An improved HTA economic evaluation framework for Australia

Report by Access Economics Pty Limited for

Medical Technology Association of Australia
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### GLOSSARY

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<th>Description</th>
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<tr>
<td>AHCAM</td>
<td>Australian Health Ministers Advisory Committee</td>
</tr>
<tr>
<td>AIHW</td>
<td>Australian Institute of Health and Welfare</td>
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<tr>
<td>BNG</td>
<td>Benefit Negotiation Group</td>
</tr>
<tr>
<td>CADTH</td>
<td>Canadian Agency for Drugs and Technologies in Health</td>
</tr>
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<td>CAG</td>
<td>Clinical Advisory Committee</td>
</tr>
<tr>
<td>CBA</td>
<td>Cost benefit analysis</td>
</tr>
<tr>
<td>CCA</td>
<td>Cost consequence analysis</td>
</tr>
<tr>
<td>CCOHTA</td>
<td>Canadian Coordinating Office for Health Technology Assessment</td>
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<tr>
<td>CEA</td>
<td>Cost effectiveness analysis</td>
</tr>
<tr>
<td>CMA</td>
<td>Cost minimisation analysis</td>
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<td>CUA</td>
<td>Cost utility analysis</td>
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<tr>
<td>DoHA</td>
<td>Department of Health and Ageing</td>
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<tr>
<td>DRG</td>
<td>Diagnosis Related Group</td>
</tr>
<tr>
<td>DSA</td>
<td>Deterministic Sensitivity Analysis</td>
</tr>
<tr>
<td>ECAHI</td>
<td>The European Collaboration for Assessment of Health Interventions</td>
</tr>
<tr>
<td>ECHTA</td>
<td>The European Collaboration for Health Technology Assessment</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>EUnetHTA</td>
<td>European network for Health Technology Assessment</td>
</tr>
<tr>
<td>GHTF</td>
<td>Global Harmonisation Task Force</td>
</tr>
<tr>
<td>HRQL</td>
<td>Health-Related Quality of Life</td>
</tr>
<tr>
<td>HTA</td>
<td>Health Technology Assessment</td>
</tr>
<tr>
<td>HTAi</td>
<td>Health Technology Assessment International</td>
</tr>
<tr>
<td>HUI</td>
<td>Health Utilities Index</td>
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<tr>
<td>HYE</td>
<td>Healthy Years Equivalent</td>
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<tr>
<td>ICER</td>
<td>Incremental Cost Effectiveness Ratio</td>
</tr>
<tr>
<td>ICH</td>
<td>International Conference on Harmonisation</td>
</tr>
<tr>
<td>INAHTA</td>
<td>International Network of Agencies in Health Technology Assessment</td>
</tr>
<tr>
<td>IQWIG</td>
<td>Institute for Health Care Quality</td>
</tr>
<tr>
<td>LYG</td>
<td>Life Years Gained</td>
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<tr>
<td>MBS</td>
<td>Medicare Benefits Schedule</td>
</tr>
<tr>
<td>MSAC</td>
<td>Medical Services Advisory Committee</td>
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<td>NHB</td>
<td>Net Health Benefit</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<tr>
<td>NHPF</td>
<td>National Health Performance Framework</td>
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<tr>
<td>NHS</td>
<td>UK National Health Service</td>
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<tr>
<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
</tr>
<tr>
<td>OHTAL</td>
<td>Ontario Health Technology Advisory Committee</td>
</tr>
<tr>
<td>PBAC</td>
<td>Pharmaceutical Benefits Advisory Committee</td>
</tr>
<tr>
<td>PBS</td>
<td>Pharmaceutical Benefits Schedule</td>
</tr>
<tr>
<td>NHPF</td>
<td>National Health Performance Framework</td>
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<td>OHTAL</td>
<td>Ontario Health Technology Advisory Committee</td>
</tr>
<tr>
<td>PBAC</td>
<td>Pharmaceutical Benefits Advisory Committee</td>
</tr>
<tr>
<td>PBS</td>
<td>Pharmaceutical Benefits Schedule</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<td>--------------</td>
<td>--------------------------------------------------</td>
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<tr>
<td>PC</td>
<td>Productivity Commission</td>
</tr>
<tr>
<td>PDC</td>
<td>Prostheses and Devices Committee</td>
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<tr>
<td>PL</td>
<td>Prostheses list</td>
</tr>
<tr>
<td>POCT</td>
<td>Point of Care Testing</td>
</tr>
<tr>
<td>PSS</td>
<td>Public Social Service (UK)</td>
</tr>
<tr>
<td>QALY</td>
<td>Quality Adjusted Life Year</td>
</tr>
<tr>
<td>QWB</td>
<td>Quality of Wellbeing</td>
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<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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EXECUTIVE SUMMARY

In 2008 the Minister for Health and Ageing and the Minister for Finance and Deregulation announced a joint Review of Health Technology Assessment in Australia. One aim of the Review is to assess ways of streamlining, improving timeliness and enhancing coordination arrangements for health technology assessment. The Review also aims to reduce regulation and costs to businesses and consumers throughout HTA processes. Rather than focusing on all areas of HTA in Australia, the Review has been restricted to:

- regulation of therapeutic goods before they are released for sale, which is currently advised by the Therapeutic Goods Administration (TGA);
- approval of Medical Benefits Schedule (MBS) funding, which is currently advised by the Medical Services Advisory Committee (MSAC); and
- listing of prostheses and devices for private health insurance coverage, which is currently advised by the Prostheses and Devices Committee (PDC).

Access Economics has been commissioned by the Medical Technology Association of Australia to develop an economic evaluation framework for health technology assessment in Australia, specifically focusing on medical devices and procedures. The framework is to be included within MTAA’s submission and representations to the Review. As noted by MTAA, focus should be on the economic evaluation of health technology for listing on the MBS.

In developing the economic evaluation framework, this study has consisted of the following tasks.

- A review the current MSAC HTA process and economic framework to:
  - assess strengths and weaknesses associated with the current HTA environment;
  - assess the limitations of, and potential improvements to, the current MSAC economic framework as an appropriate evaluation mechanism; and
  - draw out key points from recent HTA reviews that are relevant for developing an improved economic framework.

- A review of the applicability of international HTA economic frameworks to:
  - identify differences and consistencies across international HTA economic evaluation frameworks;
  - draw out key points relevant for the Australian HTA environment; and
  - ensure the economic evaluation framework developed in this study is in harmony with international HTA economic evaluation frameworks.

- Development of an improved economic evaluation framework for Australia that incorporates:
  - strengths of HTA economic evaluation frameworks currently being used in Australia;
  - strengths of international HTA economic evaluation frameworks; and

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1 Roxon, N (Minister for Health and Ageing) and L. Tanner (Minister for Finance and Deregulation), 2008, Health technology assessment processes, Joint media release, Parliament House, Canberra, 18 December
practicality with sound theoretical foundations.

In addition, three case studies have been undertaken to demonstrate the application of the improved economic evaluation framework developed in this study. The case study topics include:

- point-of-care testing (POCT) for Warfarin levels;
- three dimensional cardio radiofrequency ablation; and
- remote monitoring systems for patients with implanted cardiac devices.

This report highlights current inadequacies within the MSAC economic evaluation framework and offers suggestions for improvement. These are summarised in the following points.

- An economic evaluation’s study frame should be comprehensive and undertaken after a thorough literature search. Consultation with all stakeholders should be undertaken at this stage before the economic evaluation proceeds.

- A societal perspective should be used within all economic evaluations to incorporate:
  - direct health care system benefits and costs, including health and non-health outcomes;
  - indirect economic benefits and costs; and
  - broader impacts on society.

- New technology should be compared with the existing treatment approach it will replace (which may mean more than one comparator) and the most cost-effective existing treatment approach, which are not necessarily the same. Given the wide range of treatment approaches, a comparator could include:
  - devices;
  - procedures;
  - pharmaceuticals;
  - diagnostic techniques;
  - health promotion activities;
  - health management plans;
  - co-dependent technologies;
  - competitors on the horizon; and
  - ‘do nothing’ scenario.

- Levels of evidence developed by the NHMRC are more easily applied to the evaluation of pharmaceuticals rather than procedures and devices. This is due to the differences between the types of evidence collected.
  - Rejecting the undertaking of an economic evaluation based on ‘insufficient’ evidence should be avoided.
  - All available relevant evidence and data should be critically appraised and limitations specifically stated.
  - Where limitations exist, assumptions should be made and tested using theoretically defensible methods such as decision analytic modelling, sensitivity analysis and scenario analysis.

- The economic assessment tool should be based on the characteristics of the new technology and comparator(s) under assessment.
The types of benefits and costs, the type of clinical evidence available, and the uncertainty surrounding estimates should be the main driver of choice.

Unlike pharmaceuticals, CUA may not be the gold standard in the evaluation of procedures and devices as important non-health benefits are often associated with these types of health technologies.

Economic evaluations currently focus on three broad health care system attributes, including safety, effectiveness, and technical efficiency. However, there are several other attributes of the health care system also valued by society that needs to be assessed, some of which include:

- appropriateness;
- responsiveness;
- accessibility;
- continuity;
- capability; and
- sustainability.

All expected changes to costs should be evaluated, including direct health care system costs, indirect costs, and opportunity cost. Techniques recommended within this report for valuing the largest types of costs (productivity losses and informal carer costs) should be used.

The time horizon should reflect the period where differences in health outcomes and the use of health care resources are expected to occur.

MSAC’s recommended five per cent for discounting may not be appropriate. Any recommended discount rate made should be theoretically defensible, based on solid research, and updated regularly as social preferences change.

To avoid negative outcomes based on ‘insufficient’ evidence, uncertainty associated with evidence and data should be tested using:

- probabilistic sensitivity analysis to incorporate parameter uncertainty;
- scenario analysis to incorporate model structure uncertainty; and
- model re-application on alternative sub-groups (e.g. patients or health care systems) to incorporate known variability in inputs.

Decision analytic modelling can also be used to determine the appropriateness of conditional funding with additional research rather than using subjective assessment.

An independent, and external, review of economic evaluation methodology and results should be undertaken before a final recommendation is made.

Other factors should be considered in the final decision making process, including equity outcomes and public preferences.

Under the current MSAC process and economic evaluation framework, it is likely that Australian’s are missing out on health and non-health benefits they could have otherwise gained. Furthermore, some health technologies that are cost effective are likely to have been rejected based on ‘incomplete’ evidence rather than being based on a complete economic evaluation using the available evidence. This is problematic because it can translate directly into reduced social welfare.
This report has not proposed funding decisions be based on poor evidence. Rather it advocates the use of modern and theoretically defensible techniques to reduce the problems associated with all types of evidence, data, and model structures. The application of the economic evaluation framework presented in this report will enable the development of a more accurate estimate of the true cost effectiveness of procedures and devices in Australia. This is expected to lead to greater health and non-health net benefits to society.
1. CURRENT HTA FRAMEWORK FOR MEDICAL DEVICES AND PROCEDURES

In developing an improved economic evaluation framework for medical devices and procedures, the first task was to evaluate the current framework to identify strengths and weaknesses, and areas for improvement.

The focus of this chapter is on MSAC’s processes, methods and timeframes, including the types of analyses undertaken by MSAC, and links between HTA and reimbursement.

1.1 OVERVIEW OF MSAC

MSAC evaluates new health technologies and procedures for which funding is sought under the Medicare Benefits Scheme (MBS). It does this by assessing their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. (MSAC 2005a:7). In summary, MSAC’s terms of reference are to:

- advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness, and under what circumstances public funding should be supported;

- advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis, to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness;

- advise the Minister for Health and Ageing on references related to new and/or existing medical technologies and procedures; and

- undertake health technology assessment work referred by the Australian Health Ministers’ Advisory Council (AHMAC) and report its findings to AHMAC (MSAC 2005a).

MSAC was established in 1998 as part of a number of measures to ‘strengthen the evidence base of the MBS, strengthen the place of evidence in health financing decisions, and thereby improve health outcomes for the community’ (MSAC 2005a:8). Prior to its establishment, new medical services were assessed through consultative arrangements (MSAC 2005a:8).

1.1.1 MSAC ASSESSMENT CYCLE

The MSAC assessment cycle commences when an application for assessment of a new technology or procedure is received by the MSAC Secretariat. Applications may be received from the medical technology industry, a medical professional organisation, an individual, or the Department of Health and Ageing (DoHA). Once an application has been received, there are several stages in the MSAC assessment cycle that occur before a new health technology is either accepted or rejected for MBS listing (MSAC 2005a).

- Confirmation that the service is eligible for assessment - The proposed treatment or technology must constitute a clinically relevant, professional medical service under the Health Insurance Act 1973. In addition, devices, diagnostic kits or pharmaceutical products used in providing the service must have been approved by the Therapeutic Goods Administration (TGA).

- Assessment - As defined by MSAC an assessment includes:
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…a review of the information provided by the applicant in the application form, as well as any additional relevant data that might have been provided. MSAC may commission a systematic review of relevant literature, including a cost-effectiveness evaluation or other evaluation of the application (MSAC 2005a:10).

- Formulation of advice - MSAC formulates recommendations to the Minister for Health and Ageing on whether the:
  - evidence is strong and the service under assessment should be listed on the MBS; or
  - the evidence does not support listing on the MBS; or
  - the evidence is equivocal but suggests the procedure could be safer, more effective and more cost effective than listed comparators and MSAC recommends interim funding to enable further evaluation of the technology or procedure.

- Submission to the Minister for Health and Ageing and Ministerial Decision - DoHA makes a submission to the Minister for Health and Ageing which combines MSAC’s assessment advice with policy advice from the Department. If there is a recommendation for funding, the appropriate consultative committee draws on MSAC’s findings to determine appropriate levels and descriptors.

- Implementation — MSAC states that, ‘If the Minister for Health and Ageing endorses a recommendation for funding of a new medical service through the MBS, the appropriate consultative committee draws on MSAC’s findings to determine appropriate levels and descriptors’ (MSAC 2005a:11).

- Reporting — The MSAC report and recommendations are made public at the final stage of the process.

1.2 MSAC SCOPE

New and existing technologies

MSAC’s current emphasis appears to be on new, rather than existing, technologies and procedures. The MSAC Guidelines (2005a) and MSAC terms of reference (see Section 1.1) focus mainly on new services for which funding under Medicare is sought. However, there is also scope for MSAC to receive references to assess existing medical technologies and procedures.

According to Kearney and Blamey (2008), there is a systematic approach to assessment of promising new health care technologies. These are identified via horizon scanning undertaken by a subcommittee of MSAC (HealthPACT), and then referred to MSAC for a full HTA assessment.2 The medical industry can also apply for MSAC assessment of new technologies to obtain Medicare funding. However, a systematic approach to new technologies is somewhat constrained by the nature of the medical devices industry which is characterised by a constant flow of incremental product improvements. Some MBS service descriptors may be broad enough to encompass new procedures and devices and thus, some new procedures or devices that fit under an existing MBS item number may not be assessed, or be assessed only after the procedure is already being widely used. Further, if

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2 However, there is no similar process for drugs or vaccines. This is despite this gap being documented by the PC (2005).
improvements to existing procedures are marginal they may not require full assessment by MSAC (PC 2005).

MSAC’s specific role in assessing existing MBS services is not entirely clear from the Guidelines (MSAC 2005a). A number of studies have claimed that this area of MSAC’s scope is underdone (PC 2005; Elshaug et al 2007). The Productivity Commission (2005) concluded that while MSAC can re-assess existing MBS procedures, its ability to do so has been constrained by a lack of resources and by the type of references it has received. It notes:

Appropriate monitoring and review processes could help to improve the overall cost effectiveness of medical technologies on the MBS and Prostheses Schedule (PC 2005:266).

MSAC shares responsibility for reviewing existing MBS services with a number of consultative committees — the Pathology Services Table Committee4, the Medicare Benefits Consultative Committee5, and consultative committees on diagnostic imaging. In conjunction with DoHA, these consultative committees conduct ‘regular and periodic’ reviews of groups of professional services already listed on the MBS (MSAC 2005a:8). The processes and the nature of the analyses undertaken by these committees are not transparent, but the available information suggests they are not directly or explicitly required to consider cost effectiveness.6

It would be useful for governments to establish a transparent program of cost effectiveness assessments of health interventions currently available in Australia requiring review, transparently prioritised according to health and cost criteria. Systematic approaches would improve consistency of coverage, as well as ensuring that scarce health care resources are directed to those areas within the health care system where benefits can be maximised.

Professional services to private admitted patients and patients attending private providers in the community

Since the MBS only covers professional services to private admitted patients and patients attending private providers in the community (such as GPs or radiologists), HTAs by MSAC do not cover services to public patients in hospitals or pharmaceuticals. In addition,

3 The PDC Guidelines state that the purview of the PDC includes drawing to the attention of the Department possible amendments to Medicare Benefits Schedule (MBS) items used in the delivery of the prosthesis or device under review where review of the prosthesis or device suggests that such amendments should be considered. This is one means of identifying existing services in need of review, but whether this occurs in practice is unclear.

4 The Pathology Services Table Committee comprises representatives from the Australian Association of Pathology Practices, the Royal College of Pathologists of Australasia, the Australian Medical Association, the National Coalition of Public Pathology, Medicare Australia and the Department of Health and Ageing.

5 Membership of the Medicare Benefits Consultative Committee comprises representatives of the Department of Health and Aged Care, the Health Insurance Commission, the Australian Medical Association and the relevant craft or craft groups whose members have an interest in the items which are under review.

screening services are specifically excluded (MSAC 2005a). The fragmentation of HTA in Australia across jurisdictional and funding lines means there is potential for gaps and duplication, and scope for differences in access to medical services across different sectors or geographic regions (PC 2005). In particular, the evaluation of combined technologies (e.g., drug eluting stents) can be hampered by the organisation of HTA by technology type. The procedure and any associated equipment or tests, or devices and any associated drugs are generally considered separately, rather than (more sensibly) in an integrated manner (PC 2005). The need for a more integrated approach to HTA is increasing. As the PC (2005) argued:

*It is possible that the distinction between pharmaceuticals and medical devices will blur even further in the future. … If technology convergence continues, HTA agencies and committees will face an increasing number of ambiguous cases* (PC 2005:207-208).

### 1.3 MSAC ACTIVITY

The most appropriate means of allocating health resources is via sound economic analysis. The term ‘cost effectiveness analysis’ is typically understood by economists as a broad based examination of all of the associated benefits and costs of an illness or injury and the therapies available — not just the financial costs, or costs to government, and not limited to the impact on the health system alone, but including direct as well as indirect costs and the full range of potential benefits from cost savings to health related quality of life. As argued below in Chapter 3, ‘sound’ economic analysis needs to be broad based in order to adequately reflect the impact of an intervention on social welfare. Access and equity is also an explicit priority for MSAC investigation (MSAC 2005a:7).

Governments in the past have tended to target policy activity towards health sectors experiencing the fastest expenditure growth or which had the highest overall costs, or towards ameliorating highly prevalent diseases or illnesses with the largest individual burden of disease. While these are important considerations, priority should be given to interventions that generate the greatest benefit per unit cost in the broad sense of benefit and cost described above. The selection by the Australian Government of,

> “Australians have access to cost-effective medical services” (Australian Government Department of Health and Ageing, 2007:79).

as its third outcome indicator for the Department of Health and Ageing acknowledges this. However, given the number of assessments undertaken by MSAC, it would seem that a very small proportion of medical services currently available in Australia have been directly and demonstrably assessed for cost effectiveness.

On average, between 2001 and 2008 fewer than 20 submissions were made to MSAC each year (Table 1-1). Most submissions were made by the medical industry (Figure 1-1). Between 2002-3 and 2007-08, 54% of completed assessments resulted in some form of public funding (Table 1-2).

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8 Applications for assessment can be made by the medical profession, medical industry or others (MSAC 2005a).
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**Table 1-1: Who applies for MSAC assessment?**

<table>
<thead>
<tr>
<th>Year</th>
<th>Number submissions</th>
<th>Government</th>
<th>Medical organisation*</th>
<th>Medical industry</th>
<th>Individual</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001-2002(e)</td>
<td>11</td>
<td>3 27%</td>
<td>1 9%</td>
<td>6 55%</td>
<td>1 9%</td>
</tr>
<tr>
<td>2002-2003(d)</td>
<td>15</td>
<td>6 40%</td>
<td>2 13%</td>
<td>7 47%</td>
<td>0%</td>
</tr>
<tr>
<td>2003-2005(c)</td>
<td>39</td>
<td>12 31%</td>
<td>6 15%</td>
<td>21 54%</td>
<td>0%</td>
</tr>
<tr>
<td>2005-2006(b)</td>
<td>11</td>
<td>3 27%</td>
<td>1 9%</td>
<td>5 45%</td>
<td>2 18%</td>
</tr>
<tr>
<td>2006-2007(a)</td>
<td>18</td>
<td>5 28%</td>
<td>4 22%</td>
<td>9 50%</td>
<td>0%</td>
</tr>
<tr>
<td>2007-2008(a)</td>
<td>14</td>
<td>7 50%</td>
<td>1 7%</td>
<td>4 29%</td>
<td>2 14%</td>
</tr>
</tbody>
</table>

* Professional medical associations representing medical practitioners.

Source: (a) MSAC (2008a) (b) MSAC (2007a) (c) MSAC (2005c) (d) MSAC (2004) (e) MSAC (2003)

**Figure 1-1: Submissions to MSAC, by applicant type**

![Graph showing submissions to MSAC, by applicant type](source: (a) MSAC (2008a) (b) MSAC (2007a) (c) MSAC (2005c) (d) MSAC (2004) (e) MSAC (2003).)

