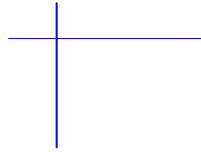




Medical Technology
Association of Australia



Review of Health Technology Assessment in Australia

Submission by
Medical Technology Association of Australia

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Medical Technology for a Healthier Australia

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1. Executive summary

The Review of Health Technology Assessment announced jointly by the Ministers for Health and Ageing and Finance and Deregulation in December 2008 is an opportunity to implement reforms to an area of the healthcare system overdue for examination. Medical technology is a key contributor to optimal patient health outcomes and offers smart solutions to many health challenges. An efficient, transparent and flexible health technology assessment system underpins the value of medical technology.

The Medical Technology Association of Australia (MTAA) adopts the all-encompassing definition of health technology assessment put forward by the International Network of Agencies for Health Technology Assessment (INAHTA) as “a multidisciplinary field of policy analysis [studying] the medical, economic, social and ethical implications of development, diffusion and use of medical technology”¹.

For the purposes of this Review, MTAA uses the term medical technologies to refer to all technologies excluding pharmaceuticals.

The Review provides the opportunity to address a cross-section of the shortcomings identifiable in current arrangements for the assessment of medical technology which are canvassed in detail in section 4 of the submission. To address these issues, MTAA proposes a simplified and streamlined model for an HTA body, supported by clearer definition of the regulatory, HTA, and reimbursement functions.

The framework recognizes and accounts for the differences between medical technologies and pharmaceuticals and the inherent need for a flexible approach to assessment. It draws on features of other HTA processes that incorporate principles of transparency and accountability. The proposed HTA body will consider all available evidence, where required, including from a societal perspective. The framework differentiates the health technology functions from the regulatory and reimbursement functions.

The submission supports the establishment of a professional, independent body, capable of building competency in assessment of medical technology and procedures. All relevant stakeholders are represented on the governing board of the assessment body.

The processes for regulatory approval and health technology assessment, and reimbursement where applicable, have a single entry point with contemporaneous and parallel examination of the technology. Regulatory approval and listing on the ARTG remains an essential pre-condition to releasing a product into the market, but there is greater alignment of process.

An early scoping meeting enables suppliers, regulators and assessors to determine the requirements for registration and assessment, although comprehensive HTA will not be required in every case. Triage of an application establishes the level of assessment required for each application – whether full, abridged, or confirmatory of a product grouping.

¹ International Network of Agencies for Health Technology Assessment (INAHTA). INAHTA Resources. Retrieved 12 April, 2009, from <http://www.inahta.org/HTA>.

Where a product may require further clinical evidence, the assessment body has the option of granting conditional coverage with conditions requiring development of further evidence. This flexibility enables emerging and beneficial technology that meets the regulatory requirements of safety and efficacy, to be made available to patients with conditions.

Where a product is listed with no claim of superiority over comparator products, the reimbursement process is simplified by automatic listing at a benchmark price, once the HTA body has undertaken confirmatory assessment of correct product grouping.

The assessment body engages with the Pharmaceutical Benefits Advisory Committee through a jointly-resourced committee to consider hybrid and co-dependent technologies.

The HTA body will evolve as the 'umbrella' to deliver consistent national evaluation of a broad range of health interventions, including horizon scanning to identify emerging technologies and procedures of benefit to patients and the healthcare system.

MTAA supports a collaborative process of stakeholder engagement similar in function to the Access to Medicines Working Group to implement and review the reformed HTA process.

The key reforms that MTAA seeks from the Review, in line with principles of better and more efficient regulation, are:

- Simplification of HTA systems with a redesigned HTA body that applies rational, evidence-based decision-making that is sufficiently flexible to recognize the diversity of medical technology
- Removal of duplication and overlap in assessment processes by concentration of HTA capability in a stand-alone HTA body and separation of the HTA body from regulatory and reimbursement functions
- Improved interaction between stakeholders and assessment bodies, based on a collaborative and transparent framework in accordance with good governance principles
- Simplified reimbursement processes which link HTA outcomes to benefit setting.

2. About the medical technology industry

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.

The medical technology industry in Australia has an annual turnover of \$6.0 billion (2007/2008), earns an export income of \$1.3 billion (2007/2008) and employs in excess of 17,500 people. Local manufacturing produces earnings of \$2.6 billion. The medical technology industry invested \$160 million in research and development in Australia in 2007/2008².

² MTAA estimate based on Australian Bureau of Statistics Report 81040DO012_200607

MTAA estimates that \$1.6 billion is spent on medical technologies in the private hospital system in Australia with a further \$2.8 billion spent in the public health system³.

There are 9,492 products listed on the Prostheses List at February 2009, of which 87% are listed by member companies of MTAA. There are a total of 25,993 (non-dental) medical devices listed on the Australian Register of Therapeutic Goods (ARTG) (at September 2008) by 1,710 sponsors.

The Australian market for medical technology is approximately 2% of the global market. Because of its small size, this means that companies developing innovative technologies will always need to consider the potential return on investment in making a decision as to whether to bring a technology into Australia or invest in development of a new technology in Australia.

3. Understanding medical technology

Medical technology refers to the diagnostic or therapeutic application of science and technology to improve the management of health conditions. Technologies may encompass any means of identifying the nature of conditions to allow intervention with devices, pharmacological, biological or other methods to increase life span and/or improve the quality of life⁴.

The range of medical technologies is far-reaching and includes diverse products:

- cardiac devices such as implantable defibrillators and catheters for ablation of atrial fibrillation
- implantable orthopaedic joints and intraocular lenses
- diagnostic tests for general pathology such as cholesterol and glucose, and infectious disease tests such as HIV and hepatitis
- diagnostic tests such as markers for HER-2 antibodies for breast cancer and K-RAS gene for bowel cancer
- radiology imaging equipment such as positron emission tomography and computed tomography x-ray scanners
- human tissues such as human heart valves, corneas, bones (part and whole) and muscle tissue.

The use of medical technology has a more recent history than its pharmaceutical cousins. In Australia public policy addressing the role and funding of medical technology has evolved in a rather piecemeal fashion. The medical technology industry has not had the benefit of a national framework policy such as the National Medicines Policy which has informed the development of public policy impacting the use of pharmaceuticals. There is no universal funding scheme for medical technologies which often means that patients have limited access to beneficial products and treatments, either as a result of waiting lists in the public health system, or because the products are unfunded or have restricted funding in the private health system.

³ This figure does not include major medical equipment in the public health system

⁴ Wikipedia. Wikipedia definition of medical technology. Retrieved 15 April 2009 from http://en.wikipedia.org/wiki/Medical_technology.

Australia has a long history of health technology assessment of pharmaceuticals. The Pharmaceutical Benefit Advisory Committee (PBAC) was one of the earliest international HTA bodies. However there has not been the same development of HTA for non-pharmaceutical products. Development of an HTA system for medical technologies is not as simple as adapting the existing PBAC system. It is essential to understand the differences between pharmaceuticals and medical technologies in considering an optimal HTA model for medical technology.

The differences between medicines and medical technology were reviewed extensively by the Productivity Commission in its Research Report on *Impacts of Advances in Medical Technology in Australia*⁵. These range over several parameters including therapeutic effect, operator skill, product life cycle, physical infrastructure, delivery environment, and evidence base.

In a recent study for the International Society for Pharmacoeconomics and Outcomes Research⁶, Drummond et al considered the challenges of economic evaluations of medical technology compared with pharmaceuticals. The reasons which they put forward as to why medical technologies are different are as follows:

- Many technologies are diagnostic. The value of improved diagnosis cannot be separated from the value of the improvement in patient outcome resulting from the subsequent treatment. A diagnostic technology can also have multiple applications which means that the overall value of the technology is the weighted average of its use in multiple applications because they are not divisible
- Medical technologies face challenges in being subject to randomized clinical trials (RCTs) because of evolving product modifications, and the clinical learning curve referred to above. The combination of these events means that there is rarely the 'steady state' required for an RCT
- The efficacy of a medical technology depends not only on the product itself but also on how it is used. The need to adjust for user characteristics complicates the design and analysis of clinical studies
- Implementation of a new therapy can have wider economic implications. The example provided by the authors is the assessment by the National Institute for Health and Clinical Excellence (NICE) on stapled haemorrhoidopexy where the cost-effectiveness of the staple gun was likely to be dependent on the potential to move more patients into day surgery in each location. The authors comment that such organizational adjustments are rarely examined in economic evaluations
- Equivalent clinical evidence may not be available for all products, making comparisons difficult. It can be less appropriate to make class effect assessments for medical technologies because they do not demonstrate differences that might be important to the patient
- The outcome of an economic evaluation based on formal technology appraisal can directly influence pricing in the market. The example given by the authors is where a technology assessment determines that clinical

⁵ Productivity Commission, 2005 *Impacts of Advances in Medical Technology in Australia*, Research Report at page 246

⁶ Drummond M, Griffin A, Tarricone R. Economic Evaluation for Devices and Drugs – Same or Different. *Value in Health* (in press)

practice should change in order to implement a new technology, which inherently determines that the 'old' technology is obsolete. The price of the 'obsolete' technology will be driven down rapidly to help create head room to fund the new 'approved' technology. If the price of the obsolete technology falls faster than the price of the new technology then the cost difference will increase, changing the implied incremental cost-effectiveness threshold.

Because of the nature of medical technology development through iterative improvement of products, the result is a more rapid life-cycle, increased competition and lower total relative returns per product than the majority of new pharmaceutical compounds. Generating sufficient evidence for HTA represents a major challenge to most medical technology manufacturers because of the costs incurred and time involved in generating data relative to the total return on investment and life of the product.

This point of difference is well-made by Hutton et al⁷ in a discussion on timing of assessment of a technology. Hutton argues that from the perspective of a decision-maker, assessment of technologies close to the time of their regulatory approval and/or launch allows for a timely decision to be made regarding their coverage and availability.

Here the difference between pharmaceuticals and other medical technologies becomes manifest. The main source of data for clinical efficacy assessment of pharmaceuticals is phase III randomised controlled trials (RCT). For medical technology the total amount and level of data may vary.

For new medical technology it may not be the case that level 1 or level 2 evidence⁸ is available at the time of registration, and randomised trials against comparators are more uncommon. The clinical evaluation of a new technology needs to take into account the totality of the evidence and ensure that the evidence is relevant to the research question at hand. Well-designed observational studies, indirect treatment comparisons and other newer methods are valid evidence platforms on which to base decisions.

Any process for health technology assessment of medical technologies must take account of those differences.

4. How HTA for medical technology works now in Australia – an industry perspective

4.1. Overview

As identified by the Productivity Commission in several reports⁹, the current processes for assessment of medical technologies are duplicative, inefficient, lacking

⁷ Hutton J, Trueman P, Henshall C. Coverage with Evidence Development: An examination of conceptual and policy issues. *International Journal Of Technology Assessment in Health Care*, 23:4 (2007), 425

⁸ National Health and Medical Research Council. *NHMRC additional levels of evidence and grades for recommendations for developers of guidelines*. Retrieved 20 May, 2009 from http://www.nhmrc.gov.au/guidelines/files/levels_grades05.pdf.

⁹ Productivity Commission, 2005 *Impacts of Advances in Medical Technology in Australia*, Research Report; Regulation Taskforce, 2006 *Rethinking Regulation: Report on the Taskforce on Reducing*

in transparency, and often insufficiently flexible to take account of the rapidly changing nature of new technologies. This will become increasingly vexed with the growing convergence of products – drugs and devices, devices and biologics (described in the Terms of Reference as hybrid and co-dependent technologies).

Medical technology of the future will include such diverse and complex products as¹⁰:

- Micro-sized nano-robots with tiny motors that roam the body and deliver radio waves to kill tumours
- Point-of-care diagnostics that result from the fusion of genomics and information technology
- Release of a pre-determined quantity of a drug stored in a silicon chip in a patient's body on receipt of a remote wireless signal sent via an electrical current
- An extension of this chip technology to enable monitoring of patients at home for signs of heart attack and hypoglycaemia in order to release the appropriate drugs.

There are several bodies which currently have responsibility for an element of health technology assessment of medical technology:

- Therapeutic Goods Administration (TGA) which looks at safety and technical performance of therapeutic products
- Medical Services Advisory Committee (MSAC) which looks at safety, effectiveness and cost effectiveness of medical procedures which make use of a medical technology
- Prostheses and Devices Committee (PDC) and its subordinate bodies, the Clinical Advisory Groups (CAGs) and Panel of Clinical Experts (PoCE), which look at clinical effectiveness, relative clinical effectiveness and cost relative to clinical effectiveness. More recently some CAGs have shown an inclination to also examine safety.

This section examines the current health technology assessment arrangements for medical technologies and the impact that current arrangements have on industry, in particular the way in which these arrangements delay the introduction of new technologies which ultimately has an impact on patients who may benefit from them.

4.2. Therapeutic Goods Administration

The TGA regulates the supply of medical technology in Australia according to criteria prescribed by the *Therapeutic Goods Act 1989* and related regulations. Since October 2002 the fundamental principles of the testing and assessment of medical technology in Australia have been based on similar principles developed for the European Union which are part of a global harmonisation approach steered through the Global Harmonization Task Force. However the control of supply in Australia is unique in that an approval process resulting in an entry in the Australian Register of Therapeutic Goods (ARTG) has to be granted.

Regulatory Burdens on Business, Report to the Prime Minister and Treasurer; Productivity Commission 2008, *Regulatory Burdens: Manufacturing and Distributive Trades*, Research Report

¹⁰ Special Report on Health Care and Technology, *The Economist*, 18 April 2009, 13

It should be noted that whereas the TGA does perform an assessment of the health technology it does so to confirm that the medical technology is safe and efficacious in accordance with the intended use as declared by the manufacturer of that technology. This assessment is done on an application by application basis. No comparisons of clinical effectiveness or cost benefit comparisons within product groups or for like products are undertaken by the TGA or are required to be undertaken under the legislation.

It should also be noted that, following assessment by TGA, medical technologies may be freely used in the health system without any further assessment of their safety, but without reimbursement in the private health system.

Under the *Therapeutic Goods Act*, the TGA is required to examine and certify the conformity assessment procedures undertaken by Australian manufacturers supplying medical devices in Australia as well as manufacturers producing medical devices containing particular designated materials, irrespective of where the manufacture occurs. One of the areas of additional burden for Australian manufacturers supplying their products in Australia is that while the TGA accepts CE certification for medical technology manufactured overseas, inspections by the TGA are required for Australian manufacturers of equivalent technology.

An additional burden has been created because restricting the choice of conformity assessment certification options for the Australian manufacturers, coupled with longer timeframes and costs in obtaining the TGA certification, the manufacturers have felt compelled to also obtain CE certification from EU Notified Bodies in order to supply their products in the EU earlier than if the TGA issued CE certification available through the mutual recognition agreement between Australia and the EU. This inconsistency is currently under review by TGA which is examining options for third party conformity assessment which would enable Australian manufacturers to also use certification granted by bodies other than the TGA.

4.3. Medical Services Advisory Committee

4.3.1. Background¹¹

MSAC was established with three key objectives¹²:

- Only medical procedures and new technologies which were safe, cost-effective and of real benefit to patients would be funded through Medicare
- There would be a more rigorous assessment by MSAC to ensure that the medical procedure and new technology was safe, cost effective and of real benefit to the patient
- The gap between research knowledge and clinical practice would narrow, and patients would benefit earlier from the most advanced procedures drawing on the best scientific and medical evidence.

¹¹ O'Malley, SP (2006), The Australian experiment: the use of evidence based medicine for the reimbursement of surgical and diagnostic procedures (1998-2004). *Australia and New Zealand Health Policy*, Vol 3

¹² Australia first in world to adopt evidence based medicine [Department of Health and Ageing. Australia first in world to adopt evidence based medicine. Retrieved 2 April 2005 from <http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/health-archive-mediarel-1998-mw7798.htm> (see [webcite](#)).]

The MSAC system is designed to determine whether the Government should fund a procedure through listing on the Medicare Benefits Schedule (MBS). However, in lieu of any over-arching HTA body for medical technology, the recommendations of MSAC, and establishment of an MBS item code, acts as a proxy HTA assessment for all Australian patients. In the absence of an MBS code, and funding private patients are not able to access treatment options although there are a small number of treatments that can be accessed without a MBS code such as cosmetic surgery. This is unique internationally, where most other countries do not have a Government committee determining access to private care.

MSAC processes are extensively critiqued in the Access Economics report at Appendix 2.

4.3.2. Duration of assessment

The period between the lodgement of an application to MSAC and the listing of the procedure on the MBS averages around 24 months. The sequential processing of medical technology approvals creates an unreasonable barrier to market entry, particularly when coupled with additional delays from TGA registration and the minimum of six months to list on the Prostheses List. The sequential periods mean that several years' delay can be imposed on patient access to new technology. Given the short life cycles of many medical technologies, beneficial products may not get to market.

4.3.3. Medical practitioners as a source of MSAC applications

When MSAC was established in 1998 it was assumed that the majority of applications would originate from the professional medical associations that represent the medical practitioners since the Medicare Benefits Schedule (MBS) is primarily a schedule of fees for the payment of the medical practitioner. However, in recent years virtually all applications have been sponsored by industry.

It is possible that some early experiences with the new system alerted medical practitioners to the fact that an MSAC application is a time consuming and risky process. An MSAC application results in attention being focused on the usage of the existing MBS Item Number to cover the new procedure. If the MSAC application is unsuccessful, the wording of the existing Item Number may be modified specifically to exclude the new procedure.

4.3.4. Industry as a source of MSAC applications

Despite the original expectation that the majority of MSAC applications would originate from professional medical organisations, the source of applications quickly moved to the medical technology industry as being the main and almost exclusive source of applications. Almost all MSAC applications come from the medical technology industry - a curious situation in respect to a process primarily designed to facilitate fees for medical practitioners.

The reason lies with the nature of the new procedures. A close examination reveals that without exception all new MSAC applications cover procedures that include the use of new technology, that is, capital equipment, consumables, disposables, prostheses or medical devices. The following case study evidences the considerable challenges faced by industry in bringing an innovative technology through the MSAC

process, with its attendant risks and costs. The applicant in this case carried the disadvantage of being the first in class which, in most circumstances should deliver market advantages. However the case study illustrates the disadvantages of being the innovator under current assessment arrangements.

