] Ibid page 33, recommendation 4.22
[11] 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 diagnostic pathology services or indeed, any medical technologies. However, simply applying a cap on expenditure for pathology 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 pathology services. A fresh approach to assessment and funding of in vitro diagnostic 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.

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