**Table 1-2: Public funding results**

<table>
<thead>
<tr>
<th>Year</th>
<th>Assessments finalised</th>
<th>Recommendations formulated</th>
<th>Public funding</th>
<th>Proportion receiving public funding³</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001-2002(e)</td>
<td>16</td>
<td>na</td>
<td>na</td>
<td>63%</td>
</tr>
<tr>
<td>2002-2003(d)</td>
<td>13</td>
<td>na</td>
<td>4</td>
<td>31%</td>
</tr>
<tr>
<td>2003-2005(c)</td>
<td>25</td>
<td>na</td>
<td>15</td>
<td>60%</td>
</tr>
<tr>
<td>2005-2006(b)</td>
<td>21</td>
<td>25</td>
<td>15</td>
<td>60%</td>
</tr>
<tr>
<td>2006-2007(a)</td>
<td>14</td>
<td>15</td>
<td>8</td>
<td>53%</td>
</tr>
<tr>
<td>2007-2008(a)</td>
<td>12</td>
<td>14</td>
<td>9</td>
<td>64%</td>
</tr>
</tbody>
</table>

Note: (a) Includes interim and restricted funding

Source: (a) MSAC (2008a) (b) MSAC (2007a) (c) MSAC (2005c) (d) MSAC (2004) (e) MSAC (2003)
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MSAC activity appears insignificant in relation to the Medicare Benefits Schedule which incorporates thousands of services. For example, in 2007-08, the Australian Government paid $13.1 billion in Medicare benefits (Medicare Australia 2008). The MTAA has estimated 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 system (this figure does not include major medical equipment in the public health system) (MTAA 2009).

MSAC activity also appears insignificant compared with Pharmaceutical Benefits Advisory Committee (PBAC) activity. For example, over 200 submissions were made to PBAC in 2007, up from 149 submissions made to PBAC in 2004, and 151 PBAC submissions (72%) were recommended for funding in 2007, up from 105 in 2004. The total cost of PBS prescriptions for the year ending 30 June 2007 was $7.6 billion (DoHA 2008a), of which Australian Government expenditure amounted to 82.6%.

There are caveats to be kept in mind in comparing between MSAC and PBAC. First, MSAC is responsible for assessing safety, effectiveness and cost effectiveness whereas PBAC’s purview is effectiveness and cost. This likely reflects the different regulatory frameworks for market approval of pharmaceuticals and devices by the TGA. Furthermore, MSAC may commission its own evaluations and tends to rely heavily on these whereas PBAC draws on assessments prepared by applicants. Second, analysing the cost effectiveness of procedures and devices is often more complex and associated with more uncertain outcomes than HTA of pharmaceuticals (PC 2005).

- There is often a lack of high level scientific evidence on the efficacy of procedures and devices because it can be difficult to isolate the effects of the procedure or device from other elements of the care provided. In addition, it is not always possible to blind patients to procedures/devices because of ethical and cost considerations. Hence, the evidence available can be more prone to bias than that for pharmaceuticals and less easily generalised.

- The safety and effectiveness of devices depends not only on the device but also on the skill of the attending team of medical professionals.

- Physical infrastructure is often required for delivery of procedures/devices.

- Product life cycles of devices are often short.

That said, the reason why there are so few submissions to MSAC relative to the number of procedures on the MBS is likely to be related to the links between MSAC approval and funding streams. For devices in particular, the reimbursement pathway for services to private patients is different to that for clinicians, pharmaceuticals and prostheses and offers substantially less certainty. Funding of devices is only indirectly linked to MSAC approval. On the other hand, reimbursement of clinicians is directly linked to MSAC approval and reimbursement of pharmaceuticals is directly linked to PBAC approval. Existing MBS items with broad descriptors can cover modifications to procedures and devices, or new procedures or devices developed over time (‘item drift’). Given the often shorter product lifecycle for devices (compared with pharmaceuticals) together with long MSAC assessment timeframes, there is likely to be little benefit for device manufacturers in incurring the costs of an MSAC assessment.

The links between HTA and reimbursement are further discussed in Section 1.7.

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1.4 TYPES OF ANALYSIS UNDERTAKEN TO SUPPORT MSAC DECISIONS

MSAC does not always require a formal economic analysis (MSAC 2005a). Given the resource intensive nature of economic evaluations, individual determinations regarding the need for a full economic evaluation of a proposed service are made on a case-by-case basis (MSAC 2005a). MSAC notes:

*If estimates of costs and utilisation suggest that the use of the proposed service is likely to be extensive or have a very high cost, MSAC may require a formal economic evaluation (MSAC 2005a).*

In some instances, MSAC does not conduct an economic evaluation of the costs and benefits of an intervention, but only undertakes a financial analysis. A high proportion of MSAC recommendations are apparently based on financial analyses rather than broad based economic evaluation. In fact, the outline of MSAC summaries of application numbers 1101 onwards in Appendix B suggests that, of the 16 applications included in Appendix B there were at least nine applications where no formal economic evaluation was undertaken. In two applications covering more than one indication economic evaluations were undertaken only for some of the indications.

The fact that more than half of the assessments by MSAC are based on a narrow financial analysis is of concern because:

- Based on the sample of MSAC reports examined for this project (Appendix C), financial analyses are narrow, comprising projections of government budget implications if funding for the intervention was approved. As noted earlier, and argued below in Chapter 3, this is not consistent with maximisation of social welfare.
- When evaluation is limited to financial analysis, there is no benchmark (with reference to the associated benefits) for assessing what expenditure level is appropriate for a given intervention.
- The complexity and quality of the financial analyses vary, strongly suggesting a need for refinement and standardisation via development of guidelines.
- In some cases, MSAC has recommended funding based a simple financial analysis, and in other cases, despite financial analysis being undertaken, MSAC’s recommendation is that there is not enough evidence to recommend funding. This suggests some inconsistency in decision making.

Comments on the transparency of the summaries in Appendix B are in Box 1.
Box 1: Transparency of MSAC summaries

MSAC summaries could be better structured to improve readers’ understanding of the analysis supporting MSAC decisions and thus transparency. One page summaries of assessments of application numbers 1101 onwards are on the MSAC website and summarised here in Appendix B (in as many cases as possible, the cost effectiveness analysis section and recommendations section have been quoted).

— Each one page summary has a methodology section. These are inadequate as they relate only to the literature review undertaken and their quality is variable — sometimes the literature databases and method of review is explained, sometimes not. The method for economic analysis (if undertaken) is not included in the method section, but is summarised in the results section where the results of cost effectiveness analyses (CEA) are described. This also varies in quality across summaries.

— The consultation undertaken and the nature of expert/clinician input is not included.

— The modelling horizon is never discussed.

A systematic approach similar to that used in abstracts for peer reviewed journals would be preferable, including: objective, context, methods, results, conclusions — and where ‘methods’ incorporates the economic evaluation methods including health outcomes (eg, quality adjusted life year (QALY)), scope of costs, discount rate, modelling horizon etc.

No explanation is provided for procedures deemed ineligible for assessment. A paragraph explaining why the procedure was deemed ineligible would be preferable.

1.4.1 THE BASIS FOR MSAC DECISIONS

As noted earlier, high quality evidence of efficacy is generally more limited for devices than for other technologies (see Section 1.3) so techniques for analysis and decision making need to accommodate this. A cautious approach to recommending funding where evidence is lacking can lead to an overemphasis on avoiding Type I errors (making available medical procedures that are ineffective or even harmful) at the expense of patient access to medical procedures that are beneficial and efficient (Type II error) (O’Malley, 2006).

As raised in the case study on cardiac radiofrequency catheter ablation, even if evidence of efficacy is limited, an economic evaluation can:

- guide and scope the additional research required. Specifically, an early economic evaluation can identify those determinants of cost-effectiveness with the highest costs of uncertainty and hence where additional information would have the most value (Hartz and John 2009);

- lead to a recommendation for temporary reimbursement while efficacy data are collected. At present, however, there is no system for MSAC to facilitate collection of
Alternatives for ensuring data are collected systematically and independently include:

- Establishment of a procedure registry. Each registry would need to collect systematic information on patient quality of life outcomes as well as on adverse events and revision rates. Notably, it is not possible to isolate the performance of the device from the nature of the associated procedure or other elements of the care provided, so the registry needs to be set up to collect information about the procedure and associated care as well as the device. Specifically, it is important to annotate the reasons for device failures which may stem from the nature of the care provided rather than the device itself.

- Collection of evidence ‘in the field’. This approach was adopted by the Ontario Health Technology Advisory Committee (OHTAC). OHTAC recommends government funding to collect evidence if the basis for a decision is too uncertain.

The frequent lack of standard health outcome measures (e.g., QALYs or years of survival) for devices means that the decision making thresholds used for other health technologies (pharmaceuticals for example) are often not available. Common benchmarks used to determine public financing thresholds for ‘purchasing’ improved quality of life are:

- gross domestic product (GDP) per capita ie, around $52,000 in 2008-09 – in line with the WHO guidelines that interventions whose cost effectiveness is between one and three times GDP per capita per QALY gained (disability adjusted life year (DALY) averted) are cost effective and those less than GDP per capita per QALY gained (DALY averted) are very cost effective;\(^{10}\)

- $60,000, in line with the Department of Health and Ageing (DoHA 2003); or

- the value of a statistical life year of $151,000 in 2007\(^{11}\).

As argued previously, all of the potential benefits of a given intervention need to be taken into consideration as potential indicators of health related quality of life — providing further justification for broad based economic evaluations, rather than narrow financial analyses. The lack of standard health outcome measures needs to be accommodated via the development of government guidelines to MSAC on what thresholds are consistent with public preferences for investment in a given technology.

### 1.5 MSAC GUIDELINES FOR AN ECONOMIC EVALUATION

MSAC’s approach to economic evaluation in HTA is specified in a set of guidelines (MSAC 2005a). The approach is not fixed, but is expected to evolve over time based on the experience of and feedback from applicants and the MSAC.\(^ {12}\)

MSAC guidelines are less detailed than those of PBAC and there are some differences in approach. Differences may be expected given the different nature of pharmaceuticals and devices, including the types of evidence available (as discussed previously). While PBAC and MSAC indicate their preferred level of quality of evidence based on NHMRC (1999), MSAC is more likely than PBAC to need to accept and consider evidence that is not of the highest quality as specified by the NHMRC (1999). In addition, health outcome measures

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\(^{10}\) [http://www.who.int/choice/costs/CER_levels/en/index.html](http://www.who.int/choice/costs/CER_levels/en/index.html) Average GDP per capita for the Western Pacific region including Australia is shown as US$30,708 with three times that shown as US$92,123 in the year 2005.


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will not be able to be the same across all economic evaluations. While MSAC and PBAC can specify a preference (for example, for QALYs), measures requiring long term follow-up will generally not be available for devices, and so more flexibility is required.

However, some aspects of the approaches of the two bodies need to be the same.

- The perspective (societal) needs to be the same.
- The scope of costs included needs to be the same. As argued throughout this report, broad based economic evaluations are optimal, so ideally both PBAC and MSAC should include patient copayments in direct costs, and should also include indirect costs (eg, productivity losses) as comprehensively as possible. At the very least, MSAC and PBAC need to agree on, and specify to applicants, the types of indirect costs that are to be included.
- The methods for calculating both direct and indirect costs need to be the same. As an example for illustration purposes, both MSAC and PBAC should agree that productivity losses need to be estimated using the human capital approach — or some other economically robust approach as long as the approach is consistent.
- The same unit cost estimates for individual health services should be used by both PBAC and MSAC. Currently, PBAC details the unit cost estimates to be applied to various types of health services in its ‘Manual of resource items and their associated costs’ (Commonwealth Department of Health and Ageing 2002). In that report, the Government argued that use of the same unit cost estimates for the same services improves consistency of decision making, ensures results from economic evaluations are comparable and improves transparency.  

- MSAC and PBAC need to use the same approaches to the discount rates used.
- MSAC and PBAC guidance on the methods used to review the literature on effectiveness need to be specified and need to be the same, to facilitate consistency in approach and to ensure high standards. Notably, Petherick et al (2007) found the quality of the methods used to review the literature on effectiveness in assessments produced for MSAC to be highly variable.

The current MSAC guidelines appear lacking in relation to some key issues and this has implications for the quality of HTA and the consistency of decision making. Key elements of MSAC’s preferred economic approach are outlined in Table 1-3. Shortcomings are summarised as follows.

- There is no discussion of whether real versus nominal approaches to costs and projections are preferred, and if deflators are required, which deflators should be used.
- No preferred modelling horizon is specified.
- Access and equity is referred to in a number of MSAC publications, but it is not clear how these issues figure in MSAC analyses (including what weight they are given compared with say, government budgetary implications) or how frequently they are taken into account.

13 Unfortunately, available Australian estimates of the costs of outpatient and emergency department services, and community or allied health services are of variable quality and improved Australian data are required as an input to cost effectiveness modelling.
While there is a discussion of using efficacy bounds to generate upper and lower limits for cost effectiveness, readers of the guidelines are referred to standard texts for approaches to sensitivity analysis and probabilistic modelling.

It is unclear how MSAC defines a societal perspective. The list of cost items against ‘indirect or society costs’ in MSAC (2005a) only includes the cost of patient time in treatment or recovery and the costs of informal care. Systematic collection of information from members of the public affected by the relevant illness would be valuable in identifying the extra-health system impacts of disease (ie, indirect costs such as informal care).

The public is represented on MSAC, but reference to public preferences for alternative HTA outcomes is rare.

Methods for estimating depreciation and user cost of capital are not specified. As such, approaches may be vastly different across studies.

It is unclear whether patient copayments for MBS (or other) services are to be included and if so, how they should be estimated.

In summary, clear instructions are required by potential applicants to MSAC for assessment on the:

- perspective of the analysis;
- required methods for systematic literature reviews;
- economic evaluation tools;
- methods for selecting an appropriate comparator or comparators;
- modelling horizon;
- scope of costs (both direct and indirect);
- how to demonstrate access and equity issues and what weight to give these;
- unit cost estimates to apply to individual health services;
- methods of calculating direct costs including capital costs (depreciation, and user cost of capital), and indirect costs;
- discount rates;
- deflators to apply;
- methods for dealing with uncertainty; and
- how to structure a report to MSAC, including an abstract (or executive summary). Notably, consistency of structure also facilitates transparency and comparability across evaluations.
<table>
<thead>
<tr>
<th>Economic method</th>
<th>MSAC approach</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost effectiveness analysis (CEA), cost utility analysis (CUA), cost benefit analysis (CBA), cost minimisation analysis (CMA). The most appropriate economic evaluation tool will depend on the claim being made for the new service, the nature of the proposed service, and the available data. An incremental (marginal) approach is required.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Access and equity</td>
<td>MSAC (2005a) suggests this is driven by applicants ‘who may wish this’ to be taken into account. Examples of access and equity issues include provision of a professional service in a way which targets an at risk population, the availability (or lack) of alternative services in a particular region, and the availability (or lack) of alternative treatment(s) for a particular disease or condition.</td>
<td></td>
</tr>
<tr>
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<td>MSAC (2005a) suggests this is driven by applicants ‘who may wish this’ to be taken into account. Examples of access and equity issues include provision of a professional service in a way which targets an at risk population, the availability (or lack) of alternative services in a particular region, and the availability (or lack) of alternative treatment(s) for a particular disease or condition.</td>
<td></td>
</tr>
<tr>
<td>Modelling horizon</td>
<td>Estimated utilisation of the proposed service for at least the first two full years. The change in the extent of use of other services should also be estimated.</td>
<td></td>
</tr>
<tr>
<td>Modelling horizon</td>
<td>Estimated utilisation of the proposed service for at least the first two full years. The change in the extent of use of other services should also be estimated.</td>
<td></td>
</tr>
<tr>
<td>Discounting</td>
<td>If the benefits and costs are likely to extend over a number of years, they should be discounted. Current economic practice is to discount five per cent per year. If other options are more appropriate, justify the reasons.</td>
<td></td>
</tr>
<tr>
<td>Discounting</td>
<td>If the benefits and costs are likely to extend over a number of years, they should be discounted. Current economic practice is to discount five per cent per year. If other options are more appropriate, justify the reasons.</td>
<td></td>
</tr>
<tr>
<td>Comparator</td>
<td>Defined as the current service most likely to be replaced or supplemented by the new service. If there is no therapy replaced as a result of the new service, describe current best conventional care. To select the appropriate comparator, applicants can review the MBS to identify possible comparators; review the literature to identify possible comparators; and consult with medical professionals to determine the current management of the condition. In unusual cases, there may be more than one comparator. In this case, applicants are to list these comparators, identify which is considered to be the main comparator for the purposes of MSAC’s assessment, and justify the choice.</td>
<td></td>
</tr>
<tr>
<td>Comparator</td>
<td>Defined as the current service most likely to be replaced or supplemented by the new service. If there is no therapy replaced as a result of the new service, describe current best conventional care. To select the appropriate comparator, applicants can review the MBS to identify possible comparators; review the literature to identify possible comparators; and consult with medical professionals to determine the current management of the condition. In unusual cases, there may be more than one comparator. In this case, applicants are to list these comparators, identify which is considered to be the main comparator for the purposes of MSAC’s assessment, and justify the choice.</td>
<td></td>
</tr>
</tbody>
</table>

Unlike pharmaceuticals, CUA should not be considered the gold standard in the evaluation of procedures and devices. This is due to differences in the level of evidence generally available, costs, and outcome types.

Access and equity is referred to in a number of MSAC publications, but it is not clear how these issues are weighted or how frequently they are taken into account.

No preferred modelling horizon is specified. The horizon should cover all expected changes in benefits and costs associated with the new technology.

The choice of only one comparator when there are many plausible comparators is problematic as alternative comparators may lead to alternative decisions. All comparators should be included in the economic evaluation.
**TABLE 1-3: SUMMARY OF MSAC GUIDELINES FOR ECONOMIC ASSESSMENT CONTINUED**

<table>
<thead>
<tr>
<th>MSAC approach</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Perspective of evaluation</strong></td>
<td>In most instances, a <em>societal perspective</em> will be preferable, as it takes into account all costs incurred, such as 'patient time costs and economic costs of delayed recovery etc'. Justification for using a more limited perspective (e.g., Commonwealth Government, hospital etc) should be provided. Although a societal perspective is advocated, a review of assessment reports suggests there are economic evaluations that have used a more narrow perspective. Furthermore, it is unclear what the 'economic costs of delayed recovery etc' are and whether these include potential adverse consequences of illnesses for labour force participation, employment and hours worked, and other indirect costs such as aids and equipment. The list of cost items against 'indirect or society costs' only includes cost of patient time in treatment or recovery and costs of informal care. Systematic collection of information from members of the public affected by the relevant illness would be valuable in identifying the extra-health system impacts of disease (i.e., indirect costs such as informal care).</td>
</tr>
<tr>
<td><strong>Levels of evidence</strong></td>
<td>It is acknowledged that medical interventions such as operative procedures are seldom investigated in the rigorous manner that has become common for drugs. Consequently, much of the evidence for a new intervention may fall into level III or level IV categories. MSAC will give little weight to level IV, particularly if there has been no attempt to eliminate selection bias. A large number of MSAC applications have been rejected due to 'insufficient' evidence. This represents an incomplete evaluation and leads to bias towards health technologies where decisions are simple. Instead, all types of evidence should be evaluated and an economic evaluation should be conducted on the evidence at hand using theoretically defensible evaluation tools such as decision analytic modelling, sensitivity analysis and scenario analysis.</td>
</tr>
</tbody>
</table>

Continued next page
### Table 1-3: Summary of MSAC Guidelines for Economic Assessment Continued

<table>
<thead>
<tr>
<th>MSAC approach</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital costs</td>
<td>The costs of major capital equipment are to be included such as purchase price, estimated life of equipment, cost of borrowing, annual maintenance costs, estimated volumes per annum. Methods for estimating depreciation and user cost of capital are not specified. Depreciation in particular may be vastly different across studies.</td>
</tr>
<tr>
<td>Direct treatment costs</td>
<td>To include proposed professional fee, cost of associated medical services, cost of associated diagnostic and investigational services, cost of hospital services, cost of community based health services, any other costs. There is no guidance on whether adjustments should be made for health care services that do not represent the true opportunity cost of using the resource (for example, subsidised services).</td>
</tr>
<tr>
<td>Medical services</td>
<td>Medical services are considered to be professional services provided by a qualified medical practitioner. Relevant MBS fee to be used. When estimating the costs of salaried medical practitioners providing care to public patients, representative costs should be obtained from hospital accounting information or the State/Territory health authority. It is unclear whether patient copayments for MBS services are to be included and if so, how they would be estimated.</td>
</tr>
<tr>
<td>Hospital care</td>
<td>The costs of hospital care can be estimated in a number of ways, and the precision of the estimate needed will depend on how large those costs are in comparison with other costs of care entailed in the proposed service. Cost estimates at the diagnosis related group level are readily available (ADHSH 1995), and daily costs may be inferred by dividing the episode cost by the reported average length of stay. DRG classes usually combine a range of primary diagnoses. However, when treatment costs vary across diagnoses, data on costs at the DRG level may overestimate or underestimate the costs of care. Such costs may also underestimate other in-hospital costs of care (eg patients requiring intensive care may be reassigned to other DRGs). Alternative sources of cost data include micro-costing of interventions (usually undertaken in the course of clinical trials) or data from hospital clinical costing systems. Care should be taken with all such data to avoid double counting of costs, particularly those incurred in the inpatient sector.</td>
</tr>
</tbody>
</table>
### Table 1-3: Summary of MSAC Guidelines for Economic Assessment Continued

<table>
<thead>
<tr>
<th>Non-inpatient and other forms of health care</th>
<th>MSAC approach</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Applicants are directed to the Manual of Resource Items (Referred to in the PBAC guidelines). MSAC does however state that these costs can be estimated on the basis of a specific micro-costing study, or from the clinical costing system data.</td>
<td>The Manual of Resource Items referred to in the PBAC guidelines relies on a costing study which is no longer current and the method of inflating these costs to the present period is not specified. Further, many of the costs (eg, for emergency department services) appear substantially lower than estimates from other sources (such as the National Hospital Cost Data Collection).</td>
</tr>
<tr>
<td>Measuring health benefits</td>
<td>A cost per unit outcome is required for the proposed treatment and the alternative, ie, $AU per cure, $AU per quality adjusted life-year, or $AU per patient free of disease at one year, depending on the condition and the data available.</td>
<td>While a member of the public is represented on MSAC, consultation with or collection of information from the public on social valuations of the procedures or devices investigated is rare.</td>
</tr>
<tr>
<td>Incorporating uncertainty</td>
<td>Sensitivity analyses should be conducted so that the effects of estimates and assumptions on the outcome of the economic evaluation can be quantified. There are a number of possible ways to carry out sensitivity analyses, and there are standard texts on economic evaluation. In evaluating the effects on the model of the uncertainty of clinical outcomes, a helpful and relatively simple approach is to use the upper and lower bounds of the estimate of the 95% confidence limits of the difference in outcomes (effects) achieved in the trials. To evaluate the effect of uncertainty in extrapolating costs, it may be helpful to carry out sensitivity analyses that vary individual costs in the model, and to construct 'best' and 'worse' case scenarios.</td>
<td>While there is a discussion of using the efficacy bounds to generate upper and lower limits for cost effectiveness, guidelines simply refer to standard texts for approaches to sensitivity analysis and probabilistic modelling.</td>
</tr>
</tbody>
</table>

Source: MSAC (2005a) and Access Economics
1.6 TIMEFRAMES FOR MSAC ASSESSMENTS

The lengthy time frames for MSAC approval were raised by the MSAC review (MSAC 2005b) and the PC (2005). It is apparent that the initiatives implemented as a result of the MSAC Review (MSAC 2005b) have not been successful in reducing the timeframe for MSAC assessments. MSAC (2005b) reported that MSAC assessments to May 2005 had taken an average of thirteen months to complete. Unfortunately, the definition of ‘time to complete’ was not documented. Subsequent MSAC Performance Reports used a consistent definition of time to completion and can be compared:

- In 2005-2006, 21 assessments took an average of 18 months to complete (MSAC 2007a);
- In 2006-2007, 14 assessments took an average of 18 months to complete (MSAC 2008a); and
- In 2007-2008, 12 assessments took an average of 17 months to complete (MSAC 2008a).