Case Study 1

Diagnostic procedure - PillCam Capsule Endoscopy

- MSAC Application 1057 sponsored by Given Imaging for PillCam (formally M2A) capsule endoscopy - evaluation of obscure gastrointestinal bleeding in adult patients, lodged in August 2003 was approved for interim funding in September 2003 and listed on the MBS May 2004. All data used in the application was based on Given Imaging's technology – PillCam and all costs of the application were borne by Given Imaging.
- MBS Item Number 11820 - capsule endoscopy to investigate an episode of obscure gastrointestinal bleeding, using a capsule endoscopy device approved by the TGA (including administration of the capsule, imaging, image reading and interpretation, and all attendances for providing the service on the day the capsule is administered). This means that the Schedule fee (\$1,883.90) includes the cost of the capsule.
- In the time period post lodgement of the PillCam MSAC Application other 'brands' of capsules have entered the Australian market and are TGA registered. These products have not been required to establish substantial clinical equivalence to the technology used for the MSAC Application (PillCam) either as part of their TGA registration or by any Australian HTA agency. Despite this, the un-proven brands have full access to funding using MBS Item Number 11820. The effectiveness of these other 'brands' has not been established relative to PillCam.
- This case study illustrates a misunderstanding of exactly what TGA registration covers in terms of the registration process's comparison of 'similar' technology. This 'loop-hole' for diagnostic technology is in contrast to similar technology applying for listing on the Prostheses List. These technologies (prostheses) must prove substantial clinical equivalence.

One of the criteria for a listing on the Prostheses List is a relevant MBS Item Number. Up until 2004, the requirement for the procedure used to implant the prosthesis or medical device to be covered by a relevant MBS Item Number in order for the prosthesis or medical device to qualify for reimbursement, was inconsistently enforced. However, with the rapidly growing levels of expenditure on prostheses and medical devices, private health insurers have lobbied for this criterion to be enforced. The Minister for Health and Ageing directed implementation of this aspect of the Doyle Report in September 2008¹³.

4.3.5. Processing MSAC applications and references

The overall average processing time (up to the known decision endorsed by the Minister), has been approximately 18 months for applications and 22 months for references. Note that it is only the Applicant and the Evaluators that have any time limits imposed on their actions.

¹³ Correspondence from Minister for Health and Ageing to MTAA, 15 September 2008

The role of the Advisory Panel is to assist in the assessment of each application and provide expert input into the assessment process as well as ensuring that the Evaluator's assessment is clinically relevant. Although the Advisory Panel is central to the process, it is also a major cause of delay owing to the time taken to form the panel. The formation and organisation of the first meeting of the panel can take in excess of six months. During this time the only progress made by the application is the briefing of the Evaluators and the resulting draft protocol from the Evaluators.

The processing times do not take into account the time between the lodgement of the application and the next MSAC meeting, a period of up to three months. However, far more importantly, once a decision has been ratified by the Minister, the application has to be processed by another committee, most often the Medicare Benefits Consultative Committee (MBCC) for the wording of the MBS descriptor and the determination of the fee for the service. This process is not commenced until the Minister has approved the MSAC recommendation. As a consequence a period of two years between the date of the lodgement of an application and the actual listing of the new procedure on the MBS as a claimable Item Number is not uncommon. It is also possible for the Department of Finance to block processing of an approval by the Minister for Health and Ageing on the basis of overall expected cost.

An example of the complex processes involved in an MSAC application and subsequent determination that a procedure not be funded, notwithstanding Ministerial approval for funding, is evidenced in the case study below.

Case Study 2

Medical Grade Diode Laser for Endovenous laser treatment for varicose veins

- The Medical Grade Diode Laser which by way of an attached bare tipped small diameter optical laser fiber ablates or destroys the inner lining of the main vein that causes Varicose Veins, 'welding' it closed to eliminate the Varicose Veins. It does this after insertion of the fiber into the vein, applying the laser energy and withdrawing the fiber as the vein is closed. This is done in an outpatient setting under local anaesthetic in a session lasting less than one hour.
CE Mark: 3 August 1995
Inclusion on ARTG: 13 November 2001
- **Date of First MSAC Submission**: August 2002 - Application 1059
Reason for Rejection: "Endovenous laser treatment for varicose veins appears to be safe in comparison to stripping of varicose veins but there is insufficient evidence pertaining to effectiveness and cost-effectiveness, therefore MSAC recommended that public funding should not be supported for this procedure at this time". The applicant was invited to re-submit when long term data became available. Report dated November 2003
MSAC Recommendation endorsed by Minister for Health & Ageing: 10 August 2004
- **Date of Second MSAC Submission**: August 2006 - Application 1113
Reason for recommendation: "MSAC has considered the safety, effectiveness and cost-effectiveness for endovenous laser therapy for varicose veins compared with saphenous junction ligation with or without vein stripping. MSAC finds that endovenous laser therapy is at least as safe, effective and cost-effective as saphenous junction ligation and vein stripping for the treatment of varicose veins. MSAC recommends that *public funding is supported* for endovenous laser therapy". Report dated March 2008.
MSAC Recommendation endorsed by Minister for Health & Ageing: 20 May 2008
- **Progress as at 31 March 2009**: At this date the applicant had received no formal advice on the fate of the recommendation however after its verbal inquiry, verbal advice from the Department of Health and Ageing was that the recommendation had not proceeded due to constraints imposed by the Department of Finance.

4.3.6. Recommendations and outcomes of applications and references to the MSAC

MSAC recommendations can be drawn from the following:

- A positive recommendation - basically a recommendation for an MBS Item Number covering the total indication applied for by the sponsor of the original application
- A partial positive recommendation - a recommendation for an Item Number covering only part of the original indication applied for by the sponsor
- An interim recommendation – is for temporary funding and is approved when the evidence is inconclusive but suggests that the procedure could be at least as safe, more effective, and more cost-effective than the existing comparable procedure. In these circumstances, the MSAC usually recommends interim funding for a period of three years to enable data collection and further

evaluation of the procedure. These applications require a reapplication at the end of the three years based on the additional evidence collected during that time in order to maintain funding

- Negative recommendation.

4.3.7. Clinical evidence

New medical procedures are often the result of a process of experimentation rather than formally conducted research. Affordability of research and the question of who should pay for the generation, collection and analysis of the clinical evidence is perhaps the most difficult to answer. This is especially the case where the new procedure is the result of a process of experimentation with an old procedure. A cost-effective way needs to be found to collect acceptable levels of evidence proving the clinical effectiveness of these new procedures, otherwise the formal processes of evaluation such as that used by MSAC will continue to run the risk of denying access to medical procedures that are beneficial and efficient.

The best timing of a clinical trial for a technology can be difficult to determine. If the trial is carried out too early the outcome may not be optimal due to the lack of the medical practitioner's experience or practice in performing the new procedure¹⁴. Conversely, a delay in running the clinical trial results in a reduction in the 'window of time' on the return of the financial investment in the clinical trial and the new technology.

In the case of a procedure that involves new technology, there is the additional timing problem created by the on-going development and refinement of the technology. Unlike a pharmaceutical that enters the market as a finished product, technology continues to evolve once in the market based on feedback from the medical practitioners and patients, resulting in newer and incrementally better versions. A clinical trial based on the first version will often generate less than optimal results. However, a delay in carrying out the clinical trial and the resulting delay in funding reduces the financial viability of the product.

Clinical trials with statistically significant outcomes in many instances are simply not feasible, especially where the change to predicate technology is incremental. Unlike pharmaceuticals, where the potential market is often measured in tens of millions of dollars per annum, the market for technology is far smaller. This limits the affordability of clinical trials covering procedures.

MSAC outcomes have been analysed in a study by O'Malley¹⁵. As would be expected, any procedure that had a serious safety concern was not recommended by MSAC. O'Malley found that applications that related to a procedure likely to be carried out on a small number of patients were more likely to be given a positive recommendation. Although often applications with positive or partial positive recommendations were based on 'solid' clinical evidence of effectiveness, this was not always the case, especially in the case of interim funding. Importantly, negative recommendations were in most cases based on insufficient clinical evidence rather than clinical evidence that clearly demonstrated a lack of clinical effectiveness. It was rare for a recommendation, either positive or negative, to be based on cost-

¹⁴ An effect known as Buxton's Law, Buxton, W. (2001). Less is More (More or Less), in Denning P (Ed.), *The Invisible Future: The seamless integration of technology in everyday life*. New York: McGraw Hill, 145 – 179

¹⁵ O'Malley supra

effectiveness since less than 10% of the literature search carried out by the evaluators resulted in finding any acceptable papers covering this criterion. Although, logically, this was to be expected for applications with negative recommendations due to insufficient clinical evidence, what was unexpected was that it appeared to be equally true for those applications with positive recommendations. Diagnostic procedures have a much higher total positive, partial positive or interim recommendation rate compared to surgical or therapeutic procedures. Therapeutic procedures were far more likely to be ineligible compared to surgical or diagnostic procedures.

4.3.8. Timetable for the processing of applications to MSAC

There is no set timetable for the processing of applications to MSAC. Despite the fact that one of the most crucial stages, the evaluation of the evidence, is given a set time of three months, unexplained delays in other stages of the process have resulted in applications taking in excess of two years to generate a new MBS Item Number.

4.3.9. Appointment of Advisory Panels

The MSAC process presently averages two years between the acceptance of the application and the listing of the new Item Numbers on the MBS. A major cause of this lengthy delay is the amount of time spent forming the Advisory Panel and agreeing on the dates of the first and subsequent meetings of this panel. When a new application to MSAC is received by the Medicare Benefits Branch, one of the first steps in the process is to write to the relevant medical association (Craft Group) and ask for nominations for positions on the Advisory Panel. This part of the process is open-ended in terms of timing of the response from the Craft Group and can take several months.

4.3.10. Interim funding

Currently, where the evidence is inconclusive but suggests that the procedure could be at least as safe and possibly more effective and cost-effective as the existing comparable procedure, MSAC may recommend interim funding for three years subject to the condition that additional data be collected to allow further and longer term evaluation of the procedure.

While approval for interim funding is welcome, data collection can be challenging and expensive. No guidance is given by MSAC on what data needs to be collected, how the data is to be collected, and who pays for it. The following case study illustrates some of the difficulties.

Case Study 3 Interim Approval

SIR-Spheres microspheres for the treatment of non-resectable liver tumours

- An MBS procedure number was approved for Sir-Spheres microspheres in 2006 following a positive MSAC recommendation in 2005. This followed consideration of the second application to MSAC in respect to SIR-Spheres microspheres. The first application was not accepted at a time when the US was accepting the product for reimbursement. An Australian-developed product, it struggled to get reimbursement recognition in Australia.
- Interim funding was provided with regard to one specific treatment using SIR-Spheres microspheres with the collection of survival data being directed for three years. Responsibility for the collection of data was not stated. However the manufacturer assumed responsibility. The data collection period has been extended to 2011.
- The sponsor (who is the manufacturer) of SIR-Spheres microspheres faces difficulties collecting data because the patients are recommended for treatment to an interventional radiologist. Following treatment the patient returns to the care of his/her oncologist who is the patient's long term supervising specialist. Some oncologists cite privacy considerations as reason for not sharing survival data with the manufacturer.
- The collection of data has to be a combined responsibility with the best placed reporter taking the lead, i.e. the presiding specialist/s. The collection of such data is an expensive clinical investigation. The patient numbers being sought are beyond those available in Australia and therefore it has to be extended into overseas sites in US and EU where the product is now considered a part of the overall care plan for all inoperable patients, however treatment includes a range of newer oncology drugs so recruiting patients into studies that do not use such drugs has proven to be extremely difficult. This is a typical problem in an area of rapidly developing technology.

4.4. Prostheses and Devices Committee and related bodies

The Prostheses and Devices Committee and its subordinate bodies, the Clinical Advisory Groups and the Panel of Clinical Experts perform a variety of HTA-related tasks. Some of these are set out in the guidance notes that regulate the activities of the PDC, such as the Prostheses List Guide to listing benefits for prostheses¹⁶. Two stated objectives of the arrangements for prostheses are to ensure that prostheses on the Prostheses List are clinically effective, and that products of similar clinical effectiveness have similar clinical benefits¹⁷. Other HTA functions have evolved over time, and not uniformly, as the related bodies have developed differing processes to deal with the technologies before them for assessment.

The key issues that the medical technology industry identifies which impede the effective functioning of the PDC and its subordinate bodies are:

- Rigid timelines (two cycles which can be missed because of external factors beyond a sponsor's control)

¹⁶ Department of Health and Ageing. Retrieved from [http://www.health.gov.au/internet/main/publishing.nsf/Content/3064D955DFB3413DCA2573A000774ED8/\\$File/PL%20Guide%20Part%201.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/3064D955DFB3413DCA2573A000774ED8/$File/PL%20Guide%20Part%201.pdf).

¹⁷ Ibid section 4.1

- Lack of understanding of the remit of the role of the PDC with respect to safety and performance of a product, compared with the TGA
- Lack of transparency in process, including the absence of an effective review mechanism
- Lack of consistency between the different CAGs in their treatment of applications
- Difficulties in ensuring availability of relevant clinical experts – a challenge that applies both to the MSAC Advisory Panels and the panels of clinicians which advise the PDC
- Lack of independent benefit negotiators.

In many procedures involving an implantable prosthesis, the manufacturer or distributor will be requested to provide clinical trials evidence for the product. These may be different from, or in addition to, the requirements of TGA for listing of the product on the ARTG. While Section 4.3 of the Prostheses Guide Part 1 acknowledges that “in some instances, clinical evidence demonstrating clinical effectiveness and/or outcomes may not be available”, it further states that “clinicians will take this into account when assessing these products”.

A recent application for listing of a product on the Prostheses List illustrates the unrealistic demands for clinical evidence that can be placed on a sponsor by the PDC for what is no more than an incremental development in the relevant product.

Case Study 4

Application to list Unicompartmental Partial Knee System – 5 components

- 11 August 2008 – the sponsor submits five applications by the closing date for the February 2009 Prostheses List
- 14 October 2008 - After consideration by the Knee Prostheses CAG, the PDC accepted the recommendation not to list with the following reasons given:
 - “This is a novel implant and concept.
 - The application did not provide sufficient clinical data and clinical outcomes specific to the prosthesis.
 - Two year data is required for novel implants.”
 - The sponsor was permitted to respond if it believed there was sufficient evidence in the application, but it could not provide additional evidence or communicate with clinical assessors to discuss the rejection. Although Application forms refer to the need for two year follow-up for “all mobile or stabilizing devices or new devices using novel technology or design”, there is no reference to the definition or implications of a “novel implant”.
- 24 October 2008 - The sponsor responded by noting that the Unicompartmental Knee System was developed as a design improvement to its currently listed products and that there are other products with similar physical properties on the Prostheses List. The sponsor’s reply was unsuccessful and the Unicompartmental Knee System was not listed on the February 2009 Prostheses List.
- The sponsor has applied to list the Unicompartmental Knee System on the August 2009 Prostheses List.

The requests for collation of evidence at times appear to misunderstand the technology or the limitations on evidence collection. At times the PDC appears to misunderstand the role played by the TGA and the analysis which is undertaken by the TGA to list a product. The Doyle Report¹⁸ noted that “many doctors involved in the CAGs stated that they saw the CAG’s role as ensuring the safety of prostheses as well as assessing their clinical effectiveness”.¹⁹ Doyle further recorded his concern “that a process...is being used to second guess the TGA process by providing marketing approval across both the public and private sectors”²⁰. Proponents of the requirement for inclusions on the Prostheses List to have undergone clinical trials for two years were observed by Doyle to be unable to identify any other jurisdiction where such trials are a condition of market approval or reimbursement.²¹

Compared with TGA’s assessment of product safety and efficacy, which is based on an internationally agreed risk methodology (the GHTF model), the individual CAGs determine their own minimum clinical research requirements. While in some cases a company can provide multi-year in-human data, this is not possible for component changes, or ‘me too’ versions of well-established technology. Two examples provide illustration:

- Example 1 – synthetic meshes: there are already 180+ products on the PL so no company will establish a new clinical trial to demonstrate version 181 of

¹⁸ Doyle, R. Report of the Review of the Prostheses Listing Arrangements. October 2007

¹⁹ Doyle Report page 16

²⁰ Ibid page 16

²¹ Ibid page 23

the technology. The technology is old (over 30 years) and manufactured to similar standards (as determined by TGA granting regulatory approval)

- Example 2 – components: it is also impossible to control for component change in a complex multi-part system. A company recently changed the temperature which a recharging battery pack can reach for its neuro-stimulators, following patient complaints. A clinical trial would not be necessary in these circumstances where the company has made the changes itself, in accordance with its internal quality system, based on patient experience.

Errors can occur when there is inadequate consultation, particularly with hybrids and co-dependent technologies, as illustrated in the following case study.

**Case Study 5
DC Beads Drug Embolisation System
(Prostheses List Billing Code DE275)**

- This is a drug delivery embolisation system. The beads are supplied by the sponsor without the drug for the primary function of embolisation of vessels. The TGA categorised the product as a device.
- 22 September 2006 - Sponsor submitted an application to the Prostheses Secretariat by the closing date for inclusion in the Prostheses List
- 10 May 2007 - The sponsor was formally advised by the Prostheses Secretariat that the Beads would not be listed until listing eligibility had been reviewed as the “PDC had been unable to reach consensus on the application”. The sponsor was advised verbally that the PDC had taken a contrary view to the TGA and regarded the product as a pharmaceutical and therefore ineligible for listing.
- July 2007 – DC Beads were not listed in the February 2007 Prostheses List
- December 2007 - The PDC resolved its issues regarding DC Beads during the next Prostheses List with the product being listed in the December 2007 List

Where the PDC resolves not to list a product on the Prostheses List there are limited review options available to a sponsor. A sponsor has the right to respond to the rejection advice but is not permitted to provide additional evidence or communicate with clinical assessors to discuss the rejection or improvements to subsequent applications. There is no independent means of appeal on the clinical merit of a decision and the clinicians who made the original decision will consider the sponsor's response or subsequent re-applications in successive listing cycles. Even in circumstances where a sponsor's request for an internal review on the basis of an error of process is upheld, a delay of six months to the next Prostheses List will invariably result. There is no mechanism to reimburse the lodgment cost for a review which is now \$1,000, or to reimburse a sponsor for the lost revenue resulting from the incorrect initial determination. Even where an application to review is upheld there is no guidance to inform future decisions by the PDC on a similar issue.