MSAC assessment timeframes remain lengthy, potentially delaying access by Australians to cost effective interventions.

1.7 USE OF HTA IN REIMBURSEMENT

After the Minister for Health and Ageing approves Medicare funding for a new medical technology or procedure, various ‘consultative’ committees are responsible for developing new or modified MBS item descriptors, and negotiating fees for new MBS items (MSAC 2005a). Again, the process is not transparent. There does not appear to be a requirement for fees and charges to be set with reference to cost effectiveness thresholds determined by relevant MSAC assessments, although ‘consultative’ committee members are likely to refer to MSAC reports. In addition, MSAC is not required to provide specific guidance to governments and insurers on the range of MBS or other fees that ensure services are cost effective.

For prostheses and devices, the Prostheses and Devices Committee (PDC) makes recommendations to the Minister for Health and Ageing about appropriate benefits to be paid for products on the Prostheses List (PL). In recommending benefit levels, the objective is to ensure that the prosthesis or device receives a fee commensurate with its clinical effectiveness relative to that of other prostheses or devices on the list. DoHA notes:

“In making its recommendations, the PDC considers the safety, clinical effectiveness and cost relative to the clinical effectiveness of other products (Australian Government Department of Health and Ageing 2008:6).

Demonstration of improved clinical outcomes for a product can be used to support a recommendation for a higher benefit. PDC assessments are not published but it seems no cost effectiveness analysis is required.

---

14 The MSAC assessment period is considered to be the time between receipt of a submission by the MSAC secretariat and the Minister’s decision on MSAC’s recommendation (MSAC 2008).
The PDC assesses products for listing on the PL. Listing is critical for certainty of funding in the private sector because insurance companies are required to pay a benefit for products on the list. The criteria for listing products are in Appendix A. Notably, the criteria include some artificial boundaries which can endanger access by Australians to products which are not considered by the PDC to fit within the criteria. While clinicians are able to use prostheses not on the PL, negotiating funding is substantially more difficult. In the private sector, exceptional funding must be sought from the insurer. In the public sector, funding is driven by a range of factors including cost and the need to undergo tendering and procurement processes (Doyle 2007).

To be listed, a Medicare benefit must be payable in respect of the professional service associated with the provision of the product. Hence, sponsors of new products not covered by existing MBS items must apply to MSAC and obtain a recommendation that public funding is supported before their product is eligible for listing on the PL.

For non-prosthetic devices in particular, unlike other sectors of the health system, there is no well-defined reimbursement pathway for services to private patients. Clinicians, pharmaceuticals and prostheses all have certainty of funding for services to private patients once listed on the relevant schedule (the MBS for clinicians, the pharmaceutical benefits schedule (PBS) for drugs or the PL for prostheses), whereas non-prosthetic devices are treated differently. Funding of devices is only indirectly linked to MSAC approval.

- First, via the requirement for listing on the PL that a Medicare benefit must be payable in respect of the professional service associated with the provision of the prosthesis.
- Second, via theatre banding (the structure guiding payments for resources used in operating theatres) or casemix payments which are often linked to the existence of an MBS item number.

Overall, the system for setting fees for private sector medical services is not consistently linked to assessments of cost effectiveness. This means that health care resources are not necessarily allocated to interventions with the highest benefit per unit cost. In addition, as noted by the Productivity Commission, there is no formalised process to translate findings and information from technology assessment into practice guidance (PC 2005). There needs to be a direct link between the HTA process, funding streams and the development of guidelines, to ensure cost effective procedures are used in everyday medical practice.

1.8 SUMMARY AND CONCLUSION

A review of current MSAC’s current activity and processes suggests the following:

- MSAC’s current emphasis appears to be on new, rather than existing, technologies and procedures. MSAC shares responsibility for reviewing existing MBS services with a number of consultative committees who are not apparently directly required to conduct assessments of cost effectiveness. It would be useful for governments to establish a transparent program of cost effectiveness assessments of health interventions currently available in Australia requiring review.

- Since the MBS only covers professional services to private hospital patients and patients attending private providers in the community, HTAs by MSAC do not cover services to public patients or pharmaceuticals, and screening services are specifically excluded. The fragmentation of HTA in Australia allows scope for gaps and duplication, and for differential access to medical services. The evaluation of combined technologies can be hampered by the current way HTA is organised.
The most appropriate means of allocating health resources is via sound, broadly based economic analysis. However, relative to the size of the MBS, a very small proportion of medical services currently available in Australia have been directly and demonstrably assessed for cost effectiveness. PBAC undertakes assessments at a much higher rate than MSAC. However, MSAC and PBAC are not directly comparable because cost effectiveness analysis of devices is frequently likely to be more complex than of pharmaceuticals because the difficulties gathering evidence of efficacy of devices. That said, the lower activity rates of MSAC are likely to stem partly because funding (at least of devices) is not directly linked to MSAC approval.

MSAC frequently does not conduct an economic evaluation of the costs and benefits of an intervention, but undertakes a narrow financial analysis, generally comprising projections of government budget implications if funding for the intervention was approved. This is of concern because sound analysis of the impact of an intervention on social welfare requires broadly based economic analysis. Further, when only financial analysis is undertaken, there is no benchmark (with reference to benefits) for assessing what expenditure level is appropriate. Lastly, the complexity and quality of the financial analyses conducted by MSAC vary and there is a need for refinement and standardisation via development of guidelines.

Since evidence of efficacy is generally more limited for devices than for other technologies, techniques for analysis and decision making need to accommodate this. A cautious approach to recommending funding where evidence is lacking can lead to an overemphasis on avoiding Type I errors (making available medical procedures that are ineffective or even harmful) at the expense of patient access to medical procedures that are beneficial and efficient (Type II error). Even if evidence of efficacy is lacking, economic evaluation can identify where additional information would have the most value and lead to a recommendation for temporary reimbursement while efficacy data are collected. However, MSAC then needs to facilitate the collection of data.

The frequent lack of standard health outcome measures for devices means that the decision making thresholds used for other health technologies (pharmaceuticals for example) are often not available. The lack of standard health outcome measures needs to be accommodated via the development of government guidelines to MSAC on what thresholds are consistent with public preferences for investment in a given technology.

MSAC applicants need clear instructions on MSAC requirements for economic evaluations. The current guidelines are lacking in specificity in key areas. While there are necessary differences between MSAC and PBAC because of differences in available evidence, there are some important areas where the MSAC and PBAC approaches need to be the same. Consistency will ensure comparability and transparency. Areas where consistency is needed include perspective, scope of costs, method of calculating both direct and indirect costs, the unit cost estimates to use for health and other services, approaches to discount rates, and methods for undertaking systematic literature reviews. Instructions are required for applicants on these as well as other issues, including how to structure an economic evaluation report.

MSAC assessment timeframes remain lengthy, potentially delaying access by Australians to cost effective interventions.

For non-prosthetic devices in particular, unlike other sectors of the health system, there is no well-defined reimbursement pathway for services to private patients and funding of devices is only indirectly linked to MSAC approval. Overall, the system for setting fees for private sector medical services is not consistently linked to assessments of
cost effectiveness. This means that health care resources are not necessarily allocated to interventions with the highest benefit per unit cost. In addition, there is no formalised process to translate findings and information from HTA into practice. There needs to be a direct link between the HTA process, funding streams and the development of guidelines, to ensure cost effective procedures are used in everyday medical practice.

In conclusion, there are shortcomings associated with MSAC’s current scope, methods, activity levels and timeframes for assessment. In addition, the analytical basis for decision making, including financial analysis methods as well as economic evaluation methods, needs to be refined. Broadly based economic evaluation is the most appropriate method for guiding the allocation of scarce health resources towards efficient health technologies. However it needs to be conducted using systematic and coordinated processes, and resourced appropriately.
2. INTERNATIONAL ECONOMIC EVALUATION FRAMEWORKS

Worldwide, there are more than 40 public sector agencies involved in assessing health care technologies (Walley 2007). The institutions and processes through which HTA is carried out vary considerably. This is because they all take into consideration the context of the values and priorities of the society, the form of decision making structures and the health care resources available.

Accordingly, different countries may not necessarily come to the same conclusions on a particular technology, even if the same assessment methods and a similar evidence base are used. This highlights the need for transparency in the processes by which the conclusions are reached, and the evidence on which they are based, to allow the reasons for the disparity in HTA recommendations to be identified. Furthermore, with the large number of countries that use HTA, and the corresponding differences in required evidence, economic evaluation methodologies, and application of HTA outcomes, there is an ongoing need for harmonisation between countries (Hutton et al 2008).

Although there are continual advancements in discussions on the need for harmonisation in HTA practices, little research has been done on exactly how to achieve harmonisation in methodology and evidence standards. However, Hutton et al (2008) has outlined key areas for international harmonisation of HTA.

- Clinical evidence, in particular, was deemed to offer the most immediate opportunities for harmonisation because clinical data are usually transferable across social and demographic boundaries.

- The context specific nature of economic evidence means that the capacity for harmonisation is less than that of clinical evidence. However, the harmonisation of outcome measurements, namely the measurement and valuation of health benefits, may provide some gains.

- Despite the guidelines provided by INAHTA on ethical and legal issues in HTA, the context-specific nature of this area of HTA ensures that identical ethical positions across countries would not be expected. However, with the lack of current information on legal and ethical issues in HTA there could be advantage in developing a common set of issues to address.

- Finally, there is potential for agreement on key principles of decision making in HTA processes. For example, transparency, right of appeal, expectation of an explanation of the basis of a decision, and the right of stakeholders to submit evidence.

Further scope for harmonisation across international HTA processes also exists in priority setting. Garcia-Altes et al (2004) argued there is a lack of explicit, quantitative methods available to develop a prioritisation process for assessment of health technologies (using societal criteria). This is evidenced by the significant variability that exists in the methods for prioritising technologies for assessment across HTA agencies, which may reflect differences in reporting structures, healthcare priorities, or societal values (Noorani et al 2007).

One large gain from HTA harmonisation lies in the reimbursement of health technologies. Manufacturers regard reimbursement requirements as the ‘fourth hurdle’ to market access, after evidence of quality, efficacy and safety (Hutton et al 2006). Due to the differences in...
reimbursement decision making systems, manufacturers and sponsors of health technologies encounter different decision making procedures, with varying information requirements, when seeking government reimbursement. Improved knowledge of other countries’ reimbursement practices and subsequent standardisation and transferability across countries may enhance the efficiency of existing systems (Hutton et al 2006).

The purpose of this chapter is to examine HTA economic evaluation frameworks adopted by other agencies, how their strengths can be incorporated, and their weaknesses avoided, when developing an improved economic evaluation framework for Australia. Of course Australians, and the Australian health care system, are unique, so any harmonisation with international economic evaluation frameworks must also consider the environment within which HTA takes place in Australia. The agencies include:

- Canadian Agency for Drugs and Technologies in Health (CADTH);
- National Institute for Clinical Excellence (NICE) in the United Kingdom; and
- European network for Health Technology Assessment (EUnetHTA).

A number of specific components within each economic evaluation framework were investigated. These include:

- perspective of the economic evaluation;
- selecting a comparator;
- selecting and using an economic evaluation tool;
- measuring outcomes and costs;
- time horizon;
- discounting;
- incorporating uncertainty; and
- incorporating equity

A summary comparison between each agency’s HTA economic evaluation framework is presented in Table 2-1. More detailed explanations of specific components within each agency’s economic evaluation framework are presented below.
<table>
<thead>
<tr>
<th></th>
<th>CADTH</th>
<th>NICE</th>
<th>EU netHTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perspective</td>
<td>Publicly funded health care system but wider perspective if costs are</td>
<td>- NHS and PSS (publicly funded health care system).</td>
<td>Societal perspective. Other possible perspectives include:</td>
</tr>
<tr>
<td></td>
<td>expected to impact results.</td>
<td>- Include impacts on other government bodies separately if approved</td>
<td>- health care sector;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>by the Department of Health</td>
<td>- third party payer;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- hospital; and</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- patient.</td>
</tr>
<tr>
<td>Comparator</td>
<td>The alternative that is most likely to be substituted.</td>
<td>Based on routine and best practice in NHS and natural history of condition without suitable treatment.</td>
<td>Alternative technologies that often include current practice or 'no intervention'.</td>
</tr>
<tr>
<td></td>
<td>- Most commonly used treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Includes ‘do nothing’ treatment strategies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Economic evaluation tools</td>
<td>- CUA when differences in HRQL between comparator and intervention.</td>
<td>CUA and CEA preferred. In making a decision on results, cost</td>
<td>- CMA when technologies are equally effective.</td>
</tr>
<tr>
<td></td>
<td>- CEA when CUA unsuitable.</td>
<td>effectiveness acceptability curves should be presented, along with:</td>
<td>- CEA when effectiveness of technologies is different.</td>
</tr>
<tr>
<td></td>
<td>- CMA when important patient outcomes are comparable across</td>
<td>- the probability that the treatment is cost effective at £20,000 to £30,000 per QALY gained; and</td>
<td>- CUA when HRQL is an important health outcome and/or activities across specialties or departments in the health care sector are compared.</td>
</tr>
<tr>
<td></td>
<td>comparators and intervention.</td>
<td>- the probability that the treatment is not cost effective</td>
<td>- CBA when non-health effects are also of importance; or only one technology is assessed; or there is a wish that the individual life’s are valued in monetary units; or activities across different sectors in society have to be compared.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measure</td>
<td>CADTH</td>
<td>NICE</td>
<td>EU netHTA</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>-------------------------------------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td><strong>Measuring benefits and costs</strong></td>
<td>- Final health outcomes</td>
<td>All direct health care effects</td>
<td>Societal costs including direct costs, indirect costs and lost production</td>
</tr>
<tr>
<td></td>
<td>- Important clinical outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Surrogate outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Time horizon</strong></td>
<td>Long enough to capture all the significant differences in costs and benefits</td>
<td>Should capture all disparities in costs and outcomes</td>
<td>Not specified</td>
</tr>
<tr>
<td><strong>Discounting</strong></td>
<td>5% for health outcomes and costs. However, 0% and 3% should be used in the sensitivity analysis</td>
<td>3.5% for health outcomes and costs</td>
<td>Not specified</td>
</tr>
<tr>
<td><strong>Incorporating uncertainty</strong></td>
<td>Sensitivity analysis (DSA or PSA); stratified analysis; one-way, multi-way or extremes analysis; model validation methods</td>
<td>Sensitivity analysis to:</td>
<td>DSA and/or PSA</td>
</tr>
<tr>
<td></td>
<td>- investigate uncertainty around structural assumptions;</td>
<td>- deal with uncertainty around selection of data sources;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- explore effects of parameter uncertainty.</td>
<td>- explore effects of parameter uncertainty.</td>
<td></td>
</tr>
<tr>
<td><strong>Incorporating equity</strong></td>
<td>Analysis of equity issues should be made within the decision process.</td>
<td>Social value judgements outlined by NICE should be applied</td>
<td>Principles of justice and equity outlined by EU netHTA should be applied to the decision making process</td>
</tr>
</tbody>
</table>

Source: Access Economics
2.1 CADTH

The Canadian Agency for Drugs and Technology in Health (CADTH) (previously Canadian Coordinating Office for Health Technology Assessment (CCOHTA)) was developed to facilitate coordination of activities and avoid unnecessary duplication across provinces in order to improve the quality of HTA in Canada (Menon and Topfer 2000). CADTH employs the Guidelines for the Economic Evaluation of Health Technologies: Canada (CADTH 2006) to assist in the production of credible and standardised economic information that is relevant and useful to decision makers in Canada's publicly funded health care system.

2.1.1 PERSPECTIVE OF THE ECONOMIC EVALUATION

According to CADTH, the perspective chosen should be that of the publicly funded health care system (see Table 2-2). The costs associated with adopting a wider perspective should be reported separately when they are likely to have an impact on the results of the analysis. Situations include when an intervention permits patients to return to work sooner than otherwise, an intervention results in savings or additional costs to other public sector agencies, or an intervention shifts costs to patients and their families.

2.1.2 SELECTING A COMPARATOR

In the CADTH guidelines, the comparator is defined as the alternative that is most likely to be substituted by the new intervention if it is adopted. For the Reference case, the comparator should be the most commonly used treatment in clinical practice for the condition (usual care). However, in some cases, doing nothing or ‘watchful waiting’ may be appropriate comparators.

In the case where more than one current intervention would be substituted all interventions should be individually compared to the potential new intervention being studied. If, however, usual care does not reflect the level of care that is recommended or that is clinically most effective, recommended or appropriate care must also be included with usual care when it is considered a feasible and relevant option.

In addition, some interventions may require comparison between treatment strategies rather than individual products. Consequently, the evaluation must distinguish between situations where the technology is an additional element in the strategy, a different treatment sequence, or an alternative that would replace another element in the strategy if the intervention is adopted. Including potential future comparators is also recommended, particularly lower cost technologies that may enter the market within the timeframe relevant to the analysis.

2.1.3 SELECTING AND USING AN ECONOMIC EVALUATION TOOL

In an economic evaluation, a cost-utility analysis (CUA) should be used where substantial differences in health-related quality of life (HRQL) between the intervention and comparators have been shown.

A cost-effectiveness analysis (CEA) should be used when a CUA is an unsuitable. The analysis should apply a final outcome (e.g. life-years gained) or an important patient outcome. Use of a surrogate outcome is only appropriate if it has a validated link with one of...
An improved HTA economic evaluation framework for Australia

those outcomes. A CEA may be an appropriate secondary analysis when the use of one important patient outcome measure (other than a quality-adjusted life-year gained) in the denominator is warranted. However, there must be a meaningful difference in such an outcome.

If the evidence shows that patient outcomes of the intervention and comparators are the same, a cost-minimisation (CMA) is appropriate. However, justification for choosing a CMA must be included. A cost-benefit analysis (CBA) should only be considered as a secondary analysis. Explanation of the steps taken to change outcomes into monetary values must be incorporated. Finally, a cost-consequence analysis (CCA) should only be used as an intermediate step in the use of other types of economic evaluations in order to enhance reporting transparency.

2.1.4 MEASURING OUTCOMES AND COSTS

Outcomes that are used to measure the health effects of interventions can be classified into three types, including:
- final outcomes that relate directly to the length and quality of life and include Quality Adjusted Life Years (QALYs) gained, deaths prevented and life years gained;
- important clinical outcomes that are important to the health of the patient and include disease-specific events such as myocardial infarction and stroke; and
- surrogate outcomes that measure how a patient functions, feels or survives through a laboratory measurement or a physical sign that is used as a substitute for a clinical endpoint (for example, blood pressure or cholesterol levels).

The preferred measure for health outcomes is the QALY because of its simplicity, clarity, ease of application, and face validity. Preferences (utilities) can be measured directly or indirectly. Where preferences are measured directly, the evaluation should use the standard gamble or time trade-off approaches. The visual analogue scale is not considered an appropriate approach due to its biases.

Where preferences are measured indirectly, methods can be specific (for example, Western Ontario-McMaster Osteoarthritis Index) or generic (for example, the EQ-5D and the SF-6D). Due to the limited applicability of specific and generic measures, the preferred approach is preference-based measures.