The function of negotiating reimbursement levels is performed by the Prostheses and Devices Negotiating Group (PDNG) whose members, although subordinate in role to the PDC, are recruited and employed by the Australian Health Insurance Association (AHIA). If the sponsor of the product and the PDNG do not agree on the proposed benefit, then the most likely outcome is a listing with a gap or co-payment to be paid by the patient. Products listed with a gap have increased from 1.2% on the first PL published in 2005 to 18.5% of the February 2009 List. The negative growth over the

last three years of prostheses benefits of -8% adjusted for CPI is justification to many sponsors that the perception of conflict of interest within the PDNG must be removed by replacing it with an unaligned and impartial body. MTAA agrees.

Unlike the TGA regulatory processes which accepts and processes applications as they are received, the Prostheses List cycle operates on a six month event driven basis. Applications are due in weeks 1 and 2 with the new Prostheses List released in week 25²² which imposes a minimum delay of 23 weeks to listing. Sponsors that miss the closing date for applications at worst may face a wait to list of 48 weeks. Some allowance is made for the time taken for TGA assessment in that a sponsor may submit a PL application ahead of ARTG listing but if this is not achieved by week 6, the application is terminated. Recommendation 2 of the Doyle Report proposed that sponsors be permitted to apply concurrently for the ARTG and the Prostheses List as he believed that any nugatory assessment effort by PL committees would not be significant.²³ While expressing support for this concurrent processing, MTAA acknowledges the primacy of TGA regulatory approval prior to any marketing.

4.5. Horizon scanning

There are multiple bodies, at both federal and State level, which undertake a range of horizon scanning activities to support or anticipate health technology assessment of medical technologies. The value of these various bodies is at times unclear although in theory, horizon scanning should add to the understanding of emerging technologies that may offer enhanced outcomes for patient and healthcare system alike.

The Health Policy Advisory Committee on Technology (HealthPACT), comprising jurisdictional representation, was established to advise the Australian Health Ministers' Advisory Committee (AHMAC) and MSAC on the introduction of new and emerging technology into the Australian health care system.

HealthPACT has oversight of the National Horizon Scanning Unit (NHSU), whose role is to identify and undertake assessments of new and emerging technologies. The NHSU is a Commonwealth funded unit which is located in the Department of Public Health at the University of Adelaide. The NHSU alerts the Health Departments of the Commonwealth, States and Territories, and New Zealand, of new and emerging health technologies that may impact on the Australian public health care system. Potentially significant new health technologies are also assessed by the NHSU for safety, effectiveness, cost-effectiveness and on ethical grounds, to assist policy makers. The NHSU also performs work directly for the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP–S) and MSAC. ASERNIP–S is a venture of the Royal Australasian College of Surgeons (RACS). Services provided include systematic and accelerated reviews of the peer literature, the establishment and facilitation of clinical and research audits or trials, the identification and assessment of new and emerging techniques and technologies by horizon scanning, and the production of clinical practice guidelines.

New and Emerging Techniques – Surgical (NET-S) was developed with the aim of providing an early warning system for identification of new and emerging surgical techniques and technologies prior to their introduction into routine clinical practice. NET–S is administered by ASERNIP–S in conjunction with RACS.

²² The Prostheses List Guide, Part 1 page 18 – see the week-by-week cycle.

²³ Doyle Report page 15

The Victorian Department of Human Services established the Victorian Policy Advisory Committee on Clinical Practice and Technology (VPACT) to consider and make recommendations regarding the application of new and existing technologies and clinical practices in Victorian public health services and hospitals. This includes identifying, prioritising, introducing, evaluating and ongoing monitoring of new and existing technologies and clinical practices. The activities of VPACT complement and supplement those being undertaken by HealthPACT. VPACT addresses Victorian specific issues and utilises HealthPACT information where available.

In South Australia, Adelaide Health Technology Assessment (AHTA) is located within the Discipline of Public Health, University of Adelaide. AHTA has conducted research on behalf of bodies ranging from MSAC to PBAC and the National Health and Medical Research Council (NHMRC). Its activities include horizon scanning, health care research, health care evaluation, and disinvestment.

5. Exploring international models of HTA and their application to an Australian model for medical technology

5.1. International models

In considering an optimal model for HTA in Australia, MTAA has had regard to the principles for a best practice HTA system (applicable across pharmaceuticals and medical technology) elaborated by Professor Michael Drummond and his global colleagues in 2008²⁴. This submission scans the best examples of the application of these principles by other HTA authorities. The Access Economics paper comprehensively examines three overseas HTA agencies from the point of view of the economic evaluation framework²⁵. The discussion in this section is therefore focused on the non-economic process framework examples of good application of the Drummond principles. The principles identified by Drummond et al require that:

1. Goal and scope of the HTA should be explicit and relevant to its use
2. HTA should be an unbiased and transparent exercise
3. HTA should include all relevant technologies
4. A clear system for setting priorities for HTA should exist
5. HTA should incorporate appropriate methods for assessing costs and benefits
6. HTAs should consider a wide range of evidence and outcomes
7. A full societal perspective should be considered when undertaking HTAs
8. HTAs should explicitly characterise uncertainty surrounding estimates
9. HTAs should consider and address issues of generalisability and transferability
10. Those conducting HTAs should actively engage all key stakeholder groups
11. Those undertaking HTAs should actively seek all available data
12. Implementation of HTA findings needs to be monitored
13. HTA should be timely

²⁴ Drummond MF, Stanford Schwartz J, Jonsson B, Luce BR, Neumann PJ, Siebert U, Sullivan SD, Key principles for the improved conduct of health technology assessments for resource allocation decisions. *International Journal of Technology Assessment in Health Care*, 24:3 (2008), 244

²⁵ Access Economics, *An improved HTA economic evaluation framework for Australia*, 2009 20ff

14. HTA findings need to be communicated appropriately to different decision makers
15. Link between HTA findings and decision-making processes needs to be transparent and clearly defined.

These principles are discussed below under the broad subject headings used by Drummond et al.

5.1.1. Structure of HTA programs (principles 1-4)

Canada

The Canadian Agency for Drugs and Technologies in Health (CADTH formerly CCOHTA) produces guidelines explaining methodology developments that have occurred. The primary audience for the guidelines is analysts in the public and private sector who conduct economic evaluations.

CADTH has been established at an “arms length” relationship, with government funding but an independent oversight board.

Europe

The Swedish Council on Technology Assessment in Health Care (SBU) undertakes assessments, not for cost-containment purposes, but to improve the efficiency and equity in access to and use of technologies proven safe and effective. Its remit is to provide the central government and health care providers with information on the overall value of medical technologies, especially new therapies, from medical, economic, ethical and social points of view. In particular, the SBU reviews the benefits, risks and costs of health technologies used in health care delivery plus assists in identifying areas in which further research is needed.

In the UK where NICE assesses only some technologies, selection priorities are set based on the following criteria:

- Burden of disease
- Resource impact
- Clinical and policy importance
- Presence of inappropriate variation in practice
- Potential factors affecting the timeliness of guidance
- Likelihood of the guidance having an impact.

It also offers an upfront consultation process that allows stakeholders to make recommendations on which technologies should be reviewed. NICE incorporates a formal appeals process, to ensure that the final guidance is robust, where organisations representing patients and carers, healthcare professionals and manufacturers can appeal against final advice given by the independent advisory committee on a specific medicine or treatment.

United States of America

In the United States, the Center for Medicare and Medicaid Services (CMS) only conducts formal HTAs (or coverage determinations) in response to strong concerns

from providers about the usefulness of new technologies. Only a tiny fraction of new medical technologies and procedures are formally reviewed each year by CMS. CMS increasingly recognizes the need for real world data to assist with conducting the assessments and increasingly will allow for limited utilization while the assessment is being done or under condition that a certain level of data is collected. A similar approach to HTA is adopted by the private payers such as BlueCross BlueShield.

The process for conducting the reviews is very transparent with a 30 day public comment period following the publication of an initial draft report by CMS. Where the subject matter is particularly controversial or may have a major impact on the target population or Medicare program, Medicare looks to an external advisory committee to provide independent, expert advice and assistance in making decisions relative to the scientific evidence. All meetings are open to the public and time is allotted for public comment on the issue under consideration.

5.1.2. Methods of HTA (principles 5-9)

In Finland, France and the UK, health technologies are reassessed after a specified period of time or upon availability of new data to enhance effective and efficient decision-making and technology utilisation over time.

HTA bodies in Europe and the US employ different analytical frameworks/criteria to guide assessments including safety and clinical effectiveness; patient need and benefit; cost effectiveness and cost of therapy (typically in relation to benefit) as set out in Table 1.

Table 1 Criteria for assessment

<i>Criteria</i>	USA	Austria	Belgium	Switzerland	Denmark	Finland	France	The Netherlands	Norway	Sweden	UK
Therapeutic benefit	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Patient benefit	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cost effectiveness		✓	✓			✓		✓	✓	✓	✓
Budget impact			✓			✓	✓	✓	✓		✓
Pharmaceutical/innovative characteristics	✓	✓	✓				✓	✓			✓
Availability of therapeutic alternatives	✓	✓						✓		✓	✓
Equity considerations									✓	✓	✓
Public health impact							✓				
Research and development						✓					

In the US, interested parties may submit clinical and other evidence related to HTA subject matter. In addition, CMS will collect published literature and other relevant information for the purpose of completing a comprehensive HTA review. HTA reviews by CMS and private payers do not include formal cost effectiveness reviews or decisions.

5.1.3. Processes for conducting HTA (principles 10-12)

SBU (Sweden) – engages health care providers, health economists, as well as representatives from health care organisations, in addition to researchers and HTA agency personnel. In order to provide timely information to key stakeholders, SBU produces, in collaboration with experts, brief assessments (Alert Reports) that are published on the internet for review and comment, followed by any necessary revision. A network of ~4000 health care professionals receives the aforementioned information. SBU also develops special topic papers (White Reports) that explore health care problems or interventions that may need to be assessed. The document serves as the starting point for future systematic (literature) reviews. There is accountability for stakeholder input, in that stakeholders are able to comment on the SBU Alert Reports once published on the internet, but must hold a subscription to the service.

Local ambassadors are used in the form of a team of local experts, operating throughout Sweden, who promulgate the use of decisions or guidance by decision-makers and providers to improve local implementation.

In England the Healthcare Commission is the health watchdog. It has a statutory duty to assess the performance of healthcare organisations, and award annual performance ratings for the NHS. It sets standards by which each NHS organisation is measured and assessed. Two of these standards relate to the implementation of NICE guidance:

- The implementation of NICE technology appraisals fall under the core Standard 'C5a', which means it is a standard (Hospital) Trusts must meet
- The implementation of NICE clinical guidelines falls under the Development standard 'D2a', which means it is a standard a (Hospital) Trust must seek to meet over a period of time.

The Healthcare Commission, therefore, has the ability to mark a hospital down in its performance rating if it is not demonstrating adherence to NICE guidance.

5.1.4. Use of HTA in decision-making (principles 13-15)

In Finland, France, Spain, and Sweden there is provision for rapid reviews and horizon scanning mechanisms to identify new and emerging technologies that might require urgent evaluation. They typically involve products of policy, clinical or cost importance and their objective is to improve timeliness and relevance of assessments.

In the UK, NICE instigated single technology appraisals (STAs), a new fast-track procedure to address time concerns regarding standard assessments. STAs place more emphasis on evidence submitted by manufacturers and less on extensive external review.

SBU and NICE each recognize that patients and the general public are also major audiences for HTA findings. In recognition of this, nontechnical versions of HTA reports are publically available for the health consumer. This assists patient understanding of the differences and varying levels of co-payments among technologies or subgroups of patients.

5.2. Australian Pharmaceutical Benefits Scheme

The system for assessment of medicines for reimbursement on the Pharmaceutical Benefits Scheme (PBS) is amongst the most developed in the world – the Australian system was the first in the world (in 1993) to require a favourable economic evaluation as a condition of reimbursement.

There are many aspects of the procedures used in the PBS process that can be examined for assessment of medical technology, but require significant adaptation to take account of the substantial differences from pharmaceuticals. The MSAC guidelines, which are based on the PBAC guidelines, are substantially different due to differences between procedures and pharmaceuticals²⁶. However, the MSAC guidelines do refer to the PBAC guidelines for evaluating economic aspects of health care. Some of the best features of PBAC's operations are its governance, professionalism, and adherence to transparent processes.

5.2.1. Objectives

The PBS has several public priorities and objectives, which include several that should be incorporated into the HTA of medical technologies and procedures (with appropriate adaptation).

- Maintaining the effectiveness and affordability of the PBS
- Streamlining of processes to reduce the time taken to list drugs on the PBS
- Maintaining productive working relationships with our stakeholders
- Maintaining open lines of communication with all stakeholders and respond promptly to their representations
- Improving transparency of, and access to, PBS processes.

5.2.2. PBS process

PBAC considers the clinical place, overall effectiveness, and cost effectiveness of a proposed drug compared with other drugs already listed on the PBS for similar indications, or if no such drugs, standard medical care.

The sponsor must prepare a detailed submission according to the guidelines.

5.2.3. Main components of a PBS submission

- Context of the submission: intended use of proposed drug, main comparator
- Clinical evidence
- Premodelling: evaluation of clinical evidence to the context of requested listing
- Economic evaluation: changes in health outcomes
- Financial analyses: including implications for PBS/RPBS and government health budgets.

²⁶ See discussion supra in section 3

5.2.4. Clinical assessment

A submission must identify the main comparator, which is defined as the therapy that prescribers would most replace with the proposed drug in practice (generally summarised as “most likely to replace”).

The PBS has a highly developed and largely prescriptive process for evaluation of clinical effectiveness relative to the main comparator. This is feasible because there is usually a full data package of controlled clinical trials already in existence, as required for the global registration of a new medicine, and these trials usually include the main comparator.

However, although the PBAC Guidelines are aimed at a uniform approach, they do allow flexibility in interpretation under certain circumstances. For example, for orphan drugs, “the committee does not set a minimum standard for the type and level of evidence or other information that can be included in a submission to PBAC.” The PBAC Guidelines include sections on how to translate the evidence where the data are not standard, eg where indirect comparison is required, and where trials are non-randomised. Nevertheless, the Guidelines state²⁷:

“The interpretation of the results of such [non-randomised] studies is difficult, and expert epidemiological guidance will be helpful if data of this type are central to the submission.”

Guidelines for evaluating clinical data for new technologies must be generally far more flexible than for drugs as discussed in section 3.

5.2.5. Economic evaluation

As with the clinical evaluation, there is a highly sophisticated process defined in the Guidelines for the economic section of a PBAC submission. The evaluation is conducted within the Pharmaceutical Benefits Branch (PBB), and reviewed by the Economic Sub-Committee of the PBAC.

There are two steps in the process. Preliminary modelling must be conducted to “translate” the clinical trial data to the proposed clinical practice in Australia, including the likely length of treatment, and the choice of patient-relevant final outcomes of treatment.

A full economic evaluation is then conducted on the basis of the modelling outcomes, and various options are described, including cost-utility (preferred), cost effectiveness, cost-benefits, and cost-consequences analyses. The Guidelines provide extensive guidance on how to conduct such evaluations.

As with the clinical evaluation, the data for most new medical technologies are not sufficient to conduct economic evaluations to the same degree of detail, and once again the process for medical technologies must be more reliant on other modes of data gathering, such as informed expert clinical opinion. While the modelling does not change, the level of evidence that populates the model, and the number of assumptions made, do change.

²⁷ Department of Health and Ageing, *Guidelines for Preparing Submissions to the Pharmaceutical Benefits Advisory Committee*, (version 4.3) December 2008, 190

5.2.6. Financial implications

The applicant must estimate the likely usage of the new drug, and from that, with estimates of impact on the use of other drugs and treatments, estimate the financial implications for government health budgets.

5.2.7. PBAC consideration

The final recommendation on whether a new drug should be listed is made by PBAC. The Guidelines list²⁸ the factors that influence decision making by PBAC:

- Comparative cost-effectiveness
- Comparative health gain
- Patient affordability in the absence of PBS subsidy
- Financial implications for the PBS
- Financial implications for government health budgets.

The Guidelines also list factors that are less readily quantifiable:

- Uncertainty
- Equity
- Presence of effective alternatives
- Severity of medical condition treated
- Ability to target therapy with the proposed drug precisely and effectively to patients most likely to benefit
- Development of resistance (antimicrobials)
- Government health priorities and other relevant factors.

The Guidelines clearly state²⁹ the role of registration versus evaluation for reimbursement:

“Registration is based on assessment of quality, safety and efficacy, a process that usually involves the Australian Drug Evaluation Committee (ADEC). PBAC therefore accepts that products included on the ARTG have established safety and efficacy adequate to allow marketing in Australia.”

5.2.8. Risk sharing

The Guidelines request proposals for risk sharing arrangements (RSAs), (also known as price-volume agreements) where there is significant uncertainty in the potential usage of a new drug with regard to:

- Overall cost to the PBS
- Cost-effectiveness of use beyond any restrictions

²⁸ Ibid, Appendix 1 page 233

²⁹ Ibid, page 23

- Extent of overall gain in outcomes.

In these arrangements, typically the sponsor agrees to reduce the price for usage above an agreed level each year. It would be difficult to apply such RSAs in systems where there is more than one payer, as with private health insurance.

These arrangements are regularly reviewed (at 1, 2 and 5 years).

5.2.9. Industry consultation on the system

The PBS undertakes frequent consultation via the joint Department of Health and Ageing and Medicines Australia Access to Medicines Working Group. As an example, the implementation of the recent PBS reforms was conducted with industry involvement, and Medicines Australia was able to achieve an outcome more aligned to the interests of the research-based pharmaceutical manufacturers than in the original proposal.

5.2.10. Timeliness

While the time from application to listing is about 8 months, with three overlapping evaluation processes each year, an application typically takes much longer. On average submissions take 1.5-2 cycles to be approved. All dates, including intermediate stages, are set at least a year in advance.