Table 2-2 explains the types of costs associated with the individual perspectives of economic evaluations. The perspective adopted by CADTH encompasses direct costs to the publicly funded health care system, direct costs to patients and their families and time costs to patients and their families. Notably, it does not include loss/gain in productivity or direct costs to publicly funded services other than health care.
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**Table 2-2: Perspectives of Economic Evaluations and Their Related Costs**

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Types of Cost</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public Payer</strong></td>
<td>Direct costs to publicly funded services (other than health care)</td>
<td>Income transfer payments paid (such as disability benefits)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Social services (such as home help)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Special education</td>
</tr>
<tr>
<td><strong>Publicly Funded Health Care System</strong></td>
<td>Direct costs to publicly funded health care system</td>
<td>Drugs, medical devices</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Equipment, space, facilities and associated overhead costs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aids and appliances paid by government</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Health care providers and other staff</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medical services, including procedures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hospital services</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Emergency visits</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ambulance services</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diagnostic, investigational and screening services</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rehabilitation in a facility or at home</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Community-based services (such as home care, social support)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Long-term care in nursing homes</td>
</tr>
<tr>
<td><strong>Publicly Funded Health Care System</strong></td>
<td>Direct costs to patients and their families</td>
<td>Out-of-pocket payments for drugs, dental treatment, walking aids</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cost of travel for treatment, paid caregivers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Premiums paid to, and benefits received from, private insurers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Income transfer payments received (such as disability benefits)</td>
</tr>
<tr>
<td><strong>Publicly Funded Health Care System</strong></td>
<td>Time costs to patients and their families</td>
<td>Patient’s time spent for travel and receiving treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lost time at unpaid work (such as housework) by patient and family caring for patient</td>
</tr>
<tr>
<td><strong>Publicly Funded Health Care System</strong></td>
<td>Productivity costs</td>
<td>Lost productivity due to reduced working capacity, or short-term or long-term absence from work</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Costs to employer to hire and train replacement worker for patient</td>
</tr>
</tbody>
</table>

Source: CADTH (2006)
2.1.5 **TIME HORIZON**

The time horizon of an economic evaluation should be long enough to capture all the significant differences in costs and outcomes between the intervention and comparators. Extension of the time horizon beyond the period where there are no meaningful differences, such as when the costs and outcomes of alternatives converge, is unnecessary. For consistency, the same time horizon should be applied to costs and outcomes. In analyses of chronic conditions and situations where alternatives have inconsistent effects on mortality, a lifetime time horizon should be used as a default.

2.1.6 **DISCOUNTING**

Costs and health technology outcomes should be discounted to present values at a standard rate of 5%. To show the impact of discounting, a rate of 0% should also be analysed. In addition, for a comparison with published evaluations in other jurisdictions, a 3% discount rate must be used in a sensitivity analysis. All benefits and costs should be estimated in real values.

2.1.7 **INCORPORATING VARIABILITY AND UNCERTAINTY**

CADTH guidelines define variability and uncertainty separately. Variability indicates the known disparities in values that are linked with particular differences in circumstances, such as alternative parameter values or modelling methods. Uncertainty occurs when the true value of a parameter is unknown. Table 2-3 explains the different approaches recommended for managing variability and uncertainty in an economic evaluation.

**Table 2-3: Recommended approaches for handling variability and uncertainty**

<table>
<thead>
<tr>
<th>Category</th>
<th>Type of variability or uncertainty</th>
<th>Recommended approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variability</td>
<td>Differences in clinical practice patterns between geographic areas or settings</td>
<td>Sensitivity analysis</td>
</tr>
<tr>
<td></td>
<td>Variability in patient population (patient heterogeneity)</td>
<td>Stratified analysis</td>
</tr>
<tr>
<td></td>
<td>Model uncertainty: analytical methods, model structure, assumptions, data sources</td>
<td>DSA using alternative assumptions, one-way, multi-way, threshold, or extremes analysis; and model validation methods</td>
</tr>
<tr>
<td>Model-based uncertainty</td>
<td>Parameter uncertainty</td>
<td>DSA using one-way, multi-way, threshold, or extremes analysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PSA using Monte Carlo simulation is encouraged</td>
</tr>
</tbody>
</table>

Source: CADTH (2006)

2.1.8 **INCORPORATING EQUITY**

Equity is defined as fairness in the allocation of resources, treatments, or outcomes among individuals or groups.
Economic evaluations should present as much information on the various features of equity as possible. The decision maker is then responsible for supplying the necessary weights or judgements to establish the redistribution of resources in various sectors of society if the new intervention is implemented.

The identity of the recipient may be a critical factor in determining the social appeal of providing an intervention or program. The consideration of equity requires that comparisons be made between social groups with different levels of social disadvantage. To avoid misunderstanding, the analysis of the distributional issues should be kept separate from the economic evaluation.

2.2 NICE

The National Institute for Clinical Excellence (NICE) was established in 1999 to advise the NHS in England and Wales on the clinical effectiveness, cost-effectiveness and service impact of new and established healthcare technologies (Taylor 2002). HTAs are a core function of NICE, through its utilisation of HTA in issuing guidance on whether a treatment can be recommended for routine use in the NHS (Woods 2001).

The Guide to the methods of technology appraisal (NICE 2008a) outlines the principles and methods of health technology assessment and appraisal within the context of the NICE appraisal process. It provides a guide for all organisations, manufacturers, and other types of sponsors considering submitting evidence to its technology appraisal program.

2.2.1 PERSPECTIVE OF THE ECONOMIC EVALUATION

The objective of the Institute is to provide guidance on the efficient use of available government resources. Consequently, the perspective adopted on costs should be that of the National Health Service (NHS) and personal social services (PSS).

Assessments of health technologies that have a substantial impact on non-health outcomes or costs to other government bodies should also provide the benefits and costs (or cost savings) to other government bodies, although this must be agreed with the Department of Health before the assessment takes place. Productivity costs and costs borne by patients and carers that are not reimbursed by the NHS or PSS are not included.

The perspective on outcomes should be all direct health care effects, whether for patients or, when relevant, other people (principally carers). This is consistent with an intention of maximising health gain from available healthcare resources.

2.2.2 SELECTING A COMPARATOR

The choice of appropriate comparators is based on routine and best practice in the NHS (including existing NICE guidance) and the natural history of the condition without suitable treatment. Routine practice may differ across the NHS because best alternative care may vary from routine NHS practice. Thus there will often be more than one appropriate comparator technology. Comparators may also include interventions that do not have marketing authorisation for the indication defined but are routinely used for the indication in the NHS. When both technology and comparator form part of a treatment sequence, the appraisal may need to compare alternative treatment sequences.
2.2.3 SELECTING AND USING AN ECONOMIC EVALUATION TOOL

The focus of NICE on maximising health gains from a fixed NHS/PSS budget means CUA and CEA are the preferred forms of economic evaluation. In making a decision based on these methods, cost-effectiveness acceptability curves should be presented, with the inclusion of a representation and explanation of the cost-effectiveness acceptability frontier. The probability that the treatment is cost-effective at thresholds of £20,000 to £30,000 per QALY gained and the probability that the treatment is not cost-effective should be presented. These are in addition to the mean results (costs, outcomes and ICERs).

2.2.4 MEASURING OUTCOMES AND COSTS

The QALY is deemed to be the most relevant generic measure of health benefit that reflects both health related quality of life (HRQL) and mortality effects. Although alternative measures exist, few NICE HTAs have incorporated these methods and their strengths and weaknesses have not been fully determined. If the assumptions underlying QALYs (constant proportional trade-off and additive independence between health states) are regarded as unsuitable in a specific case, then evidence of this should be supplied and analyses using alternative measures may be provided as an additional non-reference case analysis.

The measurement of changes in HRQL should be reported directly from patients and the value of changes in patients' HRQL (utilities) should be based on public preferences using a choice-based method. The preferred measure of HRQL in adults is EQ-5D. For the EQ-5D classification system, a set of preference values elicited from a large UK population study using a choice-based method of valuation (the time trade-off method) is available. To generate health-related utility values, this set of values can be applied to people’s self-reported descriptions of their HRQL.

In measuring total costs, data is required on the effect of health technologies on resource use, and prices and unit costs relevant to the NHS and PSS should be used to value this resource use. However, it is recognised that these may not always reflect the full social opportunity cost.

2.2.5 TIME HORIZON

To reflect all important disparities in costs or outcomes between the technologies being compared, the time horizon for estimating clinical and cost effectiveness should be sufficiently long. For technologies that have impacts on costs and outcomes over a patient’s lifetime, particularly treatments for chronic diseases, a lifetime time horizon for cost effectiveness is relevant. Also, to quantify the implications of any differential survival effect between alternative technologies a lifetime time horizon is also required. If, however, there is no differential mortality effect between options, and the differences in costs and HRQL relate to a relatively short period (such as in the case of an acute infection) a shorter time horizon could be justified.

2.2.6 DISCOUNTING

Cost-effectiveness results should reflect the present value of the stream of costs and benefits accruing over the time horizon of the analysis. An annual discount rate of 3.5% should be used for both costs and benefits in the reference case. This rate is based on the recommendations of the UK Treasury for the discounting of costs.
2.2.7 INCORPORATING UNCERTAINTY

The economic evaluation should identify possible selection bias in the inputs to the model and quantify the decision uncertainty associated with a technology (the probability that a different decision would be reached if the true cost-effectiveness of each technology could be determined before making the decision). Sensitivity analysis should therefore be used to:

- investigate the uncertainty around the structural assumptions incorporated in the evaluation;
- deal with uncertainty around the selection of data sources; and
- explore the effects of parameter uncertainty.

A probabilistic sensitivity analysis should be used to translate input uncertainty into decision uncertainty. Structural assumptions within the economic evaluation should be undertaken using a scenario analysis.

2.2.8 INCORPORATING EQUITY

NICE (2008b) outlines the principles NICE adheres to when applying social value judgements to the processes it uses to develop guidance, and during the development of individual forms of guidance, principally when making decisions about effectiveness and cost-effectiveness. The aim of the principles is to provide a simple, accessible and culturally neutral approach that covers most moral issues that arise in healthcare.

2.3 EUnetHTA

Since the UK introduced explicit HTA decision making process through the development of NICE, many European countries have also created formal decision making structures. Sweden and Belgium adopted the UK approach to include more than just clinical and cost-effectiveness. Portugal, Netherlands, Norway, Denmark, Hungary, Spain and Poland mandate the use of pharmacoeconomic analysis. Conversely, Italy and France give more attention to budgetary impacts than full economic evaluation or HTAs. The creation of the Institute for Health Care Quality (IQWiG) has indicated Germany’s move toward more formal use of HTA methods in decision making. This disparity amongst reimbursement decision making systems in European countries partly reflects the differences in the organisation of their health sectors and political systems, which have shaped the political and health objectives behind the introduction of HTA (Hutton et al 2006).

The EUnetHTA was established as a European network for HTA by bringing together the recommendations of a series of European Union (EU) funded projects from 1993 to 2002 on increasing co-ordination of HTAs across the EU states (EUnetHTA 2008). The European Commission and Member States co-funded the three year project (2006 to 2008) with the aim of developing a sustainable network and information resources to inform health policy making (Banta and Oortwijn 2000). The objectives of the EUnetHTA project are to:

- provide a robust, multifaceted input to decision making;
- reduce duplication of work across member states;
- gain a better understanding of the links between HTA policy making in different member states; and
- to support countries with limited HTA experience.
The goal is to ensure that the resulting collaboration between HTA agencies becomes permanent from 2009. Rather than centralising decision making or standardising approaches, the emphasis of EUnetHTA is on co-ordination, facilitation and knowledge transfer. The EUnetHTA partnership involves 64 organisations (EUnetHTA 2009) while 33 countries participated in the project (EUnetHTA 2009). These included:

- 25 EU and 2 EEA countries (Norway and Iceland), Switzerland and Serbia; and
- Australia, Canada, Israel, and the USA.

A key result of the EUnetHTA is the development of a comprehensive, evidence-based and validated common framework that can be applied to diagnostic technologies (EUnetHTA 2008a) and medical and surgical interventions (EUnetHTA 2008b). The framework is still in draft stage but is expected to be completed in 2009.

2.3.1 PERSPECTIVE OF THE ECONOMIC EVALUATION

Ideally, the economic evaluation is performed from the broadest perspective with the most thorough perspective being societal. Other possible perspectives are the health care sector’s perspective, third party payer’s perspective, hospital perspective or patients’ perspective. The purpose of the economic evaluation ultimately determines the perspective chosen. If the purpose is to inform societal resource allocation, the societal perspective should be taken. For hospital HTA, the hospital perspective would be more relevant.

All direct and indirect costs should be included in the economic evaluation. Direct costs include costs assumed inside the health care sector (e.g. materials, equipment, personnel, and tests - direct health care costs) as well as outside the health care sector (e.g. patients’ travel time - direct non-health care costs). Indirect costs include the patient’s temporary absence from work due to illness, reduced working capacity due to illness and disablement, or lost production due to an early death. To measure lost production, either the human capital method or the friction cost method can be used. Lost production is generally reported separately and not included in the cost estimate used for the calculation of the ICER or cost-utility ratio. Lost production should not be confused with a transfer payment like sickness benefit.

2.3.2 SELECTING A COMPARATOR

The choice of comparator consists of the alternative technologies that include, but are not limited to, current practice or ‘no intervention’.

2.3.3 SELECTING AND USING AN ECONOMIC EVALUATION TOOL

The four main types of economic evaluations which can feature in a HTA are CUA, CEA, CBA, and CMA. The choice between each technique depends on the purpose of the evaluation, the availability of specific data and potentially the guidelines for economic evaluations that are to be followed in a specific context. A summary of when to use each economic evaluation tool is presented in Table 2-4.

The decision matrix used to determine whether a health technology is cost effective is shown in Table 2-5. If the situation in cells one and nine occur, an incremental cost-effectiveness ratio (ICER) threshold is needed to determine which technology is preferable. The intervention is considered cost-effective if it has an ICER above the specified threshold.
To overcome the inability of the ICER to indicate the appropriate scale or size of the interventions upon implementation into the health care system, net monetary benefit (NMB) and net health benefit (NHB) measures can be used.

**TABLE 2-4: TYPES OF ECONOMIC EVALUATIONS PROMOTED FOR USE BY EUnetHTA**

<table>
<thead>
<tr>
<th>Type of economic evaluation</th>
<th>Appropriate if...</th>
<th>Valuation of costs</th>
<th>Valuation of outcomes</th>
<th>The question to be answered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost-minimisation analysis (CMA)</td>
<td>The compared technologies are equally effective; data on costs suffice.</td>
<td>Monetary units</td>
<td>None</td>
<td>Which intervention is the least costly?</td>
</tr>
<tr>
<td>Cost-effectiveness analysis (CEA)</td>
<td>The effectiveness of the compared technologies is different (i.e. the differences in costs have to be weighed against the difference in effectiveness); activities with the same aim and measure of effectiveness are compared.</td>
<td>Monetary units</td>
<td>Natural units (e.g. life years gained, disability-days saved, points of blood pressure reduction, etc.)</td>
<td>What is the intervention’s incremental cost per additional unit of outcome as compared to its best alternative?</td>
</tr>
<tr>
<td>Cost-utility analysis (CUA)</td>
<td>HRQL is an important health outcome and/or activities across specialities or departments in the health care sector are compared.</td>
<td>Monetary units</td>
<td>QALYs, HYEs</td>
<td>What is the intervention’s incremental cost per additional unit of outcome as compared to its best alternative?</td>
</tr>
<tr>
<td>Cost-benefit analysis (CBA)</td>
<td>Non-health effects are also of importance (e.g. the treatment process itself, utility of information); or only one technology is assessed (net benefit); or there is a wish that the individual life’s are valued in monetary units; or activities across different sectors in society have to be compared.</td>
<td>Monetary units</td>
<td>Monetary units</td>
<td>What is the economic trade-off between different activities that matter for society?</td>
</tr>
</tbody>
</table>

Source: EUnetHTA (2008)
Table 2-5: The Cost-Effectiveness Decision Matrix

<table>
<thead>
<tr>
<th>A new technology compared with an old one</th>
<th>Less effective</th>
<th>Same effectiveness</th>
<th>More effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less costly</td>
<td>1. No clear decision</td>
<td>4. Adopt the new technology</td>
<td>7. Adopt the new technology</td>
</tr>
<tr>
<td></td>
<td>Non-dominance-incremental analysis needed</td>
<td>The new dominates the old (weak dominance)</td>
<td>The new dominates the old (strong dominance)</td>
</tr>
<tr>
<td>Same costs</td>
<td>2. Keep the old technology</td>
<td>5. The technologies are equal</td>
<td>8. Adopt the new technology</td>
</tr>
<tr>
<td></td>
<td>The old dominates the new (strong dominance)</td>
<td></td>
<td>The new dominates the old (weak dominance)</td>
</tr>
<tr>
<td></td>
<td>The old dominates the new (strong dominance)</td>
<td>The old dominates the new (weak dominance)</td>
<td>Non-dominance-incremental analysis needed</td>
</tr>
</tbody>
</table>

Source: EUnetHTA (2008)

2.3.4 Measuring Outcomes and Costs

Health outcomes of interventions are measured by natural units of health (e.g. deaths, life years gained (LYG)), valuations of health states or utilities, or in monetary terms. A composite outcome measure, such as QALY or Healthy Years Equivalent (HYE) should be used if the intervention affects both the length and quality of life. As QALYs and similar approaches are generic and permit broad comparisons between interventions and across diseases they are most useful in policy analysis and program decision making and are therefore preferred.

2.3.5 Time Horizon

There is no specification on the appropriate time frame to use for an economic evaluation.

2.3.6 Discounting

EUnetHTA acknowledges that cost and health outcomes should be discounted, however a discount rate is not specified.

2.3.7 Incorporating Uncertainty

Deterministic and/or probabilistic sensitivity analysis should be incorporated into an economic analysis to account for parameter and model uncertainty. To determine the impact on the results of all uncertain model inputs, a complete sensitivity analysis should be performed. Justification of any model inputs that are not included in the sensitivity analysis should be provided.
2.3.8 INCORPORATING EQUITY

Within the EUnetHTA cost-effectiveness framework, the applicant is encouraged to address ethical questions such as:

- What are the consequences of implementing/ not implementing the technology on justice in the health care system?
- Are principles of fairness, justness and solidarity respected?
- How are technologies presenting with similar ethical problems treated in the health care system?
- Can the technology be applied in a way that there is equal access to those in equal need?

These, in conjunction with a thorough ethical analysis incorporated in the HTA, highlight that HTA is a value-based process and should be deemed more than just a purely technical tool for maximising the health-economic benefits of technology.
3. AN IMPROVED ECONOMIC EVALUATION FRAMEWORK FOR HTA IN AUSTRALIA

Health technology assessment, recommendations made by MSAC, and decisions made by the Commonwealth Government, are undertaken through a collective process. The process aims to allocate resources towards areas of the health care system that reflect the preferences of society, whether that is in improved health or some other benefit. In doing so, scarce health care system resources are directed towards areas that have the greatest value, thereby maximising social welfare.

One goal of current health technology assessment in Australia is to ensure recommendations deliver safe and effective health care outcomes at the least cost. The question to be answered within an economic evaluation is whether the proposed health technology leads to a more technically efficient allocation of scarce health care resources. That is, does the proposed health technology lead to greater benefits per unit of cost?

As simple as the question may seem, there is great diversity among health technologies in terms of health outcomes, other benefits they can deliver, and their costs. Furthermore, levels of evidence regarding a device or technology are highly variable. This means an economic framework used to evaluate health technologies must be flexible.

However, there is a trade-off. Too much flexibility can lead to an inconsistent methodological approach across economic evaluations and to outcomes (and therefore assessment decisions) that are directed by the methodology chosen. As economic evaluation outcomes are used to inform decisions on resource allocation, a common set of methods is required that enables comparability of results.

The purpose of this chapter is to present an improved economic framework to be used in HTA in Australia. The framework has been developed using current Australian health economic evaluation frameworks (NHMRC 2001; MSAC 2005, 2005a; PBAC 2008), health technology assessment frameworks used in Canada, the UK, and the European Union (see Chapter 2), and the large amount of peer reviewed literature that has investigated health technology assessment and economic evaluation throughout the world. It represents a practical approach to health technology assessment in Australia, based on the theoretical fundamentals of health technology assessment.

3.1 SCOPE OF AN ECONOMIC EVALUATION FRAMEWORK

Health technology can be broadly defined as equipment, instruments, pharmaceuticals, clinical procedures, knowledge and support systems that are used to provide health care (PC 2005). In line with the HTA Review’s Terms of Reference (DoHA 2009), this economic framework has been developed to encapsulate devices and procedures that currently fall under MSAC.

Pharmaceuticals have not been specifically incorporated within the development of this economic framework. There are important differences between pharmaceuticals and other types of health technology, such as the types of study designs used and product life cycles. Table 3-1 provides a further breakdown of these differences.
### Table 3-1: Differences between health technology devices and pharmaceuticals

<table>
<thead>
<tr>
<th></th>
<th>Health technology devices</th>
<th>Pharmaceuticals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic effect</td>
<td>Effective by mechanical and/or electrical action</td>
<td>Effective when absorbed and metabolised by the body</td>
</tr>
<tr>
<td>Operator skill</td>
<td>Outcomes often depend on surgical skill</td>
<td>Rarely relevant</td>
</tr>
<tr>
<td>Product life cycle</td>
<td>Relatively short (2 to 4 years)</td>
<td>Longer (10 to 20 years)</td>
</tr>
<tr>
<td>Physical infrastructure</td>
<td>Often necessary for delivery of treatment</td>
<td>Usually not required</td>
</tr>
<tr>
<td>Delivery environment</td>
<td>Often delivered in hospitals</td>
<td>Usually administered in community settings</td>
</tr>
<tr>
<td>HTA processes</td>
<td>Recently established</td>
<td>Long-established process</td>
</tr>
<tr>
<td>Evidence base</td>
<td>High level evidence often not available</td>
<td>High level evidence usually available</td>
</tr>
</tbody>
</table>

Source: PC (2005)

However, many of the principles presented within this economic framework can be applied to the evaluation of pharmaceuticals and other health technology areas, such as alternative modes of care. This is important as it provides the flexibility to compare alternative health care technologies (comparators) using the same economic framework.

The high cost of an assessment means low cost replacement devices should not be included in the MSAC process. For example, it has been estimated that the cost to the Australian Government of a full MSAC assessment is around $250,000 (DoHA 2009). From an economic perspective, an evaluation should not take place unless the benefits of doing so outweigh the costs. However, the evaluation needs to take place to determine potential benefits. Thus a ‘chicken and egg’ situation.

As noted by Drummond et al (2005), economic evaluations impose a cost so they will be most useful when the new health technology and the comparator are significantly different, or a large amount of resources would be required if approved. Currently, MSAC only investigates those technologies that are expected to have a significant cost impact on the health care system. Although this should continue, a better definition of ‘significant cost’ needs to be developed.

Finally, a process needs to be further developed and implemented that can prioritise and select health technologies currently listed on the MBS. This is particularly the case for existing technologies within the health care system that may be inefficient or are being used inappropriately.

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15 This is not the only cost associated with an assessment. As the introduction of new goods and services are delayed while an assessment takes place, the technology company also loses the opportunity to extract a producer surplus from the market, while consumers lose any health benefits they might have received.
3.2 FORMULATING THE STUDY FRAME

Formulating the study frame involves first defining a research question that reflects the context of the assessment. The study frame should include the following items.

- **Perspective of the analysis.**

- **The epidemiology of the condition that will be targeted by the new technology including:**
  - incidence;
  - prevalence;
  - patient characteristics;
  - risk factors; and
  - trends in the above.

- **The current health technology used to treat the condition that would be replaced if the new technology was approved, including:**
  - devices;
  - procedures;
  - pharmaceuticals;
  - diagnostic techniques;
  - health promotion activities; and
  - other health programs.

- **The target groups for the new technology and comparator, including:**
  - the number of people within the target group; and
  - characteristics of the target group (demography and risk factors).

- **Health and non-health outcomes, including:**
  - principal measures of health outcomes;
  - other changes to the healthcare system; and
  - impact on costs.

- **The technical aspects of the new technology, such as:**
  - settings for its use;
  - its role in the treatment pathway; and
  - whether the technology can be used for other treatments.

- **The likely diffusion of the new technology within the health care system, including**
  - adoption rate;
  - adoption profile; and
  - any barriers to entry for the new technology to overcome.

- **Any other special considerations such as:**
  - patient subgroups;
  - legislation; and
  - existing guidance associated with other health technologies (in the case of co-dependent technologies).
Collecting background information on the above topics will help develop the study frame and further define the research question.

The study frame should also clarify and explain the methodology and concepts that will be used. Furthermore, it should identify whether the evidence derived from a sub-set of the target population will have to be generalised (Drummond et al 2005). This should include generalisation across alternative types of individuals, across alternative health care systems (for example, Australia versus international), and across different health care settings within Australia (for example, states and territories).

MSAC should undertake a consultation process at this stage with applicants and relevant stakeholders. This is to ensure the relevant issues have been considered and incorporated within the study frame.

3.3 PERSPECTIVE OF THE ANALYSIS

An important consideration when undertaking an economic evaluation is which perspective should be taken. Different perspectives will change the scope of benefits and costs included in the evaluation. For example, an economic evaluation based on a government perspective implicitly excludes any costs borne by the patient, family and friends, and the unfunded private sector, whereas an evaluation undertaken with a societal perspective would capture these types of costs.

Using a narrow perspective in an economic evaluation may exclude important benefits and costs, leading to economic evaluation outcomes that do not represent the true benefits and costs to the health care system, economy, and society. This can create a bias in health care policy (for example, health technologies that impose a large societal cost are likely to be favoured) and lead to a sub-optimal allocation of resources (Johannesson and O'Connor 1997).

To avoid this outcome, a full societal perspective should be used when undertaking an economic evaluation (Drummond et al 2008). This perspective is advocated by the Productivity Commission, which noted:

*From a public policy perspective, economic evaluation of the overall impact to the community of advances in medical technology should encompass all costs and benefits – to individuals, organisations and others in the community; tangible and intangible* (PC 2005, pp. 321).

While the current MSAC economic evaluation framework claims to adopt a broad health care system perspective including societal benefits and costs when they are expected to be significant (MSAC 2005), some studies have only addressed direct health care system benefits and costs (for example, MSAC 2005b). Consideration of costs other those incurred by governments is especially rare in financial analyses. This may be due to societal benefits and costs between the new technology and the comparator not significantly changing, reflect inadequate data relating to societal costs, or the perceived notion that these types of benefits and costs should not be included in an economic evaluation.

Expected changes to all benefits and costs resulting from a potential new technology must be included in the economic evaluation. These include:

- direct health care system benefits and costs, including any impacts on supplementary technologies;
indirect economic benefits and costs; and

benefits and costs on society in general, such as individual health impacts and broader impacts on society.

If changes are expected to impact the health care system only (for example, a new technology that generates the same health outcomes but minimises costs), then a broad societal perspective is not required. However, if there will be significant changes to social costs associated with a new technology (for example, changes in labour force productivity as a result of improved health outcomes), and these costs have not been estimated and included in the assessment, then recommendations will be based on incomplete information and outcome measures will be misleading.

Using a broad societal perspective can identify any significant transfers of costs between groups, including government, private health care insurers, and patients. This can highlight any inequities that may result from the introduction of a more cost-effective technology. It may also provide an indication of the likelihood of adopting the new technology within the health care system (Drummond et al 2008).

### 3.4 SELECTING A COMPARATOR

New technology should be compared with the existing treatment approach it will replace (which may mean more than one comparator) and the most cost-effective existing treatment approach, which are not necessarily the same (Hutton and Maynard 2000). For example, within a market where new technology is evolving rapidly, or where preferences amongst clinicians vary greatly, the most cost effective technology may not have been fully adopted within the health care.

Given the wide range of treatment approaches, a comparator could include:

- devices;
- procedures;
- pharmaceuticals;
- diagnostic techniques;
- health promotion activities; and
- health management plans.

The comparator may also comprise co-dependent health technologies, for example a combined drug and specific mode of care treatment path. Alternatively, if the new technology addresses a completely new area of health care and there is no comparator, then the technology should be assessed against a ‘do nothing’ scenario. The economic evaluation should also anticipate future comparators, especially if there is a low cost alternative on the horizon.

Four approaches may help identify the appropriate comparators and all should be explored before an economic evaluation takes place. These include:

- drawing on clinical expertise from within the health care system and health technology companies;
- identifying current practice by those who work on the condition in question, noting that current practice may vary across alternative health care settings;
undertaking a literature review; and
investigating previous guidelines for the same clinical area (NHMRC 2001).

In choosing a comparator, consideration should be given to variation in clinical practice across local, regional, and national health care jurisdictions, and across patient subgroups. The economic evaluation may have to identify a small number of comparators if it is not clear which current technology would be replaced by the new technology.

A clear picture of the comparator’s role in the treatment pathway needs to be established. This means investigating:

- technical aspects of the comparator;
- relevant target population the comparator is currently applied to, including number of separations and patient characteristics; and
- how the comparator is applied within the health care system, including the processes and resources used within the treatment pathway that is directly linked to the use of the comparator.

Health technology assessment should include all technology, skills and procedures that are relevant to the treatment pathway of the condition in question. This includes

- diagnosis and treatment strategies such as imaging, pathology, drugs, devices, and procedures;
- rehabilitation and patient awareness of self care strategies; and
- training of health care providers.

The importance of selecting and confirming the most appropriate comparator at the commencement of the economic evaluation cannot be stressed enough. Failure to identify the appropriate comparator(s) renders the economic evaluation irrelevant. The comparator should have been confirmed with relevant stakeholders within the consultation period associated with the study frame.

### 3.5 DETERMINING WHICH EVIDENCE TO INCLUDE

An economic evaluation should include the best available evidence from which a robust decision can be made. The National Health and Medical Research Council (NHMRC 1999) classify evidence into specific levels according to the perceived ability to minimise bias generated by study design in the effect being measured (Table 3-2). Contrary to ‘conventional wisdom’ these levels do not represent the strength of evaluation outcomes as other factors can lead to biased results within an economic evaluation.
An improved HTA economic evaluation framework for Australia

**Table 3-2: Designated Levels of Evidence**

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence obtained from a systematic review of all relevant randomised controlled trials</td>
</tr>
<tr>
<td>II</td>
<td>Evidence obtained from at least one randomised controlled trial</td>
</tr>
<tr>
<td>III-1</td>
<td>Evidence obtained from a pseudorandomised controlled trial (alternate allocation or some other method)</td>
</tr>
<tr>
<td>III-2</td>
<td>Evidence obtained from comparative studies with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group</td>
</tr>
<tr>
<td>III-3</td>
<td>Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without parallel control group</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence obtained from case series, either post-test or pre-test/post-test</td>
</tr>
</tbody>
</table>

Source: NHMRC (1999)

Levels of evidence developed by the NHMRC are more easily applied to the evaluation of pharmaceuticals rather than procedures and devices. This is due to the differences between the types of evidence collected, including:

- Phase three, double blind, randomised, head-to-head clinical trials with statistically significant outcomes are not plausible for procedures in most cases.
  - Ethical and practical considerations limit the use of procedures within clinical trials.
  - There is often a lack of readily accessible and appropriate large samples within Australia.

- Relying on high level data as a single vehicle for economic evaluation has a number of limitations. Claxton et al (2003) notes the following problems in applying randomised trials to economic evaluations, including:
  - decisions should be based on the comparison of the new technology and the current practice, rather than a placebo (as is generally the case for pharmaceuticals);
  - high level evidence tends to be based on a strict set of rules, restricting their application to resource allocation decisions in a more liberal environment;
  - not all factors of interest for an economic evaluation are measured; and
  - clinical trials are generally focused on short term outcomes, whereas the time frame used in an economic evaluation should span all expected changes in benefits and costs

- Lack of incentive to undertake an expensive clinical trial due to expected small net benefits from MBS listing compared to PBS listed pharmaceuticals.
  - The procedure and devices market is significantly smaller compared to pharmaceuticals.
  - Companies are unable to capture all the gains from having a procedure listed on the MBS as competitors can ‘piggy back’ of the listing with a similar product.
  - If listed, benefits accrue to other stakeholders (for example, clinicians and patients) that cannot be recouped by the sponsor.
Optimal timing of the clinical trial is difficult to determine as procedural outcomes often improve through a learning effect.

- Too early and outcomes may not be favourable.
- Delaying the trial reduces the length of time until an improved technology enters the market, and therefore reduces expected return on investment.

Outcomes and costs of procedures, devices, and diagnostic technologies depend on the skill and experience of the operator, the health care environment, and the choices the patient makes after the procedure such as adherence to a rehabilitation plan.

There is a larger disconnect between efficacy and effectiveness for procedures and devices when compared to pharmaceuticals. The former evolve with feedback from clinicians and patients, while the latter generally enters the market as a finished product.

The limitations in generating high level evidence means a complete dataset on clinical evidence for procedures and devices is more than likely to come from a wider set of study designs. Consequently, the designated NHMRC evidence levels represent an impractical tool to measure the quality of evidence for the assessment of procedures and devices.

Analysis of MSAC applications within this report and evidence from O’Malley (2006) suggest the majority of negative recommendations made by MSAC are based on ‘insufficient’ evidence when compared to the designated levels of evidence used by the NHMRC. Applicants are usually directed to collect more concrete evidence before another application is made.

Obtaining further evidence before approving products for MBS listing delays the adoption of new products into the health care system. From a societal perspective, this can result in delays to potential benefits as MSAC and clinical advisory groups try to avoid expenditure on products that are not cost effective (Hutton and Maynard 2000). Alternatively, benefits may be missed all together if the life cycle of the product is less than the time required to obtain further evidence.

To the health technology company, delays represent a potential loss in sales and a subsequent reduction in the rate of return to investment. If this occurs, the incentive to undertake investment in research and development is reduced. The size of the reduction would depend on the impact of a change in the rates of return in Australia on research and development policy within a health technology company (Hutton and Maynard 2000).

Given uncertainty in evidence, rejecting an application based on ‘insufficient’ evidence may mean patients and companies are missing out on additional benefits in the quest to avoid additional costs associated with introducing inefficient technologies. These can be formally classified into two error types (see Table 3-3):

- **Type I error** - concluding the new health technology is cost-effective when, given all observed and unobserved information, it is not. Under this scenario, society still obtains any benefits from the new health care technology but when compared to costs, society would have been better off if the current treatment had continued. Consequently, there will be a reduction in social welfare.

- **Type II error** - concluding that the new health technology is not cost-effective when, given all observed and unobserved information, it is. Under this scenario, society misses out on net benefits that would have been provided by the new health technology, and therefore misses out on improved social welfare.
A strategy used in past MSAC economic evaluations has been to err on the side of caution when evaluating health technologies. For example, if a range of benefits and costs are presented within the evidence, then some assessments have used point estimates from the lower end of the range for benefits, and point estimates from the higher end of the range for costs. More concerning is that evidence uncertainty has led to assessors concluding an economic evaluation cannot be undertaken, and a subsequent negative recommendation based on ‘insufficient’ evidence.

Erring on the side of caution aims to avoid Type I errors. Although this is an admirable strategy it implicitly introduces a bias into economic evaluation because the probability of a Type II error is increased. Consequently, the likelihood of society missing out on social welfare improvements is increased. In the case of rejecting an application based on ‘insufficient’ clinical evidence, medical procedures that may provide additional benefits are missed out at the expense of trying to avoid the possibility of less efficient procedures being introduced.

Avoiding Type I errors at the expense of Type II errors is problematic. It implicitly trades-off additional net benefits that could have been achieved in the health care system with the avoidance of additional costs associated with a less efficient technology. This is particularly problematic when new technology is assessed against existing technology as the latter is unlikely to have gone through a formal economic evaluation. Consequently there is no indication that the current technology is the gold standard.

There is no indication that Type I errors lead to any larger reductions in welfare compared to Type II errors. Thus, rejecting applications based on a cautionary approach could be reducing social welfare in many cases. That means there are less benefits derived from the health care system than could otherwise be achieved.

There is a need for a greater balance in the assessment of new health technologies. Rather than rejecting applications based on evidence perceived to be ‘insufficient’, economic evaluations should be conducted in absence of high level evidence. Instead, all available relevant evidence and data should be assessed, including:

- randomised control trial evidence;
- non-randomised control trial evidence;
- evidence from non-comparative studies such as observational studies;
- evidence of cost effectiveness from other study designs (for example, HTAs undertaken by other countries);
- supplementary evidence, such as:
  - commercial-in-confidence data within a process that protects confidentiality; and
  - patient evidence.
- preferences for the new technology and comparator(s) from:
  - patients and their carers;
  - society in general;
  - health care professionals;
  - health insurance companies; and
  - device competitors.

There should be no specific cut-off point in the level of evidence acceptable. Evidence should be critically appraised and limitations should be explicitly stated. The type of evidence used should be determined on a case by case basis, taking into consideration the quantity and quality of evidence available. Where limitations exist, economic evaluations should make assumptions and account for any perceived inadequacies through established methods, such as decision analytic modelling, sensitivity analysis, and scenario analysis (these methods are further discussed in Section 3.11).

If the final economic evaluation outcome is not sensitive to the assumptions made, nor the perceived inadequacies of the clinical evidence, then it is not worth collecting costly and time consuming high level evidence because the outcome will be the same.

Avoiding negative recommendations based on ‘insufficient’ evidence will reduce the probability of MSAC making Type II errors and lead to greater net benefits to society.

3.6 SELECTING AN ECONOMIC EVALUATION TOOL

Economic evaluation tools include cost-utility analysis (CUA), cost-effectiveness analysis (CEA), cost-benefit analysis (CBA), and cost-minimisation analysis (CMA). Although commonly used, there is large scope for variation within each tool, and therefore potentially large variations in outcomes based on which methodology is applied and how it is applied. Table 3-4 provides a brief description of economic evaluation tools, under what circumstances they should be used, outcome measures, and the decision criteria applied.

The chosen tool used for economic assessment should depend on the characteristics of the new technology and comparator(s) under assessment. The types of benefits and costs associated with the technologies, the level of clinical evidence available, and the uncertainty surrounding estimates should be the main driver of choice.

For those technologies where outcomes are primarily related to changes in health status (or reducing in risk to health) and evidence can be readily measured in quality adjusted life years (QALYs), a cost utility analysis (CUA) should be undertaken. However, this tool focuses on health outcomes so it may not be appropriate if the new technology leads to significant non-health changes within the health care system, such as improved continuity of care. As non-health factors are not easily measured in terms of their impact on health outcomes, supplementary analysis should be undertaken in order to include these types of benefits.
within the final cost effectiveness evaluation. Both the impact on health outcomes and non-health outcomes should be considered in the decision making process.

When QALYs cannot be readily measured (which is typical for non-pharmaceutical health technology and further discussed in Section 3.7.1) but natural units of health outcomes (outcome indicators) or health care processes (process indicators) can be measured, then a cost effectiveness analysis (CEA) may be more appropriate.\textsuperscript{16}

Outcome indicators (for example, weight loss) are generally used throughout to measure the effectiveness of health care systems. Outcome indicators should be favoured when:

- there is only one outcome of interest;
- the new technology and the comparator produce the same outcome of interest;
- nature of the outcome is uncontested;
- the concept of the outcome is relatively easily captured in an operational performance measure; and
- the outcome is readily attributable to both health technologies rather than external forces (for example, the level of care after a procedure, choices made by the patient, and environmental factors) (Smith 2002).

Surrogate outcomes should only be used if there is a confirmed, well established link between the surrogate outcome and the patient outcome under investigation.

\textsuperscript{16} Health care systems also use structural indicators, for example the number of nurses per 1000 population. Within this thesis structural indicators have been incorporated within the definition of process indicators.
<table>
<thead>
<tr>
<th>Evaluation tool</th>
<th>When to use it</th>
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<th>Decision criteria</th>
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| Cost-utility analysis (CUA)                         | Use when the incremental health outcome attributable to the new health technology is measured in a common unit of health measure, such as quality adjusted life years (QALYs). This is becoming the most common economic evaluation tool because it can accommodate changes to morbidity and mortality. | Results are expressed as an incremental cost effectiveness ratio (ICER), where effects (E) are measured in QALYs or DALYs. For two programs this is calculated as: \[
\frac{C_2 - C_1}{E_2 - E_1} = \frac{\Delta C}{\Delta E}
\] | Accept new technology if ICER is lower than an external criteria developed by policy makers, such as a threshold value, or presents the lowest ICER within a league table. |
| Cost-effectiveness analysis (CEA)                   | Use when the incremental health effect of the new technology is measured in natural units (for example, cholesterol levels and number of cases detected). As outcomes are measured in natural units there is no value specifically attached to outcomes.                         | Results are expressed as an incremental cost effectiveness ratio (ICER), where effects are measured in natural units.                                                                 | Accept if ICER is lower than an external criteria developed by policy makers, such as a threshold value, or presents the lowest ICER within a league table.                                                                 |
| Cost-benefit analysis (CBA)                         | Use when outputs from health technology can be appropriately valued in monetary units. Allows the direct comparison of discounted future streams of incremental benefits with the discounted future streams of incremental costs.                          | Net present value (NPV) \[\text{Internal rate of return (IRR)}\] Net benefit investment ratio (NBIR) \[\text{Benefit cost ratio (BCR)}\] | Accept new technology if it provides a positive incremental net present value social benefit.                                                                                     |
| Cost-minimisation analysis (CMA)                    | Use when the effectiveness of the new health technology and the comparator are expected to be the same, so the difference between the two relate only to costs.                                                                                                                                  | Cost per unit of output                                                                                                                                                                  | Accept new technology if the cost per unit of output is lower than the comparator.                                                                                             |
Process indicators (for example, the number of cases detected) take a narrower perspective of the health care system, focusing on a procedure. They rely on the implicit assumption, or a proven link, that the measured intervention has a positive impact on health outcomes or quality of care. Consequently the greater number of processes will directly translate into greater health outcomes. Process indicators are generally thought to be more sensitive and feasible measures of quality of care as they are direct measures of health system outputs (Mant 2001, Marshall et al 2000). In addition they are not burdened by the need to incorporate changes in other factors affecting health care outcomes, such as the environmental impacts or behavioural change as they are simply a measure of the process itself.

Both CUA and CEA rely on the incremental cost effectiveness ratio (ICER) as a summary output measure. This is calculated using the following equation:

\[
\frac{C_2 - C_1}{E_2 - E_1} = \frac{\Delta C}{\Delta E}
\]

Decisions based on the ICER are only relevant when dominance of one technology is not evident (i.e. one technology is not more effective and cheaper than the other). In general, if the ICER is smaller than some pre-established threshold (which is generally not explicit in the decision making process), then the new technology is recommended.

There are several problems associated with using an ICER within the decision making process that needs to ensure a flexible approach.

- The threshold is generally an arbitrary willingness to pay amount for a unit of change (in the case of a QALY it’s one year of perfect health) and may not represent society’s true willingness to pay for the outcome under investigation.