5.2.11. Transparency

All outcomes are published on the website of the Department of Health and Ageing, and a “Public Summary Document” that summarises the data and PBAC’s reasons for its decisions. This level of transparency arose out of negotiations for the Australia/USA Free Trade Agreement.

5.2.12. Consultation

Planning meetings with the PBAC Secretariat for proposed applications are encouraged, and expert advice is given.

After submission, there are two stages of feedback to the sponsor, calling for commentary from the sponsor before proceeding to the next stage:

- Response to commentaries by the Pharmaceutical Evaluation Section – pre-subcommittee
- Response to PBAC on the sub-committee advice to PBAC.

There is also the opportunity to have a hearing (10 minutes) with the PBAC if an application has been rejected.

5.2.13. Resources: staffing and cost of evaluation

A feature of the PBAC process is the support provided through a full-time chairman and a well-resourced and professional staff. The Pharmaceutical Benefits Division is staffed with people very experienced in evaluation of the clinical and economic sections of a PBAC submission, and this is a costly resource. It is estimated that under the proposed full cost-recovery model, the fees for lodgement of a PBAC

submission for a new medicine would be \$119,500.00, with a further \$25,000.00 for pricing where a price premium is sought.

To have a similar system applying to the evaluation of new medical technologies would be prohibitive in many cases.

5.2.14. Future developments

PBAC continues to investigate options for improving the assessment of drugs. Two current initiatives in progress are:

- Assessing indirect comparisons, where direct comparative data do not exist
- A framework for evaluating surrogate measures and their use in submissions to the PBAC.

PBAC has recently issued reports for comment on both of these initiatives.

6. An optimal HTA process framework for Australia

6.1. Overview

MTAA proposes a redesigned body to undertake HTA of medical technologies. In proposing an architectural redesign, MTAA has also looked at the best features of the current arrangements for HTA and proposes that these be incorporated in the redesigned HTA body. The HTA functions undertaken by PDC would come within the operations of the HTA body so that the function of the PDC is limited to benefit setting on behalf of the private health insurance payers. PDC itself does not undertake any HTA assessment. MSAC is replaced by the new HTA entity which expands the current operations of MSAC. The HTA body will also assume the horizon scanning functions of a range of other bodies. The HTA body could also undertake health technology assessment for other agencies, such as the Department of Veteran's Affairs.

The redesigned body addresses key reform requirements anticipated by the Terms of Reference for this Review:

- Simplification of the system – MTAA proposes an independent HTA body which uses a risk- and principles-based assessment to determine priorities and level of health technology assessment, and the type of HTA tools that will be used
- Streamlining – linkage between market access bodies can be streamlined through a single entry point for applications and early consultation on evidence design requirements, to meet regulatory and HTA requirements
- Removal of duplication – by clearly defining and separating the roles of each of the three key agencies, TGA, the HTA body, and the payer body, the functions and responsibilities of each becomes clearer
- Improved governance – achieved through clearly articulated procedural mechanisms, collaborative communication, increased transparency, and accountability
- International harmonization – through the acceptance of overseas data, facilitation of Australian researchers into global research programs, and the use of overseas assessments, Australia will become networked into global

HTA processes. Not only does this enhance the HTA processes in Australia, but it also means that there are no unique rules in Australia.

Where a safety concern is identified after the product is in the marketplace, the safety concern should be referred back to the TGA. There would be improved understanding of the differing roles and functions of TGA and the HTA body if a TGA staff member worked as an observer within the HTA body. This would engender closer collaboration. One of the shortcomings of the current system is that neither MSAC nor PDC has much (if any) awareness of TGA's activities which gives rise to considerable duplication and second-guessing. Closer co-operation would assist in confidence building.

MTAA believes that there needs to be closer co-ordination between the proposed HTA body and PBAC when a hybrid or co-dependent technology is subject to HTA assessment, as discussed in the response to Term of Reference 5. This might be undertaken by a standing committee with representatives of both agencies.

The HTA body has the capacity to conduct a range of HTA depending on potential budget impact, health impact, disease burden, level of innovation and purpose of the assessment. The outcome of an assessment is used by the relevant funding or reimbursement body as the basis to negotiate or determine quantum of funding or reimbursement. Triage at entry determines the level of assessment required for a product. Where a product makes no claim of superiority it may be listed at the benchmark price for the relevant product group, subject only to confirmatory assessment that the grouping is correct.

Given the nature of medical technologies and the different analysis required in the HTA process, MTAA argues that there needs to be a higher level of flexibility and less prescription in the approach to evidence assessment. This is aided through mechanisms such as coverage with evidence development which is discussed further in section 6.5. The HTA body must have the flexibility to adopt the most up to date techniques, and to include innovative evidence generation techniques. It also requires a more flexible approach to cost-effectiveness analysis, recognizing that different evidence levels and assumptions may be used than for assessment of pharmaceuticals. The economic evaluation model is discussed in section 6.3.2 and explored further in the paper by Access Economics at Appendix 2.

In addition the HTA body can undertake a wider comparative and cost-effectiveness assessment to determine the cost benefit of broad-based, publicly-funded programs such as preventative health screening programs. The National Health and Hospitals Reform Commission has given consideration to what it describes as national health intervention which covers the "patchwork" of processes for assessment of new technology but which could also include allied health services, complementary medicine, and health promotion and prevention activities³⁰. The NHRC supports the concept of an "umbrella" approach to consistent national evaluation of a broad range of health interventions. MTAA supports the use of the proposed HTA body to undertake broader assessments, in particular the examination of health prevention strategies, particularly as many preventative health programs can be informed by, and supported by, the use of medical technology. Two examples of this are the use of bone densitometry screening to identify predisposition to osteoporosis, and the other, the use of bariatric surgery to address morbid obesity and the co-morbidities

³⁰ National Health and Hospitals Reform Commission, *A Healthier Future for all Australians – Interim Report* December 2008, 283

which are found with the condition, such as heart disease, type 2 diabetes, joint disease, and depression.

6.2. Structure of HTA model

MTAA proposes a single HTA body to serve multiple purposes. The diagram at Appendix 1 provides a simple overview of MTAA's proposal for an optimal HTA model and the framework within which it operates.

MTAA argues that the body with responsibility for HTA for medical technologies and procedures should be independent of government, and independent of the roles undertaken by TGA and by price setters and funders. Some of the activity required to ascertain safety and efficacy of a product to be listed on the ARTG may also inform the requirements for HTA assessment. However HTA should not itself be part of the regulatory review for the granting of listing on the ARTG. Regulatory review is based on objective and scientifically verifiable criteria of efficacy, safety and quality. It is relevant to note that PBAC, in assessing an application for listing of a pharmaceutical, accepts the safety and efficacy of products that are included on the ARTG, without further examination of these elements.

As pointed out by Drummond³¹ et al “the responsibility for implementing any recommendations is not normally the responsibility of the body conducting the HTA, unless the organization is itself a decision-maker (eg. a branch of the health ministry or a health insurer).”³² This reinforces the separation of functions with a range of other bodies implementing the assessment recommendations. In the case of the funders, it is essential to the strength and integrity of the model that the funder body is responsible only for reimbursement decisions, based on HTA outcomes.

An independent HTA body brings a broader perspective and can take account of the benefits and cost savings accruing to the health system for a new technology, something which a funder body is unable to do.

The outcomes of an HTA assessment can be used by funders to inform decision-making on payment:

- by private health insurance payers to determine the comparative level of payment for products reimbursed through the Prostheses List
- by public health payment bodies (Area Health Services or State purchasing departments) in determining selection of new/replacement technologies
- by the Medicare fee-setting body in determining the level of fee to be paid to a doctor for a procedure.

6.3. Role of HTA body

6.3.1. When is HTA required?

MTAA proposes that there be a priority-setting mechanism to determine which medical technologies require a comprehensive, or full, health technology assessment. Clearly the system will not become streamlined if it becomes over-burdened with requests for assessments that deliver no benefit to the healthcare system. Priorities for selection of technologies and procedures for assessment might be determined in accordance with the following principles-based criteria:

³¹ Drummond (2008) supra at page 244

³² Ibid at page 247

- Health impact: impact on health outcomes (mortality, morbidity, quality of life)
- Disease burden: population(s) affected; common health problems, with significant health/economical/social consequences
- Cost impact: short- and long-term impact on health system, patients and broader public sector resources
- Ethical and social implications: equity, fairness and access
- Clinical relevance: importance to clinical practice (to reduce variation)
- Assessment feasibility: availability of relevant evidence, time and resources required to complete assessment
- Degree of innovation: extent to which a technology addresses an area with few or no treatment alternatives (unmet clinical need)
- Policy relevance: to meet government priorities.

These principles will direct selection of technologies and procedures for a full HTA assessment. The principles are not dissimilar to the criteria which NICE uses to determine priority for selection of technologies for assessment, although NICE also takes into account such practical criteria as factors affecting timeliness and the likelihood of guidance having an impact.³³

There will also be many circumstances where a degree of review or assessment is required but at a lower level of complexity, principally to confirm manufacturer's evidence. An example of a simple confirmatory review is where an assessment is required to determine if like products ("me too products") have been appropriately grouped for reimbursement purposes.

The assessment might be an abridged assessment where more examination is required than the simple review referred to above, but the technology or procedure which is the subject of the application does not meet the principles-based criteria for a full assessment. In these circumstances an abridged HTA may be undertaken. Because of the high cost of assessment, low cost replacement technologies would not be included³⁴. An abridged HTA would be appropriate in circumstances where a claim is made for increased reimbursement because of superior benefits against a comparator product. In most cases this would not meet the criteria for a full assessment unless it falls within the principles outlined above.

Management of the application is streamlined through a single portal followed by triage to direct the level of assessment required of a product. MTAA strongly supports the use of pre-lodgement conferences, particularly where a full HTA will be required, to ensure that the applicant is properly briefed and aware of the requirements of both TGA and the HTA body. During the application process the applicant will identify in the first instance the HTA which it believes is required. The HTA body secretariat will provide a triage service to verify this assessment. These processes will require guidelines which are well-publicised to assist applicants to achieve the benefits of the streamlined arrangements. Guidelines are part of the toolkit to be developed with implementation of the revised scheme.

³³ See paragraph 5.1.1 supra

³⁴ Access Economics page 34

6.3.2. What does the HTA body examine?

In undertaking a full health technology assessment of medical technologies and procedures, the HTA body will examine:

- clinical effectiveness
- comparative effectiveness
- economic evaluations.

The assessment needs to be sufficiently broad-ranging to not be used simply as a price-capping mechanism. It needs to take account of a broad range of issues, including societal impacts. The analysis undertaken by Drummond et al to identify the key features of an optimal HTA system needs to be kept in mind. Drummond et al discuss the methods of HTA³⁵ and argue that there needs to be development and consistent implementation of rigorous, analytical methods to engender stakeholder and public trust in the process and findings. Drummond also argues that HTAs require use of data from experimental, quasi experimental, observational, and qualitative studies among multiple clinical, economic and social outcomes in clinically relevant populations.

An assessment of the risk of the product or procedure, and/or the cost, provides guidance as to the level of evidence that is required.

In addition to the technical assessment, the HTA body also undertakes a broader appraisal of other factors such as the legal, social and political considerations, canvassed by Drummond et al³⁶ in their discussion referred to above of key principles for the improved conduct of health technology assessment.

Clinical effectiveness

As discussed in section 3, there are significant differences between pharmaceuticals and medical technologies. One of the key differences is the scope and degree of clinical evidence available to the assessment body. While MTAA proposes that clinical evidence from clinical trials conducted in other countries should be used by the Australian HTA body, there remains a significant cost in developing the range of clinical evidence required to satisfy a full health technology assessment.

It is instructive to see that even in the assessment of pharmaceuticals, bodies such as NICE are beginning to question the extent to which traditional clinical trials can be required in every assessment because of the significant cost. Sir Michael Rawlins, in a recent monograph³⁷, makes the point that an average randomized clinical trial in the United Kingdom now costs £3,202,000. Sir Michael also advocates looking at other options, such as observational studies and patient experience, to add to the clinical information available to assessors.

These types of assessment are particularly relevant for medical technologies which are not able to make use of some types of clinical trial for ethical reasons. It is not ethical, for example, to use a double blind trial of an implantable technology. It is

³⁵ Drummond (2008) supra at page 250

³⁶ Ibid at page 244

³⁷ Rawlins MD. De Testimonio: on the evidence for decisions about the use of therapeutic interventions. *The Harveian Oration 2008* Royal College of Physicians 2008, 25

more appropriate to observe the impact of a product once in use with the patient and to record the outcome of the trial.

Observational studies, such as well-designed registries, can provide appropriate evidence on effectiveness and are a recognised alternative to RCTs. Depending on the nature of the device clinical data from non randomised studies such as cohort studies with, for example, historic controls, case-control studies or observational data from registries must also be taken into account when assessing clinical effectiveness³⁸. Clinical trials can also be an imperfect guide when examining the effects of interactions between multiple technologies, procedures and conditions.

The evaluation system needs to be flexible and take into account a broad range of factors including stakeholder involvement, evaluation of the totality of the evidence, and focusing on evidence that is relevant to the research question at hand. The level of evidence is a function of the risk/benefit of the technology or procedure. The HTA body could consider utilizing a sliding scale of evidence requirements as a function of risk assessment.

The position of the medical device industry is well illustrated by the following summary by Professor Black³⁹:

“For too long a false conflict has been created between those who advocate randomised trials in all situations and those who believe observational data provide sufficient evidence. Neither position is helpful. There is no such thing as the perfect method; each method has its strengths and weaknesses. The two approaches should be seen as complementary [...]. When trials cannot be conducted, well-designed observational methods offer an alternative to doing nothing. They also offer the opportunity to establish high external validity, something that is difficult to achieve in randomised trials.”

In support of this approach, MTAA argues that there is a greater role for conditional coverage with evidence development where the level of uncertainty remains high but where the technology offers significant promise, discussed further in section 6.5.

Comparative effectiveness

PBAC examines some of these elements – clinical effectiveness, cost effectiveness compared with other drugs already listed on the PBS for similar indications or with standard medical care where there is no comparable listed drug but does not compare different treatment modalities for clinical and cost effectiveness.

Full comparative effectiveness assessment across modalities of treatment can be expensive and would need to be considered within a principles-based framework to determine the circumstances when it should be undertaken.

HTA should address all relevant health technologies, including standard or commonly used interventions. Drummond et al argue⁴⁰ that if this is not the case then “[o]therwise policies and clinical practices ... will inevitably be distorted, with investment and practice gravitating toward those interventions that are free of evaluation, for which regulatory barriers are lower.”

³⁸ Ibid page 6

³⁹ Black. Why we need observational studies to evaluate the effectiveness of health care. BMJ 1996, 312 (7040) cited in Eucomed, supra page 6

⁴⁰ Drummond et al supra at page 250

To this MTAA would add that there is also a risk in Australia that the treatment solution for a particular condition is more likely to be determined by availability of public funding, for example, use of a pharmaceutical which is funded through the PBS, rather than a medical technology or procedure where the procedure may be funded through Medicare but the medical technology is unfunded. A good example of this is the treatment of atrial fibrillation, where the condition can be managed by a drug, but the surgical device, which has been shown to resolve the condition, is not reimbursed through the Prostheses List.

Economic evaluations

The Access Economics paper at Appendix 2 analyses the key requirements for an effective economic evaluation process for HTA. The proposed framework acknowledges the need for flexibility but at the same time underscores the need for a consistent methodological approach.

Access Economics takes a broad perspective in considering the scope of an economic evaluation. MTAA supports this position and the argument put by Drummond et al⁴¹ that a full societal perspective should be used. It is not sufficient to assess only the direct cost to the health care system. The Access Economics evaluation framework proposes a methodology for identifying costs and benefits that are both direct health care system costs and benefits, and broader.

Access Economics also discusses the problem of Type I and Type II errors which have resulted in the current HTA processes for medical technologies within MSAC denying a positive assessment to many beneficial technologies as first identified by O'Malley in her paper, discussed in section 4.3. The outcome of a Type II error is that a new health technology is assessed as not cost-effective when the opposite should have been the outcome, based on all observed and unobserved information. This means that society misses out on a social welfare improvement. Avoiding Type I errors at the expense of Type II errors trades-off social welfare improvements that could have been achieved with the avoidance of a reduction in social welfare. Because the traditional strategy has been to err on the side of caution, there is an implicit bias in the economic evaluation⁴². The proposed economic evaluation framework addresses this bias.

The economic evaluation framework proposes that a range of economic evaluation tools be available and outlines the circumstances in which a particular tool would be selected. The analysis also points out that an important point of differentiation between the evaluation of pharmaceuticals and medical technologies is in identification and measurement of benefits⁴³. Whereas the primary benefits of pharmaceuticals tend to be improved health outcomes, non-pharmaceutical health technologies can deliver more than just changes to health status. They can be grouped into improved health and other health care system benefits. Procedures and medical technologies deliver other economic and social benefits that should be incorporated within an economic evaluation.

⁴¹ Ibid page 252

⁴² Access Economics supra page 46

⁴³ Ibid page 48

A simplified case study demonstrating cost-effectiveness assessment of an emerging technology follows⁴⁴:

Case Study 6

Cost-effectiveness assessment of an emerging technology

OBJECTIVES: Over these first 8 years of MSAC's operations, a significant number of applications for the public funding of new procedures have been given negative recommendations by MSAC based on insufficient clinical evidence or lack of cost-effectiveness. In August 2006, after almost 2 years of processing, the MSAC made the decision to fund the new procedure, laparoscopic remotely assisted radical prostatectomy (LRARP). However, they stated that there was still uncertainty about the comparative cost-effectiveness.

METHODS: An observational study using provisional cost-utility data for LRARP based on a combination of costs taken from consecutive patients at the Epworth Hospital, Melbourne, Australia, and utilities from the prospectively collected data on all patients undergoing surgery for prostate cancer over a 4-year period at the Vattikuti Urology Institute, Michigan, United States.

RESULTS: The incremental cost for LRARP compared with the open surgery alternative is A\$2,264 or A\$24,457 per quality-adjusted life-year, well below the range accepted by PBAC of A\$42,000 and A\$76,000. This figure does not take into account additional benefits such as reduced time away from employment, reduced blood loss, reduced possibility of infection, and reduced scarring.