- As benefits and costs may be non-linear, and the ratio between benefits and costs may be unstable, the ICER may change as the size of the program changes. Any differences between the assumed adoption rate of the technology and the actual adoption rate within the health care system may change the ICER and the perceived cost effectiveness of the technology. This may also occur if the new technology is used within a context where patient characteristics and the severity of the condition differ from the initial HTA.

- Two ICERs can have the same value but lead to two different policy interpretations. For example, a new technology that is more costly and more effective may have the same ICER as an alternative technology that is less effective but less costly.

CBA has the capacity to take a broader perspective on the impacts of a new technology on outcomes. It can capture non-health outcomes associated with a new technology that a CEA/CUA does not typically capture. A CBA can also address allocative efficiency concerns (resources being allocated to those areas that are most valued within the health care system). However, as it is problematic to place a monetary value on health outcomes\(^{17}\) a

---

\(^{17}\) This can be achieved for specific health outcomes through stated preference techniques such as contingent valuation and discrete choice methods (including conjoint analysis and choice modelling). However a large amount of time and resources are typically required to undertake these assessments in order to avoid inherent bias that can be introduced through methodology and sample selection.
CBA should not be used when the primary outcome is a change in health. Instead, a CBA should be used when:

- outcomes can be readily measured in a monetary value;
- an outcome from the intervention is difficult to value using health outcomes (for example, a reduction in the need to visit a GP); and
- the change of interest relates to processes within the health care system.

CMA should only be used when the new technology and comparator have the same health and non-health outcomes that can be indisputably supported by the evidence. This includes adverse events. In evaluating new technologies within the context of MSAC, it is unlikely that two technologies will have the same outcomes. This is because a new technology evaluated under MSAC is usually a significant departure from the technology currently in use (if not, the new technology is usually captured under an existing MBS item number). Under no circumstances should it be assumed that all outcomes are the same given a lack of evidence, even if some evidence suggests clinical outcomes are identical. This is because significant non-health outcomes may be different and should therefore be included in the analysis. Failure to do so may introduce bias into the analysis (for example, see the case study on point of care testing in Chapter 4 of this report).

Choosing the correct economic evaluation tool is paramount. Unlike the evaluation of pharmaceuticals where the use of a CUA is considered the gold standard, the economic evaluation of non-pharmaceutical health technologies requires greater flexibility. This is to accommodate lower levels of evidence and the benefits and costs associated with changes to health and non-health outcomes. Consequently, the use of a CUA, and the requirement to derive QALYs, is unlikely to be the most appropriate approach in evaluating new technologies that are expected to deliver significant non-health benefits. Rather, evaluators should also consider the use of CEAs and CBAs for an economic evaluation.

### 3.7 IDENTIFYING AND MEASURING BENEFITS

There is an important difference in the types of benefits delivered between pharmaceuticals and other types of health technologies that require flexibility in an economic evaluation of the latter. Whereas the primary benefits of pharmaceuticals tend to be improved health outcomes, non-pharmaceutical health technologies can provide more than just changes to health status.

Benefits from new technology can be broadly grouped into improved health and other health care system benefits. Improved health can be measured or implied through outcome and process indicators respectively, or a summary measure of health that includes changes to morbidity and mortality such as QALYs. Other health care system benefits can include a reduction in the per unit cost of an intervention (the same number of interventions for less cost or more interventions for the same level of cost) or other changes to the health care system that are valued by society, for example, care that is more appropriate to the patient’s needs. Furthermore, procedures and devices tend to deliver other economic and social benefits that should be incorporated within an evaluation.

### 3.7.1 IMPROVED HEALTH OUTCOMES

Improved health outcomes include increased wellbeing (reduced morbidity) and increased life span (reduced mortality). If a new health technology is expected to improve both these
items of health then a summary measure of health (such as a QALY) is the most appropriate tool to represent health benefits. QALYs should also be used if the health technologies being compared result in different kinds of health outcomes.

Although DALYs also represent a summary measure of health, they are not appropriate for health technology assessment. Instead they are more useful for general economic evaluations where a wide range of possible interventions for alternative diseases and conditions are considered.

The preferred theoretical methods to develop preferences for alternative health states from a specific health care intervention is through the use of standard gamble or time trade-off methods (Drummond et al 2005). However, preferences may be hard to establish using these methods within most health technology evaluations due to limited opportunity to extract preferences in a timely fashion. Furthermore it is a complex and costly task.

Another way to develop health state measures is to use multi-attribute health status classification systems that include preference scores for alternative attributes. Examples include the quality of wellbeing (QWB) scale, EQ-5D, Short Form 6D (SF-6D) and a Health Utilities Index (HUI) (Drummond et al 2005). Preference scores can be obtained:

- within a prospective study (for example, within a clinical trial or further research undertaken as part of a conditional funding arrangement);
- retrospectively and then mapped onto outcomes of the evidence used within the economic evaluation; or
- from secondary sources where they have been obtained from samples that are relevant to the health technology of interest.

Economic evaluations should use the above tools when measuring preferences associated with health outcomes because they are readily available, can be compared across alternative health outcomes, and can be interpreted relatively easily. However, the choice between instruments is crucial to determining health impacts. Each method has its own dimensions of health, number of levels for each dimension, and preference scores associated with alternative dimensions that have been derived from different samples and calculated using different modelling techniques. Consequently, different tools can lead to different health outcomes on the same sample so there should be consistency across economic evaluations.

The conditions under which the QALY is related to formal utility theory does not account for non health attributes in the utility function, that is, health and non-health attributes within the individuals utility function are mutually independent (Gafni, 2006). This is problematic for achieving a maximum welfare outcome for health programs that deliver benefits in dimensions of health care valued by society other than improved health. As discussed in Section 3.5, reliance on QALYs will not be appropriate for all new health technologies even if QALY weights can be easily obtained because health technologies can also provide significant non-health benefits. Including only a change in QALYs when assessing a health technology that also generates non-health benefits will under-estimate total benefits. This means the denominator of an ICER will also be underestimated and the perceived cost effectiveness of the health technology will be biased towards rejection.

If health preference measures are not available, then natural units of health outcomes, or changes to process outputs should be considered. This is preferred over excluding the analysis based on insufficient evidence. For example, the impact of alternative treatments for obesity could use a loss in weight over a specified time period, rather than the QALYs
associated with a loss in weight. However, the use of outcome and process indicators will only be appropriate under those specific conditions listed in Section 3.5.

In addition to direct improvements in health being measured, a change in the risk of adverse events should be included where they are clinically and economically important. The economic evaluation needs to consider their nature, frequency, duration, and severity as they may have an impact on:

- health outcomes, including mortality and morbidity;
- compliance with treatment by patients and clinicians and subsequent health impacts; and
- health care resource use (for example, risk of a prolonged hospital stay).

A reduction in the risk of adverse events should be valued in a way consistent with the expected impact of the adverse events.

**3.7.2 OTHER HEALTH CARE SYSTEM BENEFITS**

Given the aim of an economic evaluation within health technology assessment should be to maximise social welfare, an evaluation should also incorporate what society wants out of a health care system to ensure resources are being allocated to areas that are valued the most by society.

Currently, the health technology assessment process focuses on three broad health care system attributes, including safety, effectiveness, and technical efficiency. However, there are several other attributes of the health care system also valued by society but are not currently included in an economic evaluation. For example, Cutler (2008) shows that society has a distribution of preferences for attribute performance levels used in the Australian National Health Performance Framework (NHPF) (NHPC 2001). In addition to safety, effectiveness, and efficiency, these attributes include:

- appropriateness – care that is relevant to the patient’s needs;
- responsiveness – service provides respect for persons and is patient oriented;
- accessibility – ability to obtain health care at the right place and the right time irrespective of income, physical location, and cultural background;
- continuity – uninterrupted coordinated care or service across programs;
- capability – capacity to provide a health care service based on skills and knowledge;
- sustainability – contributes to infrastructure development such as workforce, facilities, and equipment, and enables the health care system to respond to emerging needs.

These are not the only attributes that are recognised and valued in the Australian health care system. The Australian Institute of Health and Welfare (AIHW) noted several other attributes in developing their recent set of performance indicators for use in future Australian Health Care Agreements (AIHW 2008). These include:

- prevention of a reduction in health of Australians;
- integration of health care services across the continuum of care;
- health care that is patient-centred, including respect and dignity and patients involved in decision making; and
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- equitable access to health care services.

Furthermore, other countries have identified additional attributes that users of their health care system recognise as valuable in addition to improved health outcomes. Some of these include (AIHW 2000):
- patient/carer satisfaction (UK);
- timeliness (US); and
- competence (Canada).

As current and future users of the health care system value these non-health attributes, an economic evaluation should take into consideration these values if allocative efficiency, and subsequent improvements in welfare, are to be achieved.

Incorporating non-health benefits associated with the health care system represents a departure from traditional application of economic evaluation tools (such as CEA, CUA, CBA, and CMA). Generally, changes to these attributes from a new healthcare technology will not be included in an economic evaluation. This could be due to unidentified changes, a lack of data to quantify any identified changes, or these attributes being outside the traditional scope of economic evaluations.

Although changes to non-health attributes could be measured, a significant barrier within an economic evaluation is determining the value (weights) individuals place on these changes. The absence of weights means trade-offs across non-health attributes as a result of a new technology cannot be determined. For example, whether a large improvement in continuity and a small decline in effectiveness are socially desirable would be unknown. Similarly, an improvement in continuity by 10% in a health care setting where continuity is already considered adequate will not provide the same benefits to society when continuity is improved by 10% from a worse base case. This is due to the alternative marginal benefits associated with each scenario.

As the value of each non-health attribute is unknown, an economic evaluation is unable to measure the impact of the new health technology on improving welfare outcomes associated with changes to non-health dimensions of health care. Considering the many combinations of changes that could result from a reallocation of resources towards a new technology, it is difficult to formally incorporate them into an economic evaluation.

Formally incorporating non-health dimensions of health care into economic evaluations will require more research to develop appropriate techniques. Cutler (2008) measured social preferences for the NHPF dimensions of health care and their relative values using a choice modelling experiment delivered to a representative sample of the Australia population. Given further research, the techniques used in Cutler (2008) could be applied to resource allocation within MSAC HTAs.

In the immediate future, changes to non-health dimensions of health care should be explicitly identified and measured within an economic evaluation, and reported within the assessment. If changes to non-health dimensions cannot be measured, they should be evaluated using a qualitative framework. This will ensure that benefits attributable to a new health technology other than improvements to health will also be considered in the decision making process.
3.7.3 GREATER ECONOMIC AND SOCIAL BENEFITS

The use of health technology not only impacts health and the health care system, but has greater reach into the economy and society in general. For example, in evaluating European HTA frameworks, Busse et al (2002) notes that HTA is a:

…multidisciplinary activity that systematically examines the technical performance, safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organisational implications, social consequences, and legal and ethical considerations of the application of a health technology (Busse et al 2002, pp. 364).

Using a societal perspective in an economic evaluation will implicitly incorporate greater economic and social benefits (if appropriately identified and measured). Greater economic benefits from a new technology are often measured as reduced economic costs, such as avoided productivity losses, or avoided informal care costs. These types of costs are further discussed in Section 3.8.2.

The problem with measuring these types of benefits for an economic evaluation is often the lack of available data. If they are expected to be significant, assumptions should be made and tested within a sensitivity analysis rather than leaving these types of benefits out of the economic evaluation. Where greater economic and social benefits are likely to result but cannot be measured at all due to data limitations, they should be identified and discussed within a qualitative framework so the decision maker can consider these additional benefits when making a decision.

3.8 IDENTIFYING AND MEASURING COSTS

Costs of a new health care technology can be classified into direct health care system costs and indirect costs associated with treatment and the condition. Furthermore there is the opportunity cost of shifting resources away from additional areas of the health care system, or economy.

An economic evaluation should identify and measure those costs that are expected to change, should the new health technology be successful. Thus, if the comparison between two health technologies identify common costs that are not expected to change, these do not have to be measured as they will not affect the outcome. Similarly, if costs are expected to change only slightly, and it is clear their change will not affect the outcome, they do not have to be measured. However, a justification for excluding the costs should be made explicit in the economic evaluation report.

It is problematic to transfer resource use and unit costs from an international setting to an Australian setting due to different health care system procedures and structures, regulations, and subsidies. Consequently it should be avoided.

3.8.1 DIRECT HEALTH CARE SYSTEM COSTS

Direct health care system costs are those costs incurred directly from the intervention. Typically, direct health care system costs are incurred at the intervention stage, within the rehabilitation process, and any treatment maintenance that is undertaken, for example lifetime administration of pharmaceuticals. Direct health system costs include:
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- inpatient and outpatient hospital services;
- residential aged care;
- specialist and primary medical care;
- pharmaceuticals;
- pathology and imaging;
- allied health care; and
- other health system costs, such as capital costs and health care administration.

There are two methods that can be used to estimate direct health care system costs. These include:

- Tops-down approach – A total cost estimate is broken down into its component parts, one of which should be applicable to the economic evaluation. Has the advantage of ensuring the sum of the parts is no greater than the total cost. However, it is often difficult to accurately break down total costs into their component parts so estimates may not be precise.

- Bottom-up costing – Individual item costs are multiplied by the change in utilisation of the item associated with a new technology. Can be a more precise costing method but can also produce unrealistic results if average costs are used but the distribution is skewed (for example, may result in the sum of the parts being greater than the true total).

The choice of method should depend on the available data and justified within the economic evaluation. Within both approaches assumptions on resource use and cost items will have to be made that should be tested within the sensitivity analysis.

As there are imperfections in the health care market, market prices of direct health care system costs may not reflect the true opportunity cost of using the resource. For example, the cost of many drugs provided to those with concession cards in Australia are heavily subsidised by the PBS. If costs resulting from market imperfections are used in an economic evaluation (rather than their true opportunity costs), then total costs will not represent the true costs of a health technology, and subsequent economic evaluation results will be distorted. Adjustments to heavily subsidised prices should be made to reflect the true opportunity cost and tested within a sensitivity analysis.

Capital costs represent the opportunity cost of resources tied up in the capital and the depreciation of the capital over its useful life. The best method to allocate capital costs is to annuitise the initial capital outlay over the useful life of the asset (Drummond et al 2005).

Overhead costs such as health care administration should be included when there is expected to be significant changes relative to other cost changes (that is, they are likely to have an impact on the economic evaluation outcome, for example, a large change in hospital bed days). Usually a simple per diem cost will suffice, although there are several alternative methods that can be used (see Drummond et al 2005). It is important there is a consistent approach.
3.8.2 INDIRECT COSTS

Indirect costs can be defined as those flow-on costs that result from an intervention but were not specifically incurred within the health care system at the time of intervention. They include costs to other sectors of the economy, costs to patients and their family and friends (for example, through informal care), and broader costs to the economy, such as productivity losses and deadweight loss.

Indirect costs that should be considered in an economic evaluation include the following.

- Productivity losses incurred by the patient due to time off work specifically related to the treatment, including:
  - reduced productivity per worker due to the impacts of the treatment on the ability to undertake work;
  - temporary reduction in the size of the labour force (total number of hours worked) due to absenteeism from treatments; and
  - permanent reduction in the size of the labour force due to premature retirement and premature mortality within working age due to treatment.

- Time spent by family and friends providing informal care to the person after treatment. For example, a new technology may require a longer period for rehabilitation, which could mean more time off work for those employed but providing informal care to the treated, or less time for leisure activities for those not in the workforce but providing informal care.

- Travel costs associated with treatment. For example, if the new technology is only offered in major capital cities then the time and cost of those travelling from outside these areas to undergo treatment should be included.

- Aids and home modifications. For example, if there is a difference in the types of equipment used in the rehabilitation process between the new technology and comparator, or results in mobility improvements.

- Deadweight loss associated with the inefficiency of raising additional taxes to fund new technology (assuming new taxes are raised rather than reallocating funds from some other part of the health care system), or additional transfer payments.

Income transfer payments (for example, disability allowances and unemployment benefits) should be excluded from the analysis because they do not represent a direct cost to the economy. Rather, they are a transfer of income from one group to another. However, additional transfer payments are likely to be generated through increased taxes, so the inefficiency (deadweight loss) associated with additional transfer payments need to be included.

The greatest indirect costs are typically productivity losses and the value of informal care. However there are different methods in evaluating these costs, which can often lead to large variations in estimated costs. Preferred methodologies to estimating these costs are outlined below.

ESTIMATING THE VALUE OF A CHANGE IN PRODUCTIVITY

Estimating the cost associated with the loss in productivity should involve the following steps:

- identify the change in productivity associated with a new technology;
measure the change in productivity (for example, the length of an episode of absence from work; and

- value the change in productivity such as the costs per unit of productivity (for example, days off work) and the change in units associated with the new health technology.

There are two approaches that are mostly used to measure productivity losses – the human capital approach and the friction cost approach.

The human capital approach maximises the value of productivity losses by incorporating all short term and long term absence from work, and any disability that reduces the capacity of the individual to work at full productivity capacity (Johanneson and Meltzer 1998).

In contrast, the friction cost approach proposes a more conservative estimate by reasoning that absence from work due to ill health would only temporarily lead to productivity loss as these people could often be replaced after a period of adjustment (Koopmanschap et al 1995). Indirect costs only occur during the time it takes to replace a worker (i.e. the friction period). The cost of the replacement worker is assumed to be zero due to unemployment (i.e. all vacancies due to long-term absence are assumed to be filled by previously unemployed persons). Johannesson and Meltzer (1998) argue that the friction cost method has no basis in economic theory and is not supported by empirical data. The assumption that all vacancies are filled by unemployed persons is not correct. If the method was valid, it would mean that unemployment could be eliminated by simply reducing the number of hours worked for employed people, since the vacancies could be filled by unemployed persons at no cost and without any loss in production.

As Australia has relatively full employment, the human capital approach is the most appropriate for estimating productivity losses. This is because the capacity to replace a worker (especially one that is skilled) from the pool of unemployed is limited and will therefore impact on the long run productivity of the country.

**ESTIMATING THE VALUE OF INFORMAL CARE**

In estimating the value of informal care two methodologies can be used – the replacement cost method and the opportunity cost method.¹⁸ The replacement cost method measures the cost of substituting informal care for formal care services. That is, it values the output of production. The opportunity cost method measures the value in alternative use of time spent caring, which is typically valued by productivity losses (or value of leisure time) associated with caring. This is based on the assumption that time spent providing informal care could be alternatively used within the paid workforce or in leisure activities. The replacement cost method and the opportunity cost method differ conceptually. The former values outputs while the latter values inputs. From a theoretical perspective, the opportunity cost method is the benchmark (van den Berg et al 2006).

The opportunity cost method measures the value in alternative use of time spent caring, which is typically valued by productivity losses (or value of leisure time) associated with caring. This is based on the assumption that time spent providing informal care could be alternatively used within the paid workforce or in leisure activities. The value of informal care using the opportunity cost method can be represented by:

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¹⁸ There is a third methodology known as the self-valuation method but this is seldom used due to the inherent bias associated with the value people place on the services they provide.
Value of informal care = \( t_iw_i \)

where \( t_i \) is the time provided by individual \( i \) on providing care and \( w_i \) is the net market wage rate of individual \( i \) (van den Berg et al 2006). For those who provide informal care but are not in paid work (for example, children or those who have retired) the value of providing informal care is the value of the lost opportunity of undertaking leisure time. This can be approximated by the willingness to pay to undertake leisure, or to avoid work. However, the value of leisure time can be proxied by an average age and sex specific wage rate (Brouwer and Koopmanschap 2000; Heitmueller 2007).

### 3.8.3 Opportunity Costs

As resources are scarce within the health care system, financing new health technologies will need to draw resources from other areas of the health care system. Consequently, existing interventions will have to be reduced in some area, ideally in relation to their cost effectiveness.

The current MSAC process implicitly assumes funds will be drawn from the treatment the new technology is set to replace. That is, resources will be shifted from the current treatment to a more efficient treatment, thereby generating a greater rate of return. This is either through a formal delisting arrangement or market forces pushing users towards the more cost effective health technology.

However, if the total cost of the new health technology exceeds that of the current treatment, then additional resources will have to be drawn from the health care system, or from other productive sectors in the economy. Currently, decision rules assume that the marginal rates of return from these other programs or sectors of the economy are no greater than the health technology under consideration (Birch and Gafni 1992). In reality this may not be the case.

An economic evaluation should therefore include an investigation on where resources are most likely to be drawn from within the health care system. If new funds are used, appropriate opportunity costs should be included, such as the cost of borrowing additional money.

Measuring opportunity costs that capture benefits foregone from shifting resources within the health care system will generally require comprehensive, disaggregated data on the likely net marginal benefits foregone from the introduction of the new technology. The true opportunity cost of a health care program cannot be calculated without knowing where additional expenditure will be drawn from, and the marginal cost of withdrawing that expenditure. In practice this will be unachievable within a sensible time frame, and are therefore is usually not attempted in HTA economic evaluations.

If a health technology requires substantial additional funds in addition to the funds expected to be released from the replaced health technology, then the opportunity cost of the additional funds should be explicitly noted within the economic evaluation. Similarly, if a significant amount of funds are expected to be released from adopting the new health technology, then this should also be noted because these funds can generate further benefits within other areas of the health care system.

Consequently, decision makers should be mindful that the use of incremental cost effectiveness ratios (ICERs), or cost-benefit ratios, that do not include the full opportunity costs will rely heavily on conditions that appear implausible and are not consistent with
welfare economics theory (Birch and Gafni 1992). As such, economic evaluation tools will only be consistent with welfare economics theory if the health technologies being compared produce the same outputs using less resources, or the health technologies produce more outputs but from the same allocation of resources analysis.