CONCLUSIONS: This case study of LRARP demonstrates that there is sufficient crude evidence to show that this new procedure is likely to be superior to the existing procedure in terms of safety, effectiveness, and cost-effectiveness. The decision to allow MBS funding was correct and will allow for the collection of additional evidence, on both economic and clinical outcomes.

The economic evaluation framework needs to also consider costs which Access Economics⁴⁵ separates into direct health care system costs and indirect costs associated with treatment and the condition. There is also an opportunity cost in shifting resources away from additional areas of the health care system or economy.

6.4. Operations of HTA body

MTAA argues that the HTA body must be properly representative of all stakeholders with a transparent and accountable governance framework. Among the most compelling reasons for review of the current HTA processes is the failure (and at times total absence) of good governance arrangements. These not only reduce confidence of all participants in the process in the capacity of the system to achieve a fair and equitable outcome, but can actively undermine efforts to ensure accountability.

⁴⁴ O'Malley SP, Jordan E. Review of a decision by the Medical Services Advisory Committee based on health technology assessment of an emerging technology: the case for remotely assisted radical prostatectomy. *Int J Technol Assess Health Care*. 2007 Spring; 23(2): 286-291

⁴⁵ *Supra* page 52

6.4.1. Who is on the HTA body?

The governing body of the HTA agency is drawn from knowledgeable people who are not necessarily experts in the field of HTA but may include health economists. The governing body should include representatives of the major stakeholders – clinicians, patients, healthcare industry (including hospital representatives), payers, and industry. MTAA supports a health technology assessment process that considers in an appropriate way all relevant stakeholders. The involvement of all stakeholders adds legitimacy to the decision-making process and acceptance of the outcomes.

The governing body is chaired by a full-time, independent person, and supported by an experienced and qualified secretariat. MTAA proposes that expert assessments are undertaken by contracted specialists. In addition there are specialist sub-committees of the HTA body which can draw on experts as needed for specific assessments.

MTAA does not have a solution to the dilemma of calling on the time and expertise of clinicians who are already busy practitioners (and they need to be if they are to be current in their knowledge of relevant procedures and technologies). MTAA supports a system that provides good reach into the clinician specialties to ensure sufficient depth of expertise. The clinicians need to be appropriately qualified and experienced subject matter experts in both the technology and the HTA process. In support of improved transparency the identity of the clinicians should also be made public so that an applicant can have confidence in the experience brought to bear by the clinician. If such openness is not supported by clinician groups then at the very least the qualifications and experience of the clinician must be disclosed.

MTAA recognizes that there will be clinicians who have a conflict of interest from time to time but these can be managed through appropriate disclosure, and potentially non-participation, where a clinician receives a personal benefit from an applicant.

There is also the opportunity to draw on the expertise and experience of clinical assessors outside Australia, particularly where the technology is cutting edge and there may not be an appropriately experienced assessor in Australia. Another source of relevant evidence is the manufacturer itself. While MTAA acknowledges that there may be some who choose to dismiss manufacturer evidence, at times it is the most up to date and rigorous. The pros and cons of using manufacturer evidence, as with other third party assessment bodies, is well-canvassed by Barbieri et al⁴⁶. Barbieri et al suggest⁴⁷ that different healthcare systems could fund and commission third-party assessments collaboratively, although decision-making would remain with each country.

6.4.2. Who can make applications?

At present applications for assessment by MSAC can be made by a clinician, a company, or a professional clinical body. MTAA proposes that the source of applications should remain broadly-based and may include other bodies such as government, particularly where the assessment is for a large-scale screening program or other considerable investment of public funds. The HTA body should be

⁴⁶ Barbieri M, Hawkins N, Sculpher M. Who Does the Numbers? The Role of Third-Party Technology Assessment to Inform Health Systems' Decision-Making about the Funding of Health Technologies. *Value in Health* 12:2 (2009), 193-201

⁴⁷ Ibid page 196

able to receive and consider applications from a wide range of sources, subject to selection of technologies and procedures guided by the principles discussed in section 6.3.1.

6.4.3. Who pays for the application?

With a move to increased cost recovery by government there will inevitably arise a discussion of cost recovery by the HTA body. However this is not as straight-forward as for applications to PBAC where it is the applicant that derives the direct commercial benefit from approval and listing of a drug on the PBS. While a medical technology company will also benefit from a positive assessment, there is no comparable automatic funding of the technology. If it is a technology that is part of a procedure, such as provision of a pathology service or radiology service, there is a payment made by the service provider, albeit remotely from the MBS listing. There is also payment to the clinician.

If the technology is an implantable device there is reimbursement by the private health insurance system where the product is listed on the Prostheses List. However there is no reimbursement otherwise for a technology with the result that there is no immediate commercial benefit available to the applicant.

The situation becomes even more complicated where an application is made by a clinician or clinical professional body. It is the clinician who will receive the MBS fee arising from a positive assessment but it is unlikely that a clinician would be willing to fund the application on a cost recovery basis.

The cost of assessing the application is, of course, in addition to the cost of preparation of a submission by the company which can be considerable.

In Canada, CADTH pays the cost of the HTA assessment. MTAA proposes that the cost of a full HTA assessment also be funded in Australia by government, subject to the application of strict selection criteria to ensure that full assessment is carried out against agreed criteria, such as the principles discussed in section 6.3.1.

In contrast, if an applicant pays the cost of an abridged HTA application then cost recovery guidelines should apply with a service charter and clear accountability to the applicant for provision of a service against known KPIs, including timeframes. These are discussed further in section 6.4.5.

Consideration might be given to a cost-sharing arrangement, with cost allocated in line with where any incentive is received.

6.4.4. How is an application lodged?

MTAA proposes that there be one entry point for the lodgement of applications with contemporaneous and parallel consideration by multiple bodies – regulatory with TGA, health technology assessment with the HTA body, and for reimbursement assessment by the reimbursement or funding body. This does not mean that the submission or set of documentation required by each body is the same, or that the outcome of the application for each purpose would be determined simultaneously. MTAA accepts that listing of a product on the ARTG is required before finalization of any assessment decision or reimbursement decision but this still accommodates simultaneous application. The process will be more efficient, particularly where the product already has FDA approval or a CE mark.

MTAA also proposes that there be an active engagement with an applicant in advance of the lodgement of the application, particularly where the technology will require a full HTA. One of the features of the NICE system that appears to be effective is the scoping which is undertaken collaboratively between the applicant and the assessment body before an application is lodged. The scoping meeting assists in informing the applicant and the assessment body on the evidence required to support the particular application. It also addresses the scope of the review, and the comparators which are to be used.

MSAC currently offers a pre-lodgement meeting, however none of these issues is addressed.

6.4.5. What are the key performance indicators?

The key performance indicators should be directed to a more efficient processing of applications and an improved transparency of process. Some of these features are already present in current HTA systems and should be retained. The best features are those that deal with the process from regulation, through health technology assessment to reimbursement, as an iterative, rolling process which moves smoothly from one stage to the next with requirements clearly understood and communicated.

The key performance indicators that MTAA expects from an optimal HTA system include:

- Specific points at which there is interaction between the HTA agency and the applicant. These might include prior to lodgement (as discussed above), at the time of submission of an application, during review of the application (eg. to enable the applicant to present on the content of the application), and in providing feedback on the outcome of an application (both positive and negative). If there is a conditional approval then consultation with the applicant is highly relevant to ensure that the applicant understands the evidence required, how it is to be developed, and who pays for the evidence development and collection
- Efficient process for appointment of expert reviewers
- Timelines with a set timetable including lodgement, reporting back following lodgement, assessment, reporting back from assessment, response to review requests
- Reporting on assessment meetings held and the outcome of the assessment.

6.4.6. Transparency of process

Drummond et al⁴⁸ state quite simply the case for good governance in the HTA process. “Inherent to HTA is that multiple parties (including payers, manufacturers, patients, healthcare professionals, healthcare institutions, and the general public) have an interest in the results. Therefore, if HTA is to be widely accepted, it needs to be unbiased and transparent in perception as well as in fact.”

MTAA strongly supports this position. To ensure that the HTA process is transparent and unbiased it must have the following characteristics:

⁴⁸ Drummond (2008) supra at page 248

- Independence from government – either as a statutory body or similar, with the capacity to engage relevant expertise on an independent and transparent basis
- Inclusive process with representation of all stakeholders, including payers, manufacturers, patient representatives, healthcare professionals, healthcare institutions, and the general public. Use of individuals with domain expertise in subcommittees and similar bodies
- Timely decision-making with fixed time periods within which specific steps are to be taken and outcomes achieved. This is an area where PBAC performs well with dates notified publicly well in advance
- Transparent decision-making, although transparency may need to have two levels – open disclosure for clinical assessment and moderated for economic assessment where there is a need to protect proprietary or competitively sensitive information. Drummond et al comment⁴⁹ that while almost all HTA bodies encourage manufacturers and other relevant bodies to provide relevant information and data, most do not have a formal mechanism for interested parties to review and critique draft analyses and recommendations before their final determination. To do so would “increase transparency and perception of independence and objectivity, thereby building acceptance of the process among stakeholders and improving HTA content and accuracy.”
- Publication of agendas and minutes of meetings of the HTA body and, subject to the comments above, publication of reports of outcomes from applications. Transparency and stakeholder engagement would also be further enhanced by publication of draft reports for public comment (as is the case with CMS in the US)
- Reviewable decision-making – where an affected party may appeal the decision on the basis of error of fact or incorrect determination. NICE provides for appeals from decisions⁵⁰
- Full disclosure of potential conflicts of interest by assessors contracted to advise the HTA body.

MTAA recognises that if the HTA body is an independent statutory body its decisions will be subject to the application of administrative law. The review mechanisms will need to be considered in this context as it will be counter-productive to implement a system which may become subject to an expensive legal process. The review mechanisms should be built into the administrative or statutory framework.

6.5. Coverage with evidence development

Coverage with evidence development is a solution in cases where there is uncertainty related to the expected benefit and where the therapy shows significant potential. In collecting the evidence however, there are a number of issues that need to be resolved. Foremost of these issues is defining the research question, ensuring the data are collected within a meaningful timeframe, and the funding of the cost of the data collection.

As Hutton points out⁵¹, coverage with evidence development (CED) “differs from traditional postmarketing evidence generation in that the objective of the additional

⁴⁹ Ibid page 249

⁵⁰ See section 5.1.2

evidence generation is to reduce uncertainty around a specific aspect of the evidence base and, thus, help to inform further decisions about ongoing coverage, often at predetermined points in the future.”

CED is used extensively by the Centers for Medicare and Medicaid Services (CMS) in the United States. CMS issued guidance in 2005, revised in 2006, to describe when CED should be applied and how it should operate. CMS has made available some promising technologies with an equivocal evidence base on the grounds that the technologies are only used in clinical trials or as part of a registry to help provide further evidence on their effectiveness.

MSAC already has the capacity to recommend interim funding to enable data collection within an agreed research framework, in order to establish the evidence base. However the system as it operates now is limited.

There are both advantages and disadvantages to CED for all stakeholders – healthcare decision-makers, healthcare providers, manufacturers and patients. While there is an advantage in making a promising technology available to patients earlier than might otherwise be the case, healthcare decision-makers are faced with the extra demands of agreeing the study design and monitoring and reviewing the data collected. The disadvantage for the manufacturer is the cost of bearing the burden of proof and the concern that a CED option may make decision-makers more inclined to demand further evidence for technologies which would otherwise not require additional data⁵². This is clearly in evidence in the case study of the SIR-Spheres technology discussed in section 4.3.10.

Hutton et al propose⁵³ that CED is best suited in circumstances “where there are reasonable grounds for believing that a technology will offer significant benefits but there is uncertainty around the clinical or cost-effectiveness of the technology that can be overcome through evidence that can be generated in an appropriate time frame and is the main source of equivocality in a coverage decision”.

6.6. Adaptation of global HTA to Australia

Hutton et al⁵⁴ suggest a range of possible benefits from harmonization of HTA which can be grouped into two broad areas: more efficient use of analytical resources; and faster and more appropriate reimbursement decisions. “The extent to which harmonization of evidence requirements in HTA can generate benefits is related to the contextual nature of the evidence. HTA is used to inform decisions in the context of the local healthcare system, and different inputs into HTA may be more or less context-specific”⁵⁵. Where evidence from international clinical trials might be context-free, simply copying data from one country to another without contextual analysis, can carry risk.

Hutton et al argue⁵⁶ in favour of harmonization of evidence requirement, stating that manufacturers would be better able to plan evidence generation activities. It could

⁵¹ Hutton J, Trueman P, Henshall C. Coverage with Evidence Development: An examination of conceptual and policy issues. *International Journal of Technology Assessment in Health Care*, 23:4 (2007), 425, at 426

⁵² Ibid at page 427

⁵³ Ibid at page 428

⁵⁴ Hutton J, Trueman P, Facey K. Harmonization of evidence requirements for health technology assessment in reimbursement decision making. *International Journal of Technology Assessment in Health Care*, 24:4 (2008), 511, at 512

⁵⁵ Ibid

⁵⁶ Ibid at 513

also lead to higher quality data if resources could be concentrated on fewer, high quality studies.

One of the side benefits for Australian researchers is that Australian sites could be used in wider global clinical trials if Australia develops a more robust and respected HTA body. This is a benefit for Australian clinical research, drawing on the capability of Australia's health and medical research institutions.

6.7. Horizon scanning

Horizon scanning can be used for multiple purposes in anticipating and preparing for future needs. It should be used as a tool to facilitate health system planning and aid health technology assessment, not to block the introduction of emerging technologies on the basis of perceived cost.

A key function of horizon scanning is to provide advice to government on the implications for the current system of the introduction of a new technology. Some technologies will alter a patient's journey or the way the technology interacts with the health system. A good example of this is the emerging use of tele-medicine which enables remote specialist consultation. Similarly further advances in remote device monitoring, and in the future, activation and programming, will change the need for clinics in rural locations. However to enable these technologies to be taken up, the Australian Communications and Media Authority has to approve the frequencies to be used. Utility providers need to change data and privacy protection measures. Effective horizon scanning would identify these overlapping regulatory hurdles and recommend that government agencies work together to respond to the challenges presented by technology which delivers benefits not only to the patient but to the healthcare system.

Other useful purposes of horizon scanning include:

- To identify changing patterns of disease – epidemiological, environmental, demographic
- To anticipate new product development based on upstream discoveries.

Australia already has multiple horizon scanning bodies⁵⁷. While these play an important role in informing various entities about future developments, and the impact those developments may have on current assessment activities, there is a strong argument to have all horizon scanning undertaken in one entity which can build up expertise and act as the national reference point. Diffusion of skills and capabilities across multiple bodies weakens Australia's horizon scanning capacity.

6.8. Monitoring of HTA implementation

MTAA argues that the outcome of an assessment should be directive for those that then need to rely on the assessment for funding purposes. This means, for example, that the PDC would rely on an assessment outcome to then determine a reimbursement level for a technology and not move to reassess it, either on a stand-alone basis, or against another product.

The purpose of building HTA capability in one body is to make a more effective use of scarce resources (such as availability of specialist clinicians), and also to ensure that the skill base is developed through experience built up in one entity.

⁵⁷ See discussion at section 4.5

MTAA notes that while NICE assessments are advisory and not binding, there is a move in England to impose some discipline in using NICE assessments. The Healthcare Commission in exercising its statutory duty to assess the performance of healthcare organisations, and award annual performance ratings for the NHS, sets standards by which each NHS organisation is measured and assessed. The Healthcare Commission has the ability to mark down a hospital in its performance rating if it is not demonstrating adherence to NICE guidance⁵⁸.

This analogy is relevant for State health purchasing entities which should also have regard to the outcome of health technology assessments in deciding on resource allocation, for much the same reason as the Healthcare Commission sees this assessment as validation of technology selection.

It follows that the HTA body must have the ability to follow up on implementation of its assessment recommendations. MTAA does not have a firm view on the way in which this could be implemented but notes that Drummond et al view the requirement for implementation of HTA as one of the key features of a good HTA system⁵⁹. Drummond argues that HTA findings need to be monitored to ensure that the original investment in conducting the HTA is valuable. He also argues that this is especially the case in jurisdictions where the HTA is performed to help guide a particular decision.

MTAA supports this position given that an assessment in Australia is used to inform decisions on reimbursement and other funding.

The second reason why it is relevant to monitor the implementation of HTA is to follow up on clinical impact and validity over time as a quality control measure. This will also feed into the cycle for ongoing assessment and feedback through the use of facilities such as registries which are discussed further in section 10.

7. Reforms to reimbursement processes

7.1. Background

The Terms of Reference address the overlapping nature of current processes for health technology assessment. However there is an additional component to the current system that requires separate examination as part of the overall review of HTA. In MTAA's model, HTA is separate from the reimbursement process. However the outcome of the health technology assessment will be used to inform reimbursement and other funding decisions as discussed above. This then leads to consideration of the current reimbursement and funding arrangements to align reform of the HTA process with reform of the reimbursement processes.

The key areas for reform are:

- The process for reimbursement of medical technologies listed on the Protheses List by the private insurance payers
- The mechanisms by which technologies are grouped and funded through Diagnosis-Related Groups
- The methodology for funding of pathology services and radiology services.

⁵⁸ See discussion at section 5.1.3

⁵⁹ Drummond (2008) at page 254

This section proposes reforms for each of the first two reimbursement areas in the context of a redesigned HTA system. In late 2008 MTAA made submissions to the Department of Health and Ageing for its reviews of the current arrangements for the funding of pathology services and diagnostic imaging⁶⁰.

The processes for reimbursement of products listed on the Prostheses List are overdue for reform. The current processes are too slow, too unwieldy, and lacking in transparency and accountability. There is a lack of clarity about the role of the PDC and its related bodies. The current arrangements also do not take account of the rapid but often iterative evolution of technologies. Many of these criticisms were made by Robert Doyle in his extensive review of the Prostheses List arrangements, discussed in section 4.4. One of the outcomes of an improved, and simplified, HTA process for medical technologies should be an improved, simplified and streamlined reimbursement process.