### 3.9 TIME HORIZON

The time horizon should reflect the period where differences in health outcomes and the use of health care resources are expected to occur. As many health technologies will impact health over a patient’s lifetime, then these benefits, along with associated treatment costs, should be extrapolated into the future and discounted back to present values. When the impact of the treatment beyond the results of the clinical evidence is uncertain, these estimates should be included in the sensitivity analysis.

If there is no difference in health effects (such as within a CMA or possibly a CEA), a shorter time horizon that captures differences in costs can be justified.

### 3.10 DISCOUNTING

All estimated future benefits and costs associated with the introduction of a new health technology into the health care system should be discounted. The rationale is to account for the concept of positive time preference (most people would rather consume the same amount of goods or health now rather than in the future), and the opportunity cost associated with using scarce resources in the health care system (Krahn and Gafni 1993).

However, there is some debate as to what discount rate should be used, and whether benefits when measured in non-monetary units such as QALYs should be discounted at the same rate as costs (Gravelle et al 2007). The argument for discounting health benefits at a lower rate is based on the assumption that the value of future health grows over time (Gravelle and Smith 2001).

However, Australian PBAC guidelines and NICE guidelines (Claxton et al 2005) currently recommend the same discount rate should be used for health benefits and costs.19 In Australia, the PBAC guidelines recommend five per cent (PBAC 2008), while international discount rates are generally between three to five per cent (Brouwer et al 2005). This follows the conventional practice of discounting in health program evaluation around the world, but it is unclear whether it reflects Australia’s true societal preferences.

Whether differential discount rates or constant discount rates are used, and at what level these discount rates should be set, are for further areas of research. However, the choice of a discount rate is not just a theoretical exercise because it will have significant impacts on economic evaluation outcomes. The higher the discount rate the less valuable benefits and costs in the future will be. Health technologies that provide benefits up-front will be perceived as being more favourable compared to health technologies that require an up-front investment but deliver health benefits over a long period of time. The choice of a discount rate will be particularly relevant if:

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19 NICE shifted away from differential discounting in their 2004 Guidelines to the methods of technology appraisal (Gravelle et al 2007).
comparing different types of health technologies such as a procedure or device with a pharmaceutical because the timing of benefits and costs are likely to differ; and

comparing therapeutic interventions with short term benefits against preventative interventions with long term benefits.

Although less relevant for health technologies that have a short term perspective, the choice between a three per cent discount rate compared to a five per cent discount rate when assessing health technologies that deliver long term benefits can mean the difference between a new technology being recommended for funding or not.

The large impact a chosen discount rate can have on economic evaluation outcomes means any recommended discount rate made within an MSAC economic framework should be theoretically defensible, based on solid research, and updated regularly as social preferences change. Discount rates should be:

- applied consistently within an economic evaluation;
- applied consistently across economic evaluations; and
- included within the sensitivity analysis.

Applying the above principles will enable the comparison of results across studies without the confounding impact of alternative discount rates.

### 3.11 DEALING WITH UNCERTAINTY

The large number of applications (and associated negative outcomes) that have not got to the economic evaluation stage due to ‘insufficient’ evidence suggests high level evidence is generally the only type of evidence acceptable by MSAC. As argued in Section 3.5 all types of evidence should be used in an economic evaluation and any assumptions and uncertainty should be captured using specifically designed techniques, such as decision analytic modelling, probabilistic sensitivity analysis, and scenario analysis. These are further discussed below.

#### 3.11.1 DECISION ANALYTIC MODELLING

Economic evaluation within an MSAC assessment should be used to inform decisions regarding resource allocation decisions under conditions of uncertainty. Decision analytic modelling provides a framework to combine evidence for each input from a range of sources and evidence types, and to assess the uncertainty surrounding outcomes associated with procedures and devices. It can reduce the need to reject applications based on ‘insufficient’ evidence and provide a framework for making decisions on whether conditional funding should be undertaken. Drummond et al (2005) notes that decision analytic modelling can satisfy five important objectives within an economic evaluation, including:

- provides a structure that enables the systematic investigation of alternative prognoses associated with a condition and how the new health technology can impact on these outcomes;
- provides an analytical framework for incorporating alternative types of evidence and incorporating uncertainty associated with the evidence;
- allows a direct translation of evidence into expected health and non-health outcomes and costs associated with the health technologies being compared. By incorporating an
economic evaluation tool, the health technology that is expected to be cost effective can be identified;

- uncertainty relating to model structure and input parameters can be incorporated; and
- can identify whether an application requires further research.

Developing a decision analytic model involves several stages. These are listed below.

- Defining the decision problem, including the groups receiving the current and new technology.
  - May also include treatment rules and clinical treatment pathways such as a sequence of treatment therapies.

- Defining boundaries for the model to exclude possible implications of an intervention that may not be appropriate for the analysis.
  - Should use the extent to which excluding items are likely to impact on economic evaluation outcomes as a guide for developing boundaries.
  - May also be naturally constructed through availability of data and complexity of condition or health technology under investigation.

- Constructing the model structure to formally develop relationships between inputs into the model to outcomes of interest (health and non-health). There are two model structures that are typically used in economic evaluations.
  - A **decision tree model** can represent all possible health outcomes following an intervention using a new health technology compared to its chosen comparators through a series of pathways. Chance nodes represent uncertainty within the model and lead to the range of pathways associated with each health technology. Pathways are built using a series of branches representing each event. The likelihood of events is represented by branch conditional probabilities. Pathway probabilities and associated costs are used to determine the probability of an event occurring and the expected costs of that event, which can then be used to determine expected cost effectiveness. The main limitation of the decision tree model is that it cannot incorporate time very well so is inappropriate for conditions where long term outcomes are expected.

  - A **Markov model** incorporates time by expressing a treatment path using a series of ‘states’ (described using probabilities) that a patient can occupy at a specific period in time. These states are assessed over cycles (discrete time periods) and the length of a cycle can be adjusted depending on the condition being investigated. Within each cycle, patients transition between states. To calculate expected outcomes and costs and associated cost effectiveness, costs and outcomes of each Markov state are weighted by the time a patient stays in that state (Drummond et al 2005). The main limitation of a Markov model is that it assumes transition probabilities are independent from time.

  - It is also possible to combine a decision tree model (to evaluate short term outcomes) and a Markov model (to evaluate long term outcomes) within an economic evaluation.

- Undertaking a systematic process to identifying and synthesising clinical and non-clinical evidence. Need to ensure evidence is not included subjectively.

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20 For further discussion relating to each stage see Drummond et al (2005).
An improved HTA economic evaluation framework for Australia

- May include the use of meta-analysis (see Sutton et al 2000)
- Incorporating uncertainty into the decision analytic model
  - Parameter uncertainty should be incorporated using a probabilistic sensitivity analysis (see Section 3.11.2).
  - Structural uncertainty should be incorporated using a scenario analysis (see Section 3.11.3)
  - Known variability in inputs, such as characteristics of alternative sub-groups (patients or health care locations), should be incorporated by re-applying the model to each sub-group.

To avoid decisions based on 'insufficient' evidence (in which case the evaluation would be incomplete and biased towards health technologies where decisions are fairly simple), decision analytic modelling should be a fundamental standard tool used in MSAC economic evaluations. This is especially the case when complex and uncertain decisions need to be made.

3.11.1.1 DETERMINING CANDIDATES FOR CONDITIONAL FUNDING

The decision to conditionally fund a health technology while undertaking additional research should be based on an economic framework. The framework should compare the expected benefits from additional research with the costs of undertaking that research. If the former is larger than the latter then conditional funding should be granted subject to additional research being undertaken.

The benefits of undertaking additional research is avoiding a Type II error (rejecting an application when the new health technology is actually cost effective) while the costs are making a Type I error (implementing a less cost effective technology) and the administrative costs of undertaking the research, such as data collection and analysis. If the expected value of a Type II error is greater than the costs, then conditional funding should be granted.

Decision analytic modelling can be used to guide a decision on whether conditional funding with evidence development may be appropriate (Claxton et al 2002; Drummond et al 2005) This is because it implicitly determines the probabilities of making Type I and Type II errors, which can be multiplied by the costs of making these types of errors to determine their expected values.

As the decision analytic model is composed of individual parameters, the uncertainty and expected cost of making a Type II error associated with a specific parameter can also be determined. This can be useful in determining what type of additional research should be undertaken in order to reduce uncertainty. Focus can then be on those inputs where more precise estimates would be most valuable in determining the true cost effectiveness of a health technology. This type of approach would limit costs associated with additional research and collection of superfluous information would be avoided.

Decision analytic modelling to inform conditional funding decisions is most useful where economic evaluations:
- contain a substantial amount of uncertainty that cannot be adequately addressed through probabilistic sensitivity analysis and scenario analysis;
- cost-effectiveness is marginal; and
there is a large population of eligible patients where a Type II error could result in a significant loss of welfare to society.

The amount and type of additional research will depend on the characteristics of the health technologies and the type of uncertainty within the model. Based on a decision analytic model, recommendations should be explicitly made within the economic evaluation on whether conditional funding with additional research should be undertaken.

3.11.2 Probabilistic sensitivity analysis

No matter how definitive a study may claim to be, all data represent point estimates of a range and distribution of possible values. Point estimates are subject to errors in data collection processes, measurement errors, and errors in interpretation. There is also likely to be variation and errors in the application of economic evaluation tools, and uncertainty in the concepts and theory behind those tools (Drummond et al 2008), which can lead to errors in economic evaluation estimates and subsequently, the final recommendation. In summary, variation in economic evaluations can stem from:

- methodology used in the economics evaluation;
- sampling variation in the evidence used in the analysis;
- uncertainty in estimates of inputs, such as unit cost data;
- uncertainty in the application of the economic evaluation tool;
- extrapolating benefits and costs into the future; and
- generalising findings from the evidence to a wider target group, or alternative health care environment.

It is important for the MSAC committee to know the uncertainty surrounding inputs and outputs used within an economic evaluation, as this will directly translate into decision uncertainty. As noted by Claxton et al (2005), a sensitivity analysis will be useful for several reasons, including:

- to inform whether existing evidence is sufficient to fully approve a technology, or partially approve a technology based on the need for further evidence;
- to assist in determining the appropriate length of time before a partially approved technology should be reconsidered; and
- provide guidance on the implications of making the wrong decision.

In essence, sensitivity analysis helps establish the confidence intervals around modelling results, assessments, and recommendations. In effect, it characterises the magnitude of the decision uncertainty (Drummond et al 2008).

In Australia, sensitivity analysis in HTA economic evaluations have generally consisted of straightforward approaches that recalculate results from systematically changing one or two parameters, or each input is set to their most optimistic and pessimistic values (NHMRC 2001). However, simple sensitivity analyses such as a one-way sensitivity analysis is likely to underestimate the uncertainty associated with results, while an extreme scenario analysis is likely to overestimate the risk (NHMRC 2001). Furthermore, uncertainty in inputs estimates may not significantly impact economic evaluation results when evaluated on their own, but when combined with uncertainty in other input estimates, may generate considerable uncertainty in economic evaluation results.
An improved HTA economic evaluation framework for Australia

Given recent advancements in technology there are much more sophisticated techniques that can be used for a sensitivity analysis within an economic evaluation of health technology. These include information analysis (Claxton 1999), real options pricing (Palmer and Smith 2000), and probabilistic sensitivity analysis (Claxton et al 2005). The latter technique is the most well developed, and well known, technique used in international health technology assessment. It is therefore recommended for MSAC assessments.

Probabilistic sensitivity analysis requires all estimate inputs used in an economic evaluation tool to be specified as probability distributions rather than point estimates. The distributions represent the uncertainty surrounding the point estimates. They can be bounded with a chosen maximum and minimum value (as in a triangular distribution), or unbounded where extreme values are allowed but are highly unlikely (as in a normal distribution).

Once distributions are placed around each point estimate, repeated sampling techniques such as Monte Carlo simulation can be used to select values from each distribution simultaneously and at random. Within each sampling iteration, model outputs are recalculated. This is performed a large number of times to develop a probability distribution of outputs that incorporates the joint uncertainty across all point estimates. The empirical distribution is used as estimates of the actual distribution from which confidence intervals can be estimated.

There is no single repeated sampling technique, although all approaches tend to follow the following steps.

- Define a probability distribution for each point estimate that contains uncertainty, including the shape of the distribution and minimum and maximum values if the distribution is bounded.
- Generate inputs into the model by simultaneously drawing random numbers from each specified distribution.
- Recalculate model outputs (for example, an ICER).
- Repeat the three steps above many times (for example, 10,000 times) to develop a distribution and establish confidence intervals.

The only subjective step in the above is determining an appropriate distribution for each point estimate. Although the normal distribution is widely used in statistics, its use is based on the central limit theorem. The normal distribution has no bounds on the value a parameter can take, whereas point estimates used in the economic evaluation usually have logical constraints. For example, a trial that estimates the number of successful interventions will typically have zero representing failure and one representing success. This is a discrete distribution, where the probability of success is naturally bounded on the interval between zero and one. Briggs et al (2002) provides some suggested distributions for alternative types of point estimates, including:

- probability parameters – Logit or probit distribution to bound a continuous probability distribution on the zero to one interval;
- resource item parameters – As the number of resources used could be considered a count variable, a Poisson distribution could be used, or alternatively a discrete distribution;
- unit cost parameters – As the unit cost of a resource is strictly continuous, and are constrained to be positive, a gamma distribution could be used to represent uncertainty, or alternatively a triangular distribution; and
relative risk parameters – As methods for calculating relative risk confidence intervals in trials typically rely on the log-normal distribution, the same distribution should be used in the probability sensitivity analysis.

Although several alternative distributions could be used to represent uncertainty, ultimately the chosen distribution, and the bounds around that distribution, should reflect the statistical uncertainty in the point estimate (Claxton et al 2005).

One limitation of Monte Carlo simulations is that results are specific to the assumptions used within each simulation. If distributions around point estimates are changed, the number of parameters change, or alternative point estimates are used, then an entirely new simulation needs to be undertaken.

### 3.11.3 SCENARIO ANALYSIS

A scenario analysis uses a set of constructed hypothetical outcomes to determine impacts on economic evaluation results. The scenarios are likely to include a base case scenario that represents the most likely outcome, and alternative scenarios that represent a departure from the base case somewhere along the evaluation path. These latter scenarios are usually constructed because there is a possibility they could eventuate.

Although evaluation using a scenario analysis can also be handled using probabilistic sensitivity analysis, it is most useful for structural uncertainty within a decision analytic model.

### 3.12 REVIEW OF ECONOMIC EVALUATION RESULTS

Best practice in health technology assessment commands an independent, and external, review of economic evaluation methodology and results is undertaken before a final recommendation is made (Busse et al 2002).

Critical assessment of an economic evaluation should be undertaken by individuals who are trained in health economics and can fully appreciate the many technical and methodological considerations within an economic evaluation. A critical assessment of an economic evaluation should aim to answer three general questions (Drummond et al 2005).

- Is the methodology appropriate?
- Are the results valid?
- Do the results apply to the current health care setting?

Drummond et al (2005) provide a summary of further relevant questions that should be answered in addressing whether the methodology is appropriate, and whether the results are valid. These are presented below.

- Was a well defined question posed in answerable form?
  - Did the study examine both costs and effects of the service(s) or program(s)?
  - Did the study involve a comparison of alternatives?
  - Was a viewpoint for the analysis stated and was the study placed in any particular decision-making context?

- Was a comprehensive description of the competing alternatives given?
An improved HTA economic evaluation framework for Australia

- Were any relevant alternatives omitted?
- Was (should) a do-nothing alternative (be) considered?

- Was the effectiveness of the programs or services established?
  - Was this done through a randomised, controlled clinical trial? If so, did the trial protocol reflect what would happen in regular practice?
  - Were effectiveness data collected and summarised through a systematic overview of clinical studies? If so, were the search strategy and rules for inclusion or exclusion outlined?
  - Were observational data or assumptions used to establish effectiveness? If so, what are the potential biases in results?

- Were all the important and relevant costs and consequences for each alternative identified?
  - Was the range wide enough for the research question at hand?
  - Did it cover all relevant viewpoints?
  - Were capital costs, as well as operating costs, included?

- Were costs and consequences measured accurately in appropriate physical units?
  - Were the sources of resource utilisation described and justified?
  - Were any of the identified items omitted from measurement? If so, does this mean that they carried no weight in the subsequent analysis?
  - Were there any special circumstances that made measurement difficult? Were these circumstances handled appropriately?

- Were costs and consequences valued credibly?
  - Were the sources of all values clearly identified?
  - Were market values employed for changes involving resources gained or depleted?

- Where market values were absent, or market values did not reflect actual values, were adjustments made to approximate market values?

- Was the valuation of consequences appropriate for the question posed?

- Were costs and consequences adjusted for differential timing?
  - Were costs and consequences that occur in the future ‘discounted’ to their present values?
  - Was any justification given for the discount rate used?

- Was an incremental analysis of costs and consequences of alternatives performed?
  - Were the additional (incremental) costs generated by one alternative over another compared to the additional effects, benefits, or utilities generated?

- Was allowance made for uncertainty in the estimates of costs and consequences?
  - If patient-level data on costs or consequences were available, were appropriate statistical analyses performed?
  - If a sensitivity analysis was employed, was justification provided for the ranges or distribution of values and the form of sensitivity analysis used?
  - Were the conclusions of the study sensitive to the uncertainty in the results, as quantified by the statistical and/or sensitivity analysis?
3.13 OTHER CONSIDERATIONS

The link between economic evaluation findings and the final recommendation needs to be transparent and clearly defined. There must be transparency in the criteria used to develop a recommendation, and transparency in the way findings from the economic evaluation impacted the final recommendation. Furthermore, there should be a direct link between economic evaluation outcomes, HTA, and the reimbursement process. Finally, an economic evaluation should be one tool used in formulating a recommendation, and not the only tool. There are other important considerations that cannot be measured through economic evaluation tools, such as equity and political concerns.

3.13.1 EQUITY AND EFFICIENCY TRADE-OFF

Equity is recognised within the Australian health care system as being of paramount importance. This can be seen from the large amount of resources that have been devoted to providing disadvantaged groups with subsidised health care, either to ensure these individuals have the capacity to access health care, to increase utilisation, or ultimately to reduce health disparities.

Decisions on whether a health care technology should be funded by the MBS should not be based on cost-effectiveness results alone. MSAC also needs to consider equity within health care spending. Often there is a trade-off between equity and efficiency in health care resource allocation.

Traditionally, measuring equity in health care has not focused on whether inequities in health exist, but whether they are related to inequalities in socioeconomic status (Wagstaff et al, 1991a). However, there are many alternative definitions of equity that can be used in the Australia health care context, each leading to different policy outcomes. At its most basic level, the definition of equity in health care has been debated on whether it relates to equity in health, health care utilisation, or equity in access to health care (Wagstaff et al 1991a, 1991b; Mooney et al 1991; Culyer et al 1992).

As equity should be incorporated in the decision making process, a clear definition of equity needs to be established. Furthermore, a framework should be developed that enables the
consistent assessment of a health technology’s impact on equity. The framework and its application should be transparent and open to critique.

In the immediate future, all equity assumptions and implications should be explored and highlighted separately within the economic evaluation report. This may include:

- **Equity associated with the choice of outcome measure.**
  - The use of QALYs implicitly assumes the value of health is not age dependent and that a large gain to a small group of people is the same as a small gain to a large group of people.

- **Equity implications associated with the chosen discount rate.**
  - Higher discount rate favours health technology that has immediate benefits and not long term outcomes (for example, prevention that may benefit the young).

- **Distributional impact of a change in costs.**
  - New technology may shift costs from one group to another (for example, from health care system to patient and informal care if more home care is required).

- **Distributional impact of a shift in health care resources or additional taxation.**
  - High cost technology may require funds shifted from other sectors of the economy in addition to funds freed up from the old technology. This could have subsequent negative health outcomes.
  - High cost technology may put pressure on the budget for funds to be sourced through additional taxation.

- **Patient subgroups that are the primary beneficiaries of the new technology and the subgroups that are negatively affected if the current technology is withdrawn from the MBS list.**
  - Given one objective of the current government is to reduce health disparities between indigenous population and the rest of Australia, particular attention should be given to the former.

### 3.13.2 INCORPORATING PUBLIC PREFERENCES

MSAC advises the Minister for the Department of Health and Ageing on which new technologies should be funded by the MBS. The MBS is funded by general taxation, which means current and future users of the health care system should have the opportunity to be involved in the decisions about how limited MBS resources should be allocated.

Consequently social preferences for health care technology should be included in the assessment process. Disregard for social preferences may represent disconnect between resource allocation and social welfare.

In general, individuals have a diversity of preferences within society, and these heterogeneous preferences extend to health technology. Although an advisory panel may contain a consumer representative, there is no guarantee that public preferences are fully incorporated within economic assessments. Assumed societal preferences may be incorporated in an assessment through proxy (that is, medical specialists on the advisory panel take into consideration what they believe to be patient preferences), but there is no guarantee they will align with true societal preferences.
4. CASE STUDIES

In order to demonstrate areas for improvement within the current economic framework, and the practical application of the improved economic framework outlined in the previous chapter, three case studies have been provided. These include:

- point of care testing (PoCT) to monitor patients receiving Warfarin therapy;
- cardiac radiofrequency catheter ablation; and
- remote monitoring of implantable cardiac devices.

The case studies do not represent a formal economic evaluation of technologies and should therefore not be treated as such. Rather, they demonstrate an approach that should be used when evaluating technologies, and highlight differences in methodologies between an assessment using the current economic evaluation framework and an assessment based on the improved economic framework presented in the last chapter.