There is another funding issue which MTAA considers should be addressed in the broader context of healthcare system reform which is outside the scope of this review but which properly should be dealt with if the full benefit of a redesigned HTA system is to be achieved. The funding mechanisms at present give no recognition to the benefit of investment in one sector of the healthcare system which does not benefit that sector but does deliver benefit, generally through cost-savings, to another sector.

This outcome is derived in part from Australia's dual healthcare system. However there is benefit in recognising the shifting cost benefits through a process of cost equalization. MTAA would like to see further work undertaken on this issue.

7.2. Prostheses List reforms

7.2.1. Simplifying the reimbursement function

MTAA has proposed a stand-alone HTA body which draws together the HTA functions currently undertaken by MSAC and PDC and its committees. The reimbursement function is therefore separated from the HTA function. Once assessed by the HTA body, reimbursement is determined and subject to favourable and concurrent assessment by the TGA, the product is available through the reimbursement list.

Put at its simplest, where a product is brought to the market claiming equivalence with another product already in the market (a "me too" product), the HTA body simply confirms the product grouping, after which no further HTA is required. The product is then listed for reimbursement with its comparator products at the prevailing benchmark rate. This is consistent with one of the recommendations of Robert Doyle that products which claim the same benefit as a comparator product be listed without further review⁶¹.

Where a supplier is seeking a premium price for a product based on claims of superior clinical performance, and has established that claim to the satisfaction of the HTA body, the product is then listed at the benchmark rate plus a premium, the

⁶⁰ MTAA's submissions can be accessed via its website at the following links:
<http://www.mtaa.org.au/pages/images/Department%20of%20Health%20Review%20of%20Funding%20of%20Diagnostic%20Imaging%20Sept%202008.pdf>;
<http://www.mtaa.org.au/pages/images/Department%20of%20Health%20review%20of%20funding%20of%20pathology%20services%20November%202008.pdf>

⁶¹ Doyle Report supra recommendation 10

quantum of which is negotiated by the supplier with an independent negotiator. The current system adopted by the PDC of attaching a suffix to denote superior clinical performance might remain an appropriate mechanism.

A similar arrangement will apply where the product is a new market entrant, whether or not subject to a full HTA. The supplier will negotiate the reimbursement amount which should reflect the market cost of the product.

7.2.2. Processes

Currently the PL is determined and published twice per year which means that the minimum time for successful applications to be processed through to reimbursement entitlement is six months. A longer period applies if product registration does not align with the PL schedule and the sponsor must wait for the next application cycle.

In the proposed simplified system for reimbursement, there is no reason why applications could not be reviewed on a rolling basis as and when they are lodged, as is the case with TGA. With a significantly reduced workload, an application can be processed on receipt and not held for processing at two specific times each year. Doyle commented⁶² that a system of rolling applications and three lists each year would be sustainable.

The process will be considerably shortened if the PDC and its associated committees restrict their attention to negotiation of the benefit to be reimbursed.

7.2.3. Product eligibility

One of the most significant shortcomings of the current Prostheses List is its inflexibility in accommodating emerging technologies. There are many newer technologies that remain unfunded, to the detriment of patients, because they do not come within the technical definition of an implantable prosthesis. There are many examples of these types of technologies which, although available in the public health system, are not available in the private health system because they fall outside the criteria for listing and therefore reimbursement.

The Minister for Health and Ageing has made an exception in the case of insulin pumps and cardiac loop recorders. MTAA argues that product eligibility should be expanded to include other high technology devices that also provide valuable health outcomes. MTAA proposes that the most effective way to review the current arrangements is to broaden the criteria for products to be listed in Part C of the Prostheses List, within clear parameters to ensure that the products meet the revised criteria. A revised Prostheses List could be known as the High Technology List to better reflect its broader coverage.

The assessments required to establish that a product meets the criteria for listing under Part C would be undertaken by the HTA body.

Proposed criteria for listing a product on an expanded Part C of the Prostheses List are as follows:

'Must' criteria:

⁶² Doyle Report supra page 14

- The product must be included on the ARTG or the manufacturer approved by the TGA
- The product must be used on a person as part of an episode of hospital treatment or hospital-substitute treatment; and
- A Medicare benefit must be payable in respect of the professional service associated with the use of the product

‘Should’ criteria:

- The product should:
 - be used on the patient and be purposely designed in order to:
 - replace an anatomical body part; or
 - combat a pathological process; or
 - modulate a physiological process;
 or
 - be essential to and specifically designed as an integral single-use aid necessary to support the surgical use of the product, as described above, which is only suitable for use with the patient in whom that product is used;
 or
 - be critical to the continuing function of a surgically implanted product to achieve the requirements above and which is only suitable for use by the patient in whom that product is used;
 and
- The product has been compared to alternate products on the Prostheses List or alternate treatments and assessed by the HTA body as being, at least, of similar clinical effectiveness⁶³.

7.2.4. Appeals

Under current arrangements, decisions are subject to an internal departmental review in the event the sponsor believes that an error of process has occurred. Errors invariably take until the next Prostheses List to be corrected. There is no appeal against decisions based on “merit”. Sponsors may correspond with the PDC requesting review of clinical decisions but the review is usually performed by the original decision makers.

Under a reformed Prostheses List process there would be an independent review mechanism where the applicant disputes the basis on which the reimbursement has been set. The reviewer should look only at the basis on which a particular reimbursement level was fixed.

Errors should be avoidable if the PDC issued clear guidelines on the reimbursement setting process and the considerations it takes into account in negotiating the reimbursement amount. Guidelines should initially be provided in draft for review and comment by stakeholders to ensure that the proposed procedures are optimal from a practical point of view. A collaborative approach will ensure a better outcome for the funding bodies and stakeholders alike.

⁶³ It is envisaged that proof of substantial clinical equivalence would satisfy this requirement.

7.2.5. Gaps

Suppliers would prefer to list products without the need to have patient copayments, that is, they would prefer that the result of benefit negotiations was agreement on a minimum benefit amount rather than disagreement resulting in a maximum benefit and a patient liability to pay a gap. The first Prostheses Lists contained 111 gapped items or 1.2% of listings whereas the February 2009 List contained 1,755 gapped items or 18.5% of listings.

Suppliers would prefer to retain the option of listing a product with a gap for flexibility so that prices can be adjusted if necessary between a minimum and a maximum price to accommodate factors outside the control of the manufacturer, such as an increase in manufacturing costs.

7.2.6. Product review

The Prostheses List of February 2009 has 9,492 product listings. In the listing cycle leading up to the February 2009 List, the PDC recommended 4,342 changes to details in the preceding list. This reflects an immense workload which places stress on the PDC, CAGs and panel clinicians, as well as the Prostheses Secretariat.

Once listed on the Prostheses List a product should be reviewed by exception only, that is, where the sponsors of products in a grouping or the PDC can show that there have been significant and material market changes that call for a review of the pricing structure. A product should also be reviewed where the sponsor has established a claim of clinical superiority through the HTA body.

A form of benefit indexation should be applied for all products on the PL which would also remove the need for many requests for review. MTAA is conscious of not building in an automatic inflation factor and would like to explore this issue further with government and the private health insurers.

7.2.7. Benefit negotiations

The current negotiation process lacks transparency and is negotiation in name only. Doyle noted that the negotiation process is really a price-setting process⁶⁴. The PDC is extremely reliant on the negotiators to fairly calculate benefits because its ability as a committee to scrutinize all benefit proposals is extremely limited. Members of the PDNG are recruited and employed by the health funds through their industry association.

MTAA is strongly of the view that, consistent with principles of transparency and fairness, any perception of bias would and should be removed by the appointment and employment of independent negotiators. The negotiators should be individuals qualified to work with sponsors to determine appropriate market rates for reimbursement. Benefit negotiations must be conducted in an open manner with reasons offered for any reduction in benefit amount. The use of generic explanations is unacceptable.

⁶⁴ Doyle Report supra page 25

7.2.8. Cost recovery

On 2 February 2009 the Department of Health and Ageing notified sponsors of significant increases to application and listing fees. The table below shows the increased amounts and percentages.

Fee	Previous Fee	New fee	% increase
Ongoing & initial listing	\$110	\$200	82%
New application	\$400	\$600	50%
Internal review of errors	\$40	\$1,000	2,400%

MTAA acknowledges the need on the part of the Department for cost recovery but argues that there should be a service provided in exchange for fees paid in accordance with a service charter. Furthermore, the fee payable for a review of a decision should be refundable in circumstances where the appeal is upheld.

7.2.9. Strengths of the current process

The greatest strengths of the Prostheses List process are that it provides predictability of reimbursement and manages reimbursement arrangements on behalf of multiple private payers. This acts as positive reinforcement for individuals and families to retain membership of health funds as it enables clinicians on behalf of a patient to select the most clinically appropriate device (although this feature is being eroded by the growth in the proportion of gapped products on the Prostheses List). These strengths should be retained.

7.3. Australian Refined Diagnosis Related Groups (AR DRGs)

7.3.1. Executive summary

AR DRGs underpin the measurement, planning, budgeting and negotiation for payment of the delivery of inpatient healthcare services in Australia.

The development of AR DRGs is complex and slow, and does not adequately keep up with the pace of change in medical technology and innovation. Equally the measurement of costs is based on significantly lagging information.

This lag in development of funding for technology may result in poorer outcomes overall for both patients and for the bigger picture of health funding, when technology that has been deemed to be cost effective after an HTA process is delayed by potentially many years whilst DRGs are developed, and then budgets and hospital contracts are negotiated. During this time the technology in question may well be superseded, and more importantly patients continue to be treated using less effective technologies.

Australian patients and the Australian health care system will be the beneficiaries when the systemic delays and costs outlined in this submission are addressed.

MTAA recommends that the HTA body, having reviewed a technology and made a positive assessment decision on cost effectiveness be able to trigger the development or modification of any related DRGs so as to actively reflect in a timely manner the costs associated with that technology.

7.3.2. Definition

Australian Refined Diagnosis Related Groups (AR DRGs) is an Australian admitted patient classification system which provides a clinically meaningful way of relating the number and type of patients treated in a hospital (that is, its casemix) to the resources required by the hospital. Each AR-DRG represents a class of patients with similar clinical conditions requiring similar hospital services. The classification categorises acute admitted patient episodes of care into groups with similar conditions and similar usage of hospital resources, using information in the hospital morbidity record such as the diagnoses, procedures and demographic characteristics of the patient.

The AR DRG classification is separated into 23 Major Diagnostic Categories (MDCs) and further categorised into medical, surgical and other groupings. AR DRG assignment is also influenced by procedures, medical conditions and other factors that differentiate processes of care.

7.3.3. Australian Coding Classification Centre

The National Centre for Classification in Health (NCCH)⁶⁵, under contracting arrangements with the Department of Health and Ageing, produces the Australian Coding Classification (first component of the System). This Coding Classification is utilised in public and private facilities for the production of statistical data and to support funding submissions to the Australian Institute of Health and Welfare (AIHW) and the Department.

Using as a base the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10), published by World Health Organisation (WHO), the NCCH provides Australian modification (ICD-10-AM) for the diagnoses codes. These are 4th and 5th digit levels providing extra specificity to some areas where clinicians would like to differentiate particular conditions. The Centre also creates a list of procedure codes:

- The Australian Classification of Health Interventions (ACHI) based on the Medicare Benefits Scheme with further expansion to meet clinical requirements.
- The Australian Coding Standards (ACS) based on the work undertaken by the Coding Standards Advisory Committee. Australian Coding Standards are created with the objective of sound coding convention according to the Australian Coding Classification and to ensure accurate coding practice. The Standards explain how the analysis of the entire clinical record should be performed before code assignment.

Australian Coding Classification provides documentation, code assignment, and reporting of diagnoses and procedures at the national level.

Using the Coding Classification, the Department of Health and Ageing maintains the AR DRG Classification and the Definitions Manual. Each DRG of the system consists of the diagnoses and/or procedure codes which define it.

⁶⁵ National Centre for Classification in Health. NCCH ICD-10-AM. Retrieved 13 April 2009 from http://nis-web.fhs.usyd.edu.au/ncch_new/2.aspx.

To ensure that DRGs remain valid over time and continue to reflect changes to medical, surgical and coding practices, the Department provides resources for clinical consultation and statistical analyses.

The AR DRG Classification System is updated every two years to reflect the latest technology and medical practice, and to ensure that the new procedures and techniques are incorporated into the Classification as rapidly as possible. Each release of the Classification investigates both statistical and clinical effects.

7.3.4. Uses for AR DRGs

In the public system all States with the exception of NSW use a DRG based casemix funding model, although the application and weightings differ significantly across the states.

Victoria which was the first user and has the most sophisticated DRG based system measured the average cost per patient across all DRGs and gives this a WIES (weighted inlier equivalent separation) weight of 1. All DRGs are then weighted in reference to this average eg a very small cheap procedure may attract a weight of 0.3, whilst a neonatal intensive care admission may attract a weight of 40+. This can then be modified for outlier patients by using “trim points”.

These DRGs are then used for setting budgets for hospitals based on historical casemix and projected casemix. All states have a hospital level capping of budgets, however for some this is an absolute cap, for others there are methods to top up payments if a particular DRG is over represented. Some states exclude the fixed costs component from their case mix payments and only pay on variable costs and some states include both fixed and variable. All states have some separate funding models outside of the DRG/Casemix for some specialised areas of care. It appears that for most uses of DRGs the funding and weighting does not happen upfront when the DRG is created or modified. Effectively what happens is that a “bucket” is created for collecting information about the usage and costs associated with that DRG and over time the information is analysed and the DRG is then weighted.

There does also appear to be a mechanism to use DRG data to refer a particular area to the Australian Institute of Health and Welfare (AIHW) for and HTA style assessment for recommendations to make public funding available. Although it is unclear in the readily accessible literature whether this occurs and how the decisions of AIHW bind governments and payers if at all.

In the private system there has been an evolution over time from per diem type payments for hospitalization towards a DRG based casemix episodic payment. These are individually negotiated between health funds and hospitals and are varied in their weightings, payments and application, however the DRG system is used as the initial basis for the negotiations. There is an additional lag here though as there is the initial lag as DRGs are evaluated and incorporated into the system, and then there is a lag as each fund/hospital agreement comes due for renegotiation. In the private system the CEP payments currently exclude separately reimbursed components such as prostheses, physician fees, rehabilitation etc.

7.3.5. Discussion

Funding of hospital care in Australia is exceedingly complex and there are multiple modalities for budgeting for, funding and measuring hospital care. DRGs and the multiple versions of DRGs (AR DRG, AN DRG, Vic DRG) are one significant method

by which a large proportion of hospital funding is derived. However the use and application is varied across states, and across health funds in the private system. Casemix funding based on DRGs is widely used in both the public and private sector in Australia however it is used in varying ways. This analysis is necessarily extremely simplified.

AR DRGs are updated every two years, with every third edition being a major update and the two intervening being minor updates. The last release was AR DRG Version 6.0 in 2008 which was a major update. However it is interesting to note that patient level cost data for financial years 2003-04 and 2004-05 was the latest available data for use in developing the weights.

Recommendations for version 6.0, with associated data analysis reports, clinical advice and proposed changes, were presented at the Clinical Casemix Committee meeting, and the State and Territory meeting for discussion and comment. After considering the comments from the meetings, the Department then finalised all the recommendations.

When developing code revisions the committee can take public submissions from interested parties. It is difficult from publically available information to identify a simple map of the process for the development of new DRGs and the updating of existing DRGs however there appears to be both some internally generated review as well as consideration of public submissions from Healthcare practitioners and other interested parties. These are then considered by various bodies, and there does appear to also be the ability to refer questions to independent HTA bodies such as ASERNIP-S.

7.3.6. Advantages of current AR DRG system

The AR DRG system provides a consistent language and classification system for payers, planners and policy makers to use when measuring the costs of healthcare, and allocating budgets and negotiating payments.

7.3.7. Disadvantages of current AR DRG system

The AR DRG system is applied very inconsistently across health sectors and jurisdictions.

The fundamental drawback of the AR DRG system is that it takes a very long time to develop or modify a DRG and when a DRG is developed it is based on data that is up to five years behind when it is published. In a medical technology environment when innovation takes place in a rapid timeframe, a system that may take significantly more than six years to catch up is not supportive of timely access for patients to cost effective technology, and contributes to budgetary pressures in hospitals by basing budgeting information on outdated data.

7.3.8. Implications for patients and industry

The delays in processing DRGs potentially severely limits the ability of patients to access technology which is found to be cost effective, and assessed positively for funding. The lag process between DRG updates, and then the information collection period before funding budgets are developed in the public system or contracts renegotiated in the private system means that access is delayed by many years in some cases.

The result is that by the time funding streams are developed for a new technology it may have already been superseded. By the same token both patients and health budgets suffer from the continued use and funding of less effective technology.

7.3.9. Recommendations

MTAA proposes that the DRG system be overhauled to include:

- the ability to update cost data in real time so as to ensure that at the time of updates the data being used is not more than 12 months old
- the ability to continually assess DRGs and update to online coding databases as decisions are made
- a horizon scanning function be added to actively update codes in anticipation of changes in healthcare practice
- a consistent agreement on the application of DRGs across states and health funds
- the automatic development of a new or updated DRG to reflect the costs of the new technology based on the positive assessment of the HTA body to adopt a cost effective technology.

8. Term of Reference No 1 – simplification and better co-ordination of Commonwealth health technology assessments

A key area for reform is the streamlining and co-ordination of current processes. As discussed in section 6, MTAA sees a separation of functions between TGA, the HTA body, and the reimbursement process. The HTA functions undertaken by PDC would come within the operations of the HTA body so that PDC's function is restricted to that of benefit setting body on behalf of the private health insurance payers. PDC and its subsidiary committees do not undertake any HTA assessment. MSAC is replaced by the new HTA entity. It also takes on a horizon scanning function and coverage with evidence development.

Further consideration needs to be given to the HTA processes for hybrid and co-dependent technologies. These are discussed further under ToR 5.

Key questions

How can the interaction between different HTA agencies (ie. TGA, MSAC and PDC) and their processes for the registration and approval for market entry and public and private health funding of new medical services and devices be improved?

MTAA proposes (in the extensive discussion in section 6) a clear separation between the body responsible for HTA and the regulatory and funding roles. The linkage between the bodies can be streamlined through a single point of entry and early consultation on evidence design requirements, to meet regulatory and HTA requirements.

Where a safety concern is identified after the product is in the marketplace, the safety concern should be referred back to the TGA. There would be improved integration between TGA and the HTA body if a TGA staff member acted as a liaison officer within the HTA body. This would engender closer collaboration. One of the

shortcomings of the current system is that neither MSAC nor PDC has much (if any) awareness of the scope and rigour of TGA's activities which gives rise to considerable duplication and second-guessing. Closer co-operation would assist in confidence building.

How could the administrative processes of each individual HTA agency (ie. TGA, MSAC and PDC) be simplified without compromising the scientific rigour underpinning the HTA process?

The MTAA model proposes the establishment of a single and central HTA body which considerably simplifies processes through removal of duplication and redundancy. The model also proposes that scientific rigour and expertise in health technology assessment be developed within the HTA body and not be duplicated within the other bodies. TGA's role is to assess absolute safety and efficacy of the product. The HTA body has the broader role of assessment of clinical effectiveness, cost effectiveness and comparative clinical effectiveness.

Triage during application assessment determines the level of HTA required. Where a product is brought to the market claiming equivalence with another product already in the market, then no further HTA assessment is required, subject only to confirmation that the product is correctly grouped with comparator products. The product is listed for reimbursement with its comparator products at the prevailing benchmark rate.

In a risk-based system, such as the GHTF model adopted by TGA, there is no absolute safety. Safety is a question of risk management. Feedback on safety performance of the product post-registration is therefore essential.

How can HTA undertaken by other countries be used in the Australian context? What are the limitations, risks and opportunities that would need to be considered?

MTAA considers that clinical evidence can be gathered from around the world. However it is harder to apply economic evidence from other countries because of different healthcare settings (see discussion at section 6.6). The same evidence, methodologies and models can be used but these need to be extrapolated to apply to Australia. Similarly costs and comparators from other studies can be used but cost effectiveness needs to be reinterpreted for Australia.

Horizon scanning can be used to bring overseas evidence into Australia. There are also obvious cost savings both to the manufacturer and to the HTA system to take overseas HTA and remodel for the Australian context.

How can assessment of cost effectiveness be improved to ensure HTA can inform government decisions in a timely manner?

The HTA process needs to distinguish between full health technology assessment where selection of technologies and procedures for assessment is based on a set of principles (discussed in section 6.3.1) and the confirmatory or abridged assessment which is used for more limited purposes such as determining that products have been grouped correctly (confirmatory), or for determining a superior claim to effectiveness for the purposes of a reimbursement premium (generally, abridged). The 'gold standard' would be used for breakthrough technologies and procedures and also for programs which attract significant public funding such as:

- Screening programs
- Major intervention in place of drugs
- Mass public funding programs for interventions eg. gastric banding.

A protocol is required to set out when a higher HTA standard is required based on the principles discussed in section 6.3.1 and based on the level of risk and the type of evidence that needs to be generated.

A product needs to be in the market to generate real world data. If the requirements to generate this data are too extensive, the product will be superseded before the data is collected because of the iterative nature of product development. The inputs also need to be flexible in scope and much broader than a cost effectiveness evaluation. As MTAA has argued in section 6.3, where the only consideration is cost-effectiveness the result is used to restrict expenditure without assessment of the broader benefits. Both Drummond et al and Access Economics (referenced in section 6.3) put the case that a broader societal approach is needed to ensure a legitimate assessment.

Are there regulatory impediments to enhancing the evidence base for items approved for interim funding, either through collaboration or individually?

MTAA does not believe that there are regulatory impediments to enhancing the evidence base but there are cost impediments in evidence development. For many medical technologies, approval with the requirement to develop evidence post-registration and post-HTA can provide the opportunity to bring a product through to market more rapidly than deferring until all evidence is collected.

MTAA has discussed coverage with evidence development at section 6.5. Notwithstanding the benefits for products with rapid and iterative development there can still be a substantial cost to the manufacturer, which has to be weighed up against the size of the Australian market, if the evidence requirements exceed what a manufacturer can develop and offer through overseas-based evidence generation.

There is additional evidence available through the Department of Health and Ageing which is not currently made available, such as the cost of rehospitalisation arising from infection. A recommendation of the Health Stream at the 2020 Summit (and the source of considerable discussion) was the need for greater availability of the considerable data held by the Department, for the general benefit of the healthcare system.

9. Term of Reference No 2 – improving role clarity and addressing duplication between processes

Clarification of roles and appropriate allocation of tasks will contribute significantly to the streamlining of HTA in Australia. MTAA has proposed a model for HTA which delineates the roles and functions but which also enables each entity within the redesigned system to add to the work of the other entities. In particular MTAA sees benefit from a closer alignment of the work of TGA and the proposed redesigned HTA body. This is supported by one entry point for applications for (separate but parallel) registration purposes and HTA purposes. Simultaneously an applicant can lodge an application for reimbursement purposes, recognizing that a favourable

reimbursement decision cannot occur unless the product has an ARTG listing (for these purposes MTAA includes products such as custom-made devices which are not listed on the ARTG but which are reimbursable). Where the applicant is making no additional claims of product superiority above those already reimbursed (ie. a 'me too' product), it will be automatically listed for reimbursement once listed on the ARTG (subject to confirmation of appropriate grouping).

Another area of duplication and role confusion which would benefit from clarification, but is not within the Terms of Reference, is the interplay between the States and Federal Government in health care delivery. One area that could be looked at that does fall within the Terms of Reference is the horizon scanning function now undertaken at both levels of government, and even within individual hospitals. This issue is discussed in section 6.7.

Key questions

What HTA roles and functions require clarification?

MTAA has proposed an optimal framework for HTA of medical technologies in Australia (see section 6). The model clearly segments the requirements of the regulatory body and the requirements of the payers, from HTA assessment. At present there is considerable confusion between the roles undertaken by each of TGA, MSAC and PDC. The requirement to monitor safety is not an HTA function and can therefore be separated from HTA. The HTA body may be required to consider safety of a procedure in conjunction with use of a device. Ongoing safety can be informed by post-market surveillance and reporting back to TGA if and when safety issues are identified.

Similarly in the model proposed by MTAA the role of the payers (public and private) in benefit or price negotiation is separate from the HTA function. The payers need to be satisfied that they are getting best value for money from use of a product or procedure. Value for money also needs to take account of patient outcomes and societal benefit. These can be assessed by the HTA body with the payers' role to determine price, guided by the outcome of the comparative assessments undertaken by the HTA body.

Does duplication and/or overlap of HTA processes occur? If so, where? How could this be resolved?

In short, yes there is overlap and duplication in HTA processes as identified by the Productivity Commission and others over many years. This in part is the result of a system for HTA that has evolved in a piecemeal fashion, responding to immediate needs and without the long term foresight to develop a system that can evolve as technologies evolve.

The payer bodies, such as the PDC, should have no role in determining safety of a product nor setting the level of evidence required but increasingly have taken on this role, through the CAGs.

The overlapping requirements mean that there is reduced effectiveness of the reviews undertaken by the various HTA bodies which do not have the capability or resources to undertake HTA.

10. Term of Reference No 3 – enhancing post marketing surveillance mechanisms to ensure ongoing safety and efficacy

MTAA has considered mechanisms to address post-marketing surveillance needs. These needs may be addressed through post-market clinical follow-up or through a system of registries. One of the benefits of post-market surveillance is that it enables the pre-market risk assessment requirements to be managed more effectively. There are other mechanisms available, such as the adverse event reporting system (IRIS) within TGA, although the use to which this information can be put (other than for safety purposes) appears limited.

MTAA is supportive of the use of post-market clinical studies, including clinical registries, as tools to assist post-market surveillance, and to inform post-HTA assessment of a product balanced with pragmatism on the added value of information to reduce uncertainty. Decisions on when to implement post market evidence collection should be developed on a case by case basis. However there are many issues to be addressed in implementing comprehensive post-market surveillance, not the least of which is the considerable cost involved.

10.1. Definitions

Post Market Surveillance (PMS) is defined as the “pro-active collection of information on quality, safety or performance of Medical Devices after they have been placed in the market”⁶⁶.

Post Market Vigilance (PMV) covers a range of programs undertaken by the TGA and the manufacturer or sponsor after they become aware of:

- Adverse events
- Malfunctions
- Results of testing⁶⁷.

PMV is an essential subset of PMS. PMS is a mix of proactive and reactive activities. PMS includes all vigilance activities as well as injury prevention, development of standards, regulatory refinement and product improvement. It therefore involves both risk assessment and risk management.

TGA currently conducts both Pre Market Assessment (PMA) and PMV. It conducts PMV by means of the IRIS Adverse Event reporting vehicle, and the annual report on Class IIb and above devices. However it only threatens to audit PMS which is left up to the manufacturer to conduct. There is an argument that it is not the classification that determines the post market risk, but the incidence and hazard.

⁶⁶ GHTF SG2 N47R4

⁶⁷ Therapeutic Goods Administration, *Australian Medical Devices Guidelines: Postmarket Activities*, Guidance Document Number 11, Version 1.7

10.2. Post-Market Clinical Studies

Certainly the most critical determinant of safety and effectiveness, whether comparative or not, should be evidence-based. Collection of data in the clinical setting is probably the best mechanism.

A post-market clinical follow up study may be valuable in certain well-defined circumstances. These have been considered recently by GHTF⁶⁸ to include:

- Innovation – where the design of the device, the materials, the principles of operation, the technology, or the medical indications are novel
- A new indication or claim has been approved
- Changes to medical practice
- High risk anatomical locations
- Sensitivity of target population
- Severity of disease/treatment challenges.

The elements that are essential to the study include:

- A clearly stated objective
- A scientifically sound design with appropriate rationale and statistical analysis plan
- A study plan
- Implementation of the study according to the plan, an analysis of the data and appropriate conclusions.

Agreement needs to be reached on scope of the study, data required to be collected, and by whom, and at whose cost. It is not reasonable to expect that it will always fall to the applicant/sponsor to meet what might be extensive cost. The case study of the SIR-Spheres technology in section 4.3.10 is a case in point.

10.3. Registries

A registry can provide one set of data to inform post-market surveillance and clinical follow up. However well-designed registries are extremely costly and careful consideration needs to be given to defining areas of high risk for selection and implementation of a registry. The indiscriminate use of registries is not only costly and burdensome but can also stifle innovation and be unachievable for niche technologies and low revenue technologies. Selection of a suitable candidate technology for development of a registry needs to be informed by the level of risk. A registry should also look at all aspects of patient treatment and care, including patient selection, treatment protocols, physician technique and learning curve, and hospital factors such as infection control. Technology performance is but one factor.

⁶⁸ Global Harmonization Task Force, Proposed Document “Post-Market Clinical Follow-Up Studies”, SG5(PD)N4R7

In Australia at present there is only one current universal mechanism for data collection on prostheses - the National Joint Replacement Registry (NJRR) - which is limited to orthopaedic prostheses. The NJRR arguably has other limitations also, including its only endpoint of revision, and concomitant interpretation of that revision purely as prosthetic failure. The NJRR was cited in the Doyle Report as needing to be augmented by outcomes data beyond just revision rates⁶⁹ to demonstrate clinical effectiveness.

The Australian Orthopaedic Association, the NJRR and MTAA have jointly considered the use to which data collected on the NJRR may be put for clinical evaluation purposes by the PDC and its CAGs. This consideration is informative for the role that clinical registries may have in the future as part of the post-market surveillance loop. The agreed principles include that:

- NJRR data sets are used as part of the clinical assessment of new applications, at the discretion of the applicant, to make comparisons with comparator devices
- The PDC and CAGs are not involved in any ongoing clinical review process for previously approved prostheses. TGA considers NJRR data in this context through its expert orthopaedic working group which assesses the information from the NJRR, after taking into account comment from the relevant company
- To be awarded a premium, a company has to apply, supported with appropriate data. The CAGs are interested in data after 10 years which the NJRR is not yet able to provide as it has not collected data for that amount of time.

Extrapolating these principles to the proposed HTA mechanism put forward by MTAA, there is merit in considering clinical data generated by the NJRR for similar purposes, as part of an abridged HTA.

Doyle suggested further registries be established, beginning with a cardiac prosthesis registry. MTAA argues, for the reasons set out above, that a cardiac registry must monitor cardiac procedures and not be limited to devices.

Doyle also recommended these registries be funded by sponsors. However this raises several issues:

- Would a sponsor-funded registry be regarded as a conflict of interest? It could be argued that a company has a conflict of interest, but similarly, all stakeholders may have a conflict of interest: the NJRR by its method of data collection and publication protects surgeons, the interpretation of the data by health insurance bodies could be vested, and even the interests of the creator/owner of the registry itself. Even the regulator may be dependent on the revenue stream if it managed the registry, thereby distracting it from its role of protecting the public.
- Cost is high. If sponsors pay, the assessment may lower the barrier to trade, but increase the cost of the prosthesis, throwing up a different barrier. The significant investment required may not be offset by any increase in safety or value for money improvements. Conversely, the potential for monopolies, or technology freezing could easily outstrip the advantages. Furthermore, Doyle

⁶⁹ Doyle Report supra page 24

incorrectly assumed that registries would only examine prostheses-related interventions. Real world information needs to also include alternative surgical or pharmaceutical based treatment paths. Technology sponsors should not have to incur the expense of collecting information on alternative therapies.

- Clinical acceptance and participation. The willingness of doctors to participate in registries will be determined by:
 - ease of contributing (time, staff, complexity)
 - cost associated with contributions (whether its unpaid)
 - use of the data (especially if it could be used to raise questions about individual clinician practice, used in litigation, or to decrease doctor income)
 - overall participation rate.

10.3.1. Levels of Registries

There are various types of registries which could be considered for use in post-market surveillance.

Device or Procedure Specific

Registries established to assess the specifics of a single device. These types of registries are often required by regulators to address questions about the real life characteristics of a product.

Class Registries

Registries that collect data on all devices and procedures used in a specific class of surgery. The NJRR is a class registry.

Comparative Registries

These types of registries look at a range of treatment options for a specific type of disease. They collect information on different treatment paths, surgical, pharmaceutical, and devices. It is this type of registry that many funders are seeking.

Comparative registries are extremely expensive and difficult to establish. They require information from very different medical settings. For example, comparing a medical technology to pharmaceutical treatment requires information from both the hospital and general practitioner environment. This becomes more complex if it also compares device treatment to a surgical procedure. Information from the surgical procedure, device implantation, alternative treatment from the general practitioner, and information directly from the patient is required. In addition, follow-up is complicated if the patient changes treatment regimes from pharmaceutical to surgical for example.

The SYNTAX Trial (Boston Scientific Corporation) was an example of this type of comparative registry. It compared the use of Drug Eluting Stents and CABG for complex patients. The SYNTAX Trial cost \$10,000 USD per patient, limited to approximately 3000 patients over 85 sites.

Case study 7 SYNTAX trial

A Boston Scientific commissioned comparative clinical trial and registry to compare PCI with CABG. The trial includes two randomised arms of approximately 900 patients in each arm, and a registry of 1300 patients. (n3100). The SYNTAX Trial focused on complex cardiac patients from 85 sites in the US and EU.

SYNTAX is an unusual study, for three reasons.

1. It compared a device procedure (drug eluting stents) with a surgical procedure (CABG).
2. It has both a two arm randomised trial, and all patients registry.
3. The design included economic evaluation factors, including quality of life surveys (QoL) and cost input data.

Traditionally sponsor studies compare similar products, such as BMS vs DES, or DES brands; and it is extremely rare for a study to be powered to include economic information.

Costs

SYNTAX is a five year trial. At one year, SYNTAX has cost BSC \$33m USD. That is \$10,645 per enrolled patient.

The economic evaluation has cost \$1.1m alone. BSC contracted 3 vendors to manage the QoL questionnaire collection and analysis, US HE analysis, EU HE analyses.

Both the cost and complexity of comparative registries cannot be underestimated. Collecting data from many hospitals, in different treatment settings, and in a consistent manner is a major challenge. Significant incentives would be required to overcome these challenges.

10.3.2. Critical components

Clinical Buy-In

Clinical buy-in and participation is critical to the success of any registry. The NJRR achieved clinical buy-in via the Australian Orthopaedic Association (AOA) lobbying its members to comply in the name of scientific pursuit. This is an example of a doctor-lead registry.

Doctor-lead registries such as the NJRR are also relatively inexpensive because the clinician receives little or no payment for participation. This is not the norm. Most registries use direct financial incentives to the doctor and practice to gain participation. MTAA does not support the payment of doctors for contribution of data to a registry. The registry output includes informed clinician education which is of value in itself.

Affordability

In addition to clinical buy-in, registries need to be affordable in terms of both cost and time. It is unrealistic to expect clinicians to dedicate ever-increasing time to furnishing differing registries without being compensated.

Clinicians will expect and demand to be paid for their time and information. The cost of this will be determined by the number of registries, and the complexity involved. There is a risk that local registries for specific products, device class registries, and comparative registries may well overlap. This could result in clinicians having to supply information to a number of registries for the same procedure. This would use up a lot of clinician or practice time, and could be distracting for doctors when the priority should be patient care.

Fiscal discipline

Financial incentives should also be imposed on the creation and management of registries. While it is easy to conceive of medical questions that could be answered via surveillance and registries, a determination of their relative cost effectiveness also needs to be considered. Appropriate incentives will reduce the risk of duplication and excessive surveillance systems.

MTAA proposes that full financial responsibility for the establishment and management of registries be placed on the party seeking the information. Using this rationale, sponsors would continue to have responsibility for safety and quality registries.

Questions of comparative or relative cost effectiveness would be the responsibility of the funders or professional colleges. The funder is seeking information on more than one product and its costs and benefits compared with an alternative path. This type of information cannot be the responsibility of a single sponsor; rather it needs to be the responsibility of the funder seeking the answers. This in itself would incentivize the funder to prioritize the questions it seeks answers for.

By clearly aligning the cost of obtaining the information with the persons seeking it, it will provide fiscal discipline. Failure to align the incentives could result in a proliferation of registries and significant escalation of cost to the health sector. Ultimately, it is the funders (overwhelmingly the Federal Government) that will bear the costs of any increase in post market registries.

Credibility = transparency and independence

Credibility underpins the usefulness of surveillance systems, and this can be best achieved with transparent and independent governance. Surveillance systems, especially registries, need to be appropriately managed. But for them to be credible, the potential users of the information must feel that the information is not tainted by bias. This requires specific actions to ensure that users can see how the information was derived, and feel that it is appropriate for the circumstances.

This becomes even more critical when multiple bodies seek to use the information, be they regulators, funders and/or medical colleges.

Regulatory Responsibilities

It should again be noted that it is a condition of ARTG certification on Class III and AIMD products, and proposed for Class IIb, to submit annual reports to the TGA for the first three years of supply. Sponsors of therapeutic goods supplied in Australia

have a responsibility that provides feedback on the performance of these products in the marketplace during the initial critical usage of any new product or even technology. This is in addition to the adverse event reporting from sponsors and hospitals under the IRIS scheme.

This information, although informative, is obviously of limited clinical validity, and would need to be bolstered by a clinical registry.

Key questions

What changes, if any, are needed to current HTA arrangements for post market surveillance of health technologies?
How could the arrangements for post market surveillance of medical devices for ongoing safety and clinical effectiveness be improved?
What additional arrangements for post market surveillance could be considered or implemented?

There is currently no HTA of post market surveillance. As discussed above, vigilance is all that is practiced. Surveillance is the proactive tracking of products to analyse outcomes when the products are in the market.

In considering an appropriate system for post market surveillance, a broader perspective needs to be taken, including the setting of a procedure, doctor training, the quality and safety of the environment in which a procedure takes place.

For a big cost, high risk investment there may be justification in running a comparative registry but otherwise the registry can be very expensive and out of reach of any of the principal stakeholders (see discussion at section 10.3.2).

There needs to be clarity around the purpose of the registry. Is it required only to track safety of products (in which case it is of interest to TGA)? Or is it used to track comparative performance of products to identify poorly-performing products against comparator products (in which case it may be of interest to payers). What are the parameters to determine poor performance, particularly where the performance is not related to safety? How does a registry operator ensure doctor compliance in reporting where safety is not the issue?

How should post market surveillance be managed?

Management of post market surveillance needs to be looked at from different angles – safety and ongoing performance. Safety is managed by TGA with feedback from industry, from the HTA body where it identifies safety issues, from clinicians and from patients, as now. These pathways are reasonably clear in the current system but often not followed because other bodies have begun to take on the role of assessment of safety of a product, rather than referring the matter back to TGA.

The one area that is less clear in the current system is the obligation on industry to report adverse events. While this is straight forward when a company becomes aware of an adverse event, it is often the case that a company will not be aware that an event has occurred. MTAA has been working with AOA and the NJRR to develop a mechanism, for example, that will enable real time identification by a company of a revision of one of its orthopaedic joints, rather than having to wait for the annual report of the NJRR. This does not mean that each revision is an adverse event, but it does enable the sponsor to investigate further.

MTAA supports the use of registries to manage post market surveillance of product performance but proposes that there be clear guidelines on use of the data. MTAA also proposes that the collection of data be sufficiently broad to enable identification of other issues, such as clinician performance, safety and quality of the procedure setting and healthcare environment.

As discussed in section 10.3.1, there are numerous conflicts of interest in registry management, regardless of the manager. There are also considerable costs in managing a registry that has sufficient data collection to be of value. The costs should be a public good expense, as with the current NJRR. It is not appropriate to require industry to support the cost of the registries when the benefit is shared by all users of the health care system.

11. Term of Reference No 4 – strengthening transparency and procedural fairness

Transparency and procedural fairness contribute to the robustness of a process and build confidence in those using the system, whether they be applicants, patients, clinicians, or payers. It is in the interest of everyone using the HTA system that criteria of transparency and procedural fairness are intrinsic to the process. MTAA has highlighted some of the mechanisms that work well now and which we would like to see retained (see section 6.4.6). MTAA also strongly supports a process that is collaborative rather than combative. Not only is this a more cost effective approach but it usually produces improved shared outcomes.

Key questions

What aspects of Australia's HTA system are working well in relation to transparency and procedural fairness? Provide specific examples.

The following aspects of Australia's HTA system are seen by MTAA to be working well at present are few in number but drawn from several bodies.

PBAC:

- Collaborative process; contact between companies and assessors
- Fixed timeframes for submissions and meetings
- Transparency of reporting outcomes of PBAC meetings and submissions

MSAC:

- Pre-submission meeting to assist applicant to understand MSAC requirements (although not as comprehensive as NICE scoping meeting)
- Transparency of identity of participants which builds confidence to understand the capability of the decision-makers
- Clinical input and expertise (although this can add to the length of the process)

- Flexibility to be able to make decisions in the face of uncertainty and to adapt assessments to the available evidence. Flexibility can be compromised however by a lack of independence
- Recent initiative inviting applicants to suggest clinicians for appointment to the Advisory Panel
- Transparency of reporting outcomes of submissions on website and meeting outcomes (although these are now considerably behind)
- Debrief meeting with applicants

TGA:

- Iterative, rolling process for applications – they are not fixed to specific deadlines
- Use of delegate process
- Readiness to consult with sponsors and talk through issues identified in the application process
- Advance notice is given of intention to reject an application
- Performance objectives are agreed with industry (although only the time period for full conformity assessment is addressed in legislation)

PDC:

- All stakeholders are represented on the PDC
- Publication of dates for lodgement and release of each PL enables planning for product release (although there has recently been a consistent failure to meet the dates).

What could be improved to assist transparency and procedural fairness?
Provide specific examples.

The elements of the processes that could be improved to assist transparency and procedural fairness include the following:

- Higher level of interaction and collaboration to assist a co-operative relationship and avoid an adversarial environment
- Publication of minutes and outcomes of applications has the effect of making the participants more accountable
- Availability of a review mechanism and appeals process in accordance with the principles of natural justice
- Communication with applicants so that there are no surprises and the applicant can provide the best quality information available to it
- Opportunity for an applicant to make a presentation on its application to the assessment body
- Use of detailed guidance to fully inform applicants
- Institutionalizing of a process for declarations of conflicts of interest.

The requirements for transparency and good governance are also discussed in section 6.4.6.

What key performance indicators could be developed and reported on to improve transparency for HTA processes?

Key performance indicators should provide guidance to the HTA body for measurement of its performance against expectations and commitments. They should not be over-engineered and should be accessible to all stakeholders. They might include the following:

- Timelines which are to be adhered to for lodgement, processing, decision-making, announcement of outcomes
- Electronic lodgement of an application with the capacity to track progress of the application through the system
- Annual reporting
- Adherence to a governance framework
- Impartial and open benefit negotiation process
- Transparency of reviewers' qualifications and experience and ability to challenge selection of experts
- Transparency of accounting for costs recovered from applicants.

Key performance indicators are also discussed in section 6.4.5.

12. Term of Reference No 5 – enhanced arrangements for assessment of co-dependent and hybrid technologies

Many of the issues identified in section 4 as shortcomings in the current HTA processes for medical technology are magnified when applied to co-dependent and emerging technologies.

Members of an ad hoc working group within the Global Harmonization Task Force (GHTF) have recently considered principles for the regulatory management of combination (or hybrid) products which may be worthy of examination⁷⁰. These principles may also be considered for broader application to HTA treatment of hybrid technologies. The principles include:

- No claim to superiority in one body over another
- No accumulation of requirements – the appropriate elements of more than one existing regulatory model (medicines, medical devices, biological materials) should be considered when determining the necessary evidence, evaluation, and quality requirements for a particular combination product
- Guiding consideration in determining the primary regulatory requirements from which the "hybrid" requirements are developed is the principal intended mode of action of the product on the human body, and taking into account any secondary modes of action. The "principal mode of action" is

⁷⁰ Global Harmonization Task Force Ad Hoc Working Group on Combination Products. May 2009. Unpublished. Note that this document and the principles referred to have not been considered by the GHTF Steering Committee nor have they been adopted by the Ad Hoc Working Group as yet.

understood to be the mode of action (mechanical, physical, pharmaceutical, metabolic, immunologic, etc) which plays the principal role in achieving the medical effect on the patient.

The “principal mode of action” can be understood by contrasting a pre-filled syringe and a coronary drug-eluting stent. In the case of a pre-filled syringe, the principal medical effect on the patient is the one generated by the liquid contained in the syringe, even though the correct functioning of the syringe also has an important role. In the case of a drug-eluting stent, the principal intended medical effect on the patient is to re-establish an appropriate blood flow rate through a compromised coronary artery by re-creating a clear lumen which had been reduced by, for example, an accumulation of atherosclerotic plaque.

Other countries have the benefit of an assessment structure which addresses all technologies and procedures, including pharmaceuticals. The HTA process needs to provide better integration of assessment processes as they apply to hybrid and co-dependent technologies.

In the United States there is an Office of Combination Products and in Canada CADTH provides healthcare decision-makers with advice on the effectiveness and efficiency of all health technologies including drugs, devices and diagnostics. NICE also looks at drugs, treatments, procedures and technologies. The benefit of a centralised agency to consider all treatments from a community perspective as opposed to a single portfolio perspective, “minimizes the risks that a technology may not be considered because it does not provide savings within the same technology portfolio. They also provide mechanisms for consistency, predictability and transparency of the technology assessment process.”⁷¹

A case study which exemplifies the problems with assessment and approval for reimbursement of co-dependent technologies is that of administration of apomorphine to patients suffering from Parkinson’s disease. Apomorphine is a dopamine agonist registered for use in patients with Parkinson’s disease severely disabled by motor fluctuations which do not respond to other therapy. Apomorphine is administered via injection. For patients with increasing requirements, treatment is administered via continuous infusion using a specific pump.

Therapy involves administration of the pharmaceutical itself, using a specific ambulatory infusion pump and associated consumable equipment (syringe, extension tubing, butterfly clip, swabs). Patients are initiated on treatment after a protocolised ‘apomorphine challenge’ conducted by a qualified specialist, and undergoing appropriate training.

The following table outlines the reimbursement mechanisms for the various component parts:

⁷¹ Deloitte Touche Tohmatsu. Improving the Quality Use of Medicines in Australia – Realising the Potential of Pharmacogenomics October 2008. Prepared for the Australian Centre for Health Research

Component part	HTA assessment/ Reimbursement mechanism	Notes
Drug	PBAC/PBS	
Infusion pump	PDC/Prosthesis List	Provides access to Privately insured patients only
Consumables	Nil	No mechanism currently exists for patients to be reimbursed for personal expenditure on this component
Initiation/maintenance of treatment by Specialist	MSAC/MBS	Often not specific to the service provided. Funding for a general attendance is often an inadequate amount for additional services provided, necessitating additional submissions by Sponsors to establish more relevant item numbers and fees.

It is evident that current HTA and reimbursement mechanisms do not consider the 'whole of therapy'. The consequence of the current reimbursement pathways are that:

- Each component part of a single therapy is considered separately by different bodies, using different criteria
- Sponsors must present their case to a number of different bodies, often sequentially, resulting in duplication and significant delays to access
- Coverage is incomplete with the result that there is inequity of access between public and private patients (for the ambulatory infusion pump), and no reimbursed access for the critical consumable components.

The issues identified are not isolated to apomorphine. Most hybrid technologies (drug/device combinations, drug/diagnostic test combinations) face the same issues whenever the 'whole of therapy' is comprised of component parts, and no single HTA body is able to consider the value of the whole.

A HTA solution needs to have a mechanism to centrally consider the 'whole of therapy' in terms of value. Two options include central assessment, or a central triage process:

- Central assessment – under this process a working group comprised of members of each of the HTA body and PBAC actively meet to consider an application which relates to a hybrid or co-dependent technology; leadership of the assessment is derived from the body which reflects the guiding technology (ie. dictated by the principal mode of action of the product)
- Central triage – an option is for the current established assessment bodies to remain, although with revised terms of reference and role clarity. A central triage agency could be established that assessed technologies, considered the component parts (where applicable) and channeled them into the most

appropriate group (ie. PBAC or the redesigned HTA body discussed in this submission) for 'whole of therapy' assessment.

Neither of these options precludes single item technologies (not associated with a service for example, or with a service already established) from moving directly to the relevant body. Any HTA recommendation from either of the established groups would be accompanied by a series of recommendations that cascade to the relevant reimbursement mechanisms to ensure the component parts of the technology are concurrently listed in the various funding schemes (ie. the necessary PBS and MBS item numbers are generated, alongside Prostheses Listing).

Another issue identified in the case study discussed above is the lack of mechanism for reimbursement of consumables necessary for treatment. This is incongruous with a central body recommending a particular therapy as cost-effective. MTAA proposes an 'Essential Care List' which would meet this current gap in access for Australian patients. This policy is separate from proposed reforms to the HTA mechanisms although elements of the HTA system, particularly abridged HTA, may be required for products in the Essential Care scheme.

One of the challenges for HTA of emerging technologies is the availability of clinical experts with adequate knowledge of the technology, particularly where there are multiple technologies and associated procedures involved.

Given the complexity of this area, and the rapidly evolving nature of the hybrid and co-dependent technologies, MTAA proposes that further work be undertaken on the issue with a dedicated steering committee to examine the issues raised in submissions and to develop options. Pending development of a longer term solution, the immediate response should be to develop a set of principles to guide deliberations in the interim, incorporating the options for management of assessment set out in this section.

Key questions

What are the key issues for government, regulators, medical and health professionals, industry and consumers in relation to the assessment of co-dependent and hybrid technologies?

The key issue is the fragmentation, lack of co-ordination and replication within the current system. Different bodies look at different elements of the same product, as evidenced in the case study discussed above. There is a lack of clarity in the different roles of each body and in the responsibilities attaching to each role. There is an inconsistency in approaches and methodologies. An example of this is the case study cited in section 4.4 of DC Beads, a product which is listed on the ARTG as a medical device, being an embolisation device which can be loaded with a drug. The primary intended action of the product is as a device, consistent with the manufacturer's intended purpose. However when the product came to be considered for listing on the Prostheses List the PDC's initial assessment was that the product was a pharmaceutical and was refused listing.

The end result of these shortcomings is a gap in coverage and access by patients. They also underline the need to ensure the congregation of all relevant bodies sufficiently early in the process, using one of the options outlined above.

What enhancements to current arrangements for assessment of co-dependent and hybrid technologies should be introduced?

The suggested enhancements to improve current arrangements can begin with the options suggested above – for either a triage system or a shared assessment system.

As discussed above MTAA believes that pending longer term development of an integrated HTA body, management of assessment of hybrid and co-dependent technologies should be directed on a set of principles. These might include:

- The principles for regulatory treatment discussed above
- A single entry point for applications for all elements of the technology
- Consistency of methodology and approach
- Whole of therapy assessment – considering all component parts to deliver one outcome
- Collaboration where there are different assessment bodies, adopting one of the options discussed above
- Co-ordination of the listing of the component parts eg. PBS listing for the drug, MBS listing for the procedure, and assessment for reimbursement by payers where relevant.

One of the greatest challenges is that, while there may be a positive assessment for the technology, there may be no certainty of reimbursement which raises the question of lost investment in the HTA process. While the drug and the procedure may be reimbursed through public funding pathways, unless the technology comes within the Prostheses List (as it is now) or the proposed re-examined Part C, there is no mechanism to reimburse the technology, other than through the public system with its spending caps. The absence of reimbursement is a disincentive to bringing a new technology forward for HTA.

What are the implications for assessment of clinical effectiveness and cost-effectiveness for hybrid and co-dependent technologies in relation to decision making about funding?

The principal implication is that it is not possible, nor appropriate, to separate out the inter-dependent products when undertaking a cost-effectiveness assessment. For example, where a diagnostic is required for screening to determine patient selection for a drug treatment, the cost of the diagnostic screening needs to be taken into account in assessing the overall cost-effectiveness of the drug. Each cost cannot be reviewed in isolation.

13. Conclusion

The reforms proposed by MTAA in this submission will produce a more streamlined, transparent, flexible process for the assessment and reimbursement of technologies without compromising safety and without imposing additional cost burdens on the healthcare system. MTAA's aim is to ensure improved patient access to effective technologies that deliver a smarter healthcare solution.

MTAA looks forward to working with the Government as it considers critical changes to the assessment of health technology for the benefit of all Australians.

Acronyms

ACHI - Australian Classification of Health Interventions
AHMAC - Australian Health Ministers' Advisory Committee
AOA – Australian Orthopaedic Association
AR-DRG - Australian Refined Diagnosis Related Group
ASERNIP–S - Australian Safety and Efficacy Register of New Interventional Procedures – Surgical
CAG – Clinical Advisory Group
CMS – Center for Medicare and Medicaid Services
DoHA – Department of Health and Ageing
FDA – Food and Drug Administration
GHTF – Global Harmonization Task Force
HTA – Health Technology Assessment
MBB – Medicare Benefits Branch
MBCC – Medicare Benefits Consultative Committee
MBS – Medicare Benefits Schedule
MSAC – Medical Services Advisory Committee
NET-S - New and Emerging Techniques – Surgical
NHHRC – National Health and Hospitals Reform Commission
NHMRC – National Health and Medical Research Council
NHSU - National Horizon Scanning Unit
NJRR – National Joint Replacement Registry
NPBC - National Procedure Banding Committee
PBAC – Pharmaceutical Benefits Advisory Committee
PBB – Pharmaceutical Benefits Branch
PBPA – Pharmaceutical Benefits Pricing Authority
PBS – Pharmaceutical Benefits Scheme
PDC – Prostheses and Devices Committee
PDNG – Prostheses and Devices Negotiation Group
PHIAC – Private Health Insurance Administration Council
PL – Prostheses List
PMA – Pre-Market Assessment
PMS - Post Market Surveillance
PMV – Post Market Vigilance
PoCE – Panel of Clinical Experts
RACS – Royal Australasian College of Surgeons
RCT – Randomised Controlled Trial
TGA – Therapeutic Goods Administration
VPACT - Victorian Policy Advisory Committee on Clinical Practice and Technology
WHO – World Health Organisation

Acknowledgments

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Appendix 1
MTAA Model of HTA System
(attached)

Appendix 2
Access Economics Report
An improved HTA economic evaluation
framework for Australia
(attached)