4.1 POINT-OF-CARE TESTING (POCT) FOR WARFARIN LEVELS

Oral anticoagulants (OACs) are used for the prevention and treatment of thromboembolic events, with Warfarin as the anticoagulant of choice for long-term (greater than three months) oral anticoagulation therapy (OAT) (Brown et al 2007). The therapeutic range of Warfarin is narrow. Over-dosage results in an increased risk of haemorrhagic events, and under-dosage results in an increased risk of thromboembolic events (MSAC 2005c). MSAC (2005) lists the specific indications for Warfarin therapy as:

- patients with mechanical prosthetic heart valves;
- prophylaxis of venous thrombosis;
- treatment of venous thrombosis;
- treatment of pulmonary embolism;
- prevention of systematic embolism;
- tissue heart valves (first three months);
- acute myocardial infarction (to prevent systemic embolism or recurrence);
- valvular heart disease; and
- atrial fibrillation.

International normalised ratio (INR) is a diagnostic test for the monitoring of people receiving Warfarin therapy and was developed by the World Health Organization in the early 1980s. INR testing is currently performed in pathology laboratories in Australia with a sample of the patient’s blood having been drawn from a vein. However, the technology exists for testing to be performed outside the laboratory. Point-of-care-testing (POCT) allows for greater convenience for patients because the devices are portable and only require a drop of blood from the fingertip. On-site testing allows for direct discussion of results and any indicated change in management. Some countries, such as Germany, use self-testing and self-management with POC devices as established therapeutic methods (Taborski et al 1999).
MSAC (2005) reviewed the use of INR POCT device developed by CoaguChek in general practice surgery in Australia. The economic evaluation concluded that the difference in effectiveness between CoaguChek and its comparator (laboratory testing) was uncertain. Consequently, a cost-minimisation analysis was performed and CoaguChek was concluded to be more costly. As a result, MSAC recommended to the Minister for Health and Ageing that there was insufficient evidence to support the use of CoaguChek in general practice.

By comparing the original MSAC economic evaluation with the improved economic framework presented in Chapter 3, the purpose of this case study was to demonstrate areas within the current economic evaluation framework where improvements could be made. In particular, this case study highlights:

- the need for developing an accurate study frame at the start of the evaluation using a thorough investigation of the literature;
- the need to comprehensively identify all possible changes to health status, including changes to the risk of adverse events;
- the importance of using a full societal perspective to capture expected benefits to patients incurred outside the health care system;
- the need to consider expected changes to alternative health care attributes in addition to safety, effectiveness, and efficiency;
- the inappropriateness of simple sensitivity analyses; and
- the importance of including social preferences in the decision making process.

Table 4-1 presents a summary of the MSAC economic evaluation against the improved economic framework. The conclusion is that the economic evaluation within this particular MSAC economic evaluation was unable to capture important elements of CoaguChek for the monitoring of Warfarin levels. This may have lead to an incorrect conclusion on the cost effectiveness of this device in Australia.
**TABLE 4-1: MSAC ECONOMIC EVALUATION VERSUS THE IMPROVED ECONOMIC FRAMEWORK**

<table>
<thead>
<tr>
<th><strong>Study frame</strong></th>
<th>MSAC economic evaluation</th>
<th>Improved economic framework</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- No justification for a full health economic analysis of INR POCT in general practice</td>
<td>- Use widely available modelling techniques to develop sufficient data to conduct a thorough analysis. Otherwise, results will be narrow and biased towards cost-minimising technologies (not cost-effective technologies), which ultimately redistributes scarce resources inefficiently</td>
</tr>
<tr>
<td></td>
<td>- Specific objectives of the economic assessment covered: identification and comparison of direct costs; identification of variables which may affect the indirect and flow on-costs; identification of uncertain variables</td>
<td></td>
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<table>
<thead>
<tr>
<th><strong>Perspective</strong></th>
<th>MSAC economic evaluation</th>
<th>Improved economic framework</th>
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<tbody>
<tr>
<td>Comparator</td>
<td>- Federal budget</td>
<td>- Societal</td>
</tr>
<tr>
<td></td>
<td>- Laboratory-based INR testing</td>
<td>- Usual care (laboratory-based INR testing)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Potential future comparator (self-testing)</td>
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</table>

<table>
<thead>
<tr>
<th><strong>Economic evaluation tool</strong></th>
<th>MSAC economic evaluation</th>
<th>Improved economic framework</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifying and measuring benefits</td>
<td>- CMA</td>
<td>- CEA or CUA (depending on health outcome)</td>
</tr>
<tr>
<td></td>
<td>- Reduction in direct costs</td>
<td>- Health care outcomes associated with reduction in risks (summary health measure such as QALY)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Health care system benefits (reduction in direct and indirect costs)</td>
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<table>
<thead>
<tr>
<th><strong>Identifying and measuring costs</strong></th>
<th>MSAC economic evaluation</th>
<th>Improved economic framework</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>- Increase in direct costs</td>
<td>- Direct costs</td>
</tr>
<tr>
<td></td>
<td>- Not specified</td>
<td>- Indirect costs (productivity loss, time lost and travel costs)</td>
</tr>
<tr>
<td></td>
<td>- Not used</td>
<td>- Must be clearly identified and explained</td>
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<thead>
<tr>
<th><strong>Discounting</strong></th>
<th>MSAC economic evaluation</th>
<th>Improved economic framework</th>
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<tbody>
<tr>
<td></td>
<td>- One-way sensitivity analysis</td>
<td>- Probabilistic sensitivity analysis</td>
</tr>
<tr>
<td></td>
<td>- Extreme scenario analysis</td>
<td>- Economic evaluation results should be used in conjunction with other considerations, such as equity and public preferences.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Dealing with uncertainty</strong></th>
<th>MSAC economic evaluation</th>
<th>Improved economic framework</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Provides indication on the safety, effectiveness and cost effectiveness of CoaguChek</td>
<td></td>
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<table>
<thead>
<tr>
<th><strong>Role of HTA in decision making</strong></th>
<th>MSAC economic evaluation</th>
<th>Improved economic framework</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>- Economic evaluation results should be used in conjunction with other considerations, such as equity and public preferences.</td>
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TABLE 4-2: MSAC ECONOMIC EVALUATION VERSUS THE IMPROVED ECONOMIC FRAMEWORK CONTINUED

<table>
<thead>
<tr>
<th>Review of economic evaluation results</th>
<th>MSAC economic evaluation</th>
<th>Improved economic framework</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Applicant invited to comment prior to recommendation to Minister</td>
<td>- External and independent critical review must be undertaken by an appropriately qualified person or organisation</td>
<td></td>
</tr>
<tr>
<td>- Formal mechanisms for public feedback</td>
<td>- Peer review</td>
<td></td>
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</tbody>
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Source: Access Economics

4.1.1 STUDY FRAME

MSAC ECONOMIC EVALUATION

The original MSAC economic evaluation for Warfarin POCT using CoaguChek noted that, due to the insufficient evidence demonstrating an improvement in patient outcomes between CoaguChek and laboratory testing, there was no justification for a full health economic analysis. It further noted that that ‘new technologies which cannot demonstrate a level of effectiveness which is at least equivalent to that of the comparator do not warrant a full cost-effectiveness analysis’ (MSAC 2005c, pp. 28). Thus, the study frame within the economic evaluation was limited to measuring costs associated with both types of interventions. The specific purpose of the economic assessment was to:

- identify and compare the direct costs of INR POCT in general practice and INR testing through laboratories;
- identify variables which may affect the indirect and flow-on costs of INR POCT in general practice compared with INR testing through laboratories; and
- identify any uncertain variables which may have a significant effect on the estimated cost of INR POCT in general practice.

The target audience was not explicitly identified but it was noted that INR POCT would be advantageous in rural and remote settings (improved access) as well as in paediatric populations (ease of obtaining sample). However, an attempt to quantify improved access was not undertaken.

There are some concerns with the justification of using a cost comparison approach in the MSAC economic evaluation. First, the definition of ‘outcomes’ is unclear. ‘Outcomes’ in this context should refer to immediate health impacts, a reduction in the risks associated with POCT (for example, reduced risk of injury associated with venipuncture), and an increased capacity for immediate care. ‘Outcomes’ should also incorporate non-health benefits, such as increased accessibility through a reduction in GP visits, increased continuity of care, and greater responsiveness.

Second, the justification for avoiding a full cost effectiveness analysis based on the perception that POCT is not as effective is incorrect. A full economic evaluation is justified if effectiveness is no worse than INR testing through laboratories but is associated with
improved safety (as evident in this context). It is also justified if POCT is less effective but is associated with improved safety, and the net benefits from improved safety outweigh the costs (harms) associated with reduced effectiveness.

**IMPROVED ECONOMIC EVALUATION FRAMEWORK**

The MSAC economic evaluation deemed there was insufficient evidence on clinical effectiveness to conduct a cost-effectiveness analysis. However, other studies have outlined a decision model approach to estimate the effectiveness (defined as a reduction in the number of thromboembolic and haemorrhagic events) of the POCT in comparison to laboratory testing (Disch et al 1995; Gage et al 1995; Lafata et al 2000a; Lafata et al 2000b; Naglie and Detsky 1992; Seto et al 1997; Tsetvat et al 1989). The decision model allowed researchers to incorporate the probability of adverse events occurring under each technology to determine the effectiveness of the new technology and its comparators. The number of adverse events attributable to each technology was also factored into the costs comparisons. The differences were significant enough to conclude POCT for anticoagulant levels was more effective than laboratory-based testing (Brown et al 2007).

Figure 4-1 provides an overview of the decision tree used in the 5-year Markov model which Brown et al (2007) used in conjunction with information in the scientific literature, data from a large health system and expert opinion to evaluate the health and economic outcomes associated with the anticoagulation management approaches. For each management approach, the time spent below, above or within the therapeutic range of Warfarin was used to determine the risk of thromboembolic and hemorrhagic events. This decision tree was applied to a hypothetical cohort of patients for five years after the first use of Warfarin. Patients move among the five defined health states (no prior event; prior event, non-disabling, continuing therapy; prior event, permanently disabled, continuing therapy; prior event, permanently disabled, discontinued therapy; dead) with the probabilities of each event occurring drawn from the scientific literature.

As an alternative methodology to decision models, DoHA (2009) used Generalised Estimating Equations (GEE) to model count and normal data and obtain estimated values for resource use. This further highlights the need to acknowledge the shortcomings of the data, but also find a way to overcome them to provide a thorough analysis.

By not accounting for the disparity in effectiveness between the technologies, the MSAC economic evaluation significantly underestimated the outcomes of POCT in Australia. It seems this led to the development of an inappropriate study frame, and ensured the analysis was biased towards the cost-minimising technology. Consequently, important outcomes from the use of CoaguChek likely to impact the cost effectiveness results were excluded.
Other shortcomings of the study frame include a narrow definition of the new technology, lack of acknowledgement of alternative uses of Coaguchek, and not accounting for potential change in future demand by those who are expected to receive the greatest benefits from POCT (for example, rural and paediatric populations).

Another concern with the economic evaluation was the exclusion of alternative POCT devices. For example, Brown et al (2007) included all alternative POCT devices in their cost-utility analysis to provide a wide-ranging examination of not only current treatment as a comparator but alternative device options.

### 4.1.2 Perspective of the Analysis

**MSAC Economic Evaluation**

Perspectives on costs and outcomes used in the MSAC economic evaluation were of the Commonwealth and the Australian health system. Although the economic evaluation discusses the possibility of 'indirect and flow-on costs', these are restricted to health care system costs.

**Improved Economic Framework**

Although the economic evaluation noted that POCT was likely to affect direct health care system costs and indirect costs, the latter was restricted to costs incurred within the health care system (such as costs associated with changes in the management of patients and costs associated with adverse events of warfarin therapy). Consequently, the perspective of the analysis seemed to be that of the funder, although this was not explicitly stated.
However, the economic evaluation should have adopted a societal perspective as there are likely to be significant reductions in costs to the patient (for example, a reduction in copayments and travel costs associated with repeat GP visits).

By adopting a societal perspective, the economic evaluation could have identified and quantified (if data were available) direct healthcare costs to the federal government (costs associated with anticoagulation testing, monitoring, costs of adverse thromboembolic events, and with or without nursing home costs), as well as the costs incurred by the patients and caregivers (lost leisure time, travel costs). Hence, the final recommendation would be based on an analysis that incorporates all benefits and costs.

Adopting a societal perspective would have also allowed for the investigation of the transfer of costs between groups associated with CoaguChek, and highlighted any inequities in access to testing of Warfarin levels.

Both the DoHA Trial (DoHA 2009a) and the CADTH HTA (Brown et al 2007) were investigated from a societal perspective. DoHA (2009) contended that since resources are inevitably limited, it is important that the resources allocated to INR testing are optimised, whether it is through POCT or laboratory-based testing. Brown et al (2007) presented their model from two perspectives, the health care provider perspective and the societal perspective, to determine the costs and benefits of the new technology to those who ultimately fund the health system (health providers) and to explore resource allocation (societal perspective).

4.1.3 SELECTING THE COMPARATOR

MSAC ECONOMIC EVALUATION

The comparator was chosen based on the test used most commonly in current practice in Australia. In this case that was laboratory-based INR testing in Australia.

IMPROVED ECONOMIC FRAMEWORK

The MSAC economic evaluation should have also considered potential future technologies associated with Warfarin level monitoring. One of these is the use of CoaguChek in the home setting rather than at a GP. For example, Brown et al (2007) recognised the growing demand for patient self-testing where patients use the POCT monitor at home to determine their INR and phone the results to their medical practitioner. CoaguChek has been developed for use within a general practice, at home, during mobile emergency treatment and for routine follow-up in a hospital clinic (Roche Diagnostics 2008). These alternative uses should have been explored within the MSAC economic evaluation. By not including alternative types of uses, the study limited it’s applicability to the short term.

4.1.4 USING AN ECONOMIC EVALUATION TOOL

MSAC ECONOMIC EVALUATION

Although the MSAC evaluation report does not explicitly specify which economic evaluation tool is used, it does indicate that a full cost-effectiveness analysis was not warranted. Instead the economic evaluation assumed that CoaguChek in general practice and laboratory-based testing were equally effective. Furthermore, the incremental increase in direct costs between
the new technology and comparator was only measured. This implies a cost-minimisation analysis was employed.

**IMPROVED ECONOMIC FRAMEWORK**

The assumption that CoaguChek and centralised testing have the same outcomes led to an incorrect choice in the economic evaluation tool. This resulted in a purely cost-based conclusion. Had another evaluation tool been used, the results may have been significantly different.

DoHA (2009) performed a cost-effectiveness analysis using the proportion of patients within the therapeutic range for each condition at the end of the Trial as the outcome indicator. The Trial contended that when the INR was out of its therapeutic range there were more adverse events (thromboembolic and bleeding events) and that the safety and efficacy of Warfarin was increased by maintaining good anticoagulation control. Cost-effectiveness was determined using the Incremental Cost Effectiveness Ratio (ICER) between POCT and laboratory-based testing, calculated as the difference between costs weighted by the difference between outcomes. This cost-effectiveness analysis resulted in the same conclusion as the MSAC economic evaluation (POCT was dominated by the comparator).

On the other hand, Brown et al (2007) conducted a cost-utility analysis because it allowed for direct comparisons among decision options. QALYs were calculated using utility weights available in the literature for possible adverse events such as thromboembolic and bleeding events. In contrast to the MSAC economic evaluation and the DoHA trial, Brown et al (2007) found that from a health care provider perspective, CoaguChek is cost-saving, and from a societal perspective, it is cost-effective.

The alternative choice of economic evaluation tools and the associated alternative outcomes between Brown et al (2007) compared to DoHA (2009) and the MSAC economic evaluation clearly highlights the need for consistency in the choice of economic evaluation tools in MSAC economic evaluations.

**4.1.5 IDENTIFYING AND MEASURING BENEFITS**

**MSAC ECONOMIC EVALUATION**

Benefits measured in the MSAC economic evaluation were the potential reduction in direct costs associated with implementation of INR POCT in general practice. If the new technology led to a decrease in the direct costs per unit of output, it was considered a favourable investment. However, INR POCT in general practice was deemed to cost an additional A$16.20 per test than a laboratory-based test and was thus considered less beneficial.

**IMPROVED ECONOMIC FRAMEWORK**

As the MSAC economic evaluation does not account for differences in effectiveness between CoaguChek and centralised testing (i.e. reductions in the risk of thromboembolic and haemorrhagic events), the analysis does not include a measure of improved health outcomes.

However, both changes to health care outcomes and other health care system benefits should be measured. The MSAC economic evaluation only included changes to per unit costs as the only potential benefit measure. To provide a thorough analysis of the benefits
associated with CoaguChek, the study should have included a measure of improved health care outcomes, namely a summary health measure such as a QALY (Brown et al 2007). If QALYs were not deemed appropriate, the proportion of patients within the therapeutic range could have been explored (DoHA 2009a). Furthermore, the reduction in risks associated with POCT, such as those related to venipuncture, should have been discussed and quantified (if possible) and included as benefit.

4.1.6 IDENTIFYING AND MEASURING COSTS

MSAC ECONOMIC EVALUATION

The direct costs of INR POCT included within the MSAC economic evaluation were:
- major capital costs - portion of costs that is attributable to the purchase price of the major capital equipment, which represents a fixed cost;
- the consumable equipment cost - portion of costs that is attributable to items which must be purchased each time a test is performed, which represents a variable cost; and
- the labour cost - cost of labour required to perform the test and record results.

The economic evaluation does not account for opportunity costs as it assumes resources needed to provide the new technology will be drawn from resources associated with the replaced technology.

IMPROVED ECONOMIC FRAMEWORK

The economic evaluation should have accounted for a reduction in indirect costs associated with POCT, such as gains to productivity and leisure time derived from having to make one visit to the GP rather than two, and the avoidance of costs associated with additional travel (including any costs borne by an informal caregivers). For example, DoHA (2009) found a statistically significant reduction in travel costs between POCT and centralised testing. The study also provided a more rigorous analysis of costs compared to the MSAC economic evaluation as initial costs, induced costs and averted costs were considered. Fees and charges were used as proxies for opportunity cost.

This highlights the need to include both direct and indirect costs in the economic evaluation. Excluding costs can significantly underestimate benefits and costs, and lead to incorrect conclusions regarding the true cost-effectiveness of the health technology under consideration.

4.1.7 TIME HORIZON

MSAC ECONOMIC EVALUATION

The time horizon was three years, which was based on the lifespan of the new technology.

IMPROVED ECONOMIC FRAMEWORK

As noted by Brown et al (2007), the two technologies are expected to have a different impact on the health over a patient’s lifetime (through the reduction in risks associated with adverse events). Consequently the time horizon should have spanned the expected remaining lifetime of individuals.
4.1.8 Discounting
MSAC Economic Evaluation
The discount rate used is not explicitly defined. Although not transparent, it seems future costs are not discounted in calculating the annual cost per patient.

Improved Economic Framework
The discount rate should be clearly defined to provide transparency and consistency. Furthermore, the expected changes in health outcomes resulting from the reduced risk of adverse events also need to be discounted to account for the time preference for health.

4.1.9 Dealing with Uncertainty
MSAC Economic Evaluation
One-way sensitivity analyses and extreme scenario analyses were performed by adjusting the following assumptions:
- the total number of tests performed in 2003-2004 is increased to 3.1 million (based on the upper extreme of annual usage estimated for 2003-2004 in clinical need section).
- an annual growth rate of 9% (as estimated in clinical need section) is applied to the number of INR tests performed in 2003-2004 to generate estimates for 2004-2005 and 2005-2006; and
- the higher numbers of tests are assumed (3.1 million) as well as higher labour costs (associated with the increased number of tests) to generate the combined effect on costs.

Improved Economic Framework
One-way sensitivity analyses tend to underestimate the uncertainty of results and extreme scenario analyses are expected to overestimate the uncertainty. Consequently, more advanced techniques such as probabilistic sensitivity analyses should have been undertaken. For example, Brown et al (2007) incorporated a probabilistic sensitivity analysis and investigate impact on results from changes to key parameters such as the discount rate and the price of POC monitors and associated materials.

4.1.10 Review of Economic Evaluation Results
MSAC Economic Evaluation
Prior to consideration by MSAC, the applicant was invited to comment on the draft assessment. This is the only explicit review of the results before MSAC provides a recommendation to the Minister for Health and Ageing.

Improved Economic Framework
A critical review of the methodology and results should have been undertaken. External review should be undertaken by a person or organisation that is experienced in health economic evaluations in order to generate validation and robustness to the results. This is
essential in view of the vast amounts of resources under consideration and the health policy implications of the results.

When constructing advice, MSAC should use formal mechanisms to allow alternative stakeholder groups to review their assessments. This could consist of feedback from the public (for example, through user feedback surveys and web/teleconferencing), and peer reviews. Incorporating preferences allows stakeholders to contribute directly to health policy, while peer review ensures that the methodology and interpretation of results are consistent with the academic literature, providing robustness to the final conclusions.

4.1.11 OTHER CONSIDERATIONS

MSAC ECONOMIC EVALUATION

Although MSAC’s recommendation to reject funding for CoaguChek was accepted, the assessment report does not provide specific information on how the recommendation was made (for example, the weight given to the economic evaluation results was not transparent or whether other factors were taken into consideration).

IMPROVED ECONOMIC FRAMEWORK

An economic evaluation should be used in conjunction with other considerations, such as equity and public preferences. Although the MSAC assessment report did not explicitly state how the recommendation was made, it is likely that a significant emphasis was placed on the results of the HTA given the lack of discussions within the assessment report regarding other considerations.

It is expected people in rural and remote communities who have to travel long distances to access treatment, and children who can avoid non-venous testing, would significantly prefer POCT.

There are also other changes to attributes of the health care system that should have been considered. For example, the National Health Performance Framework (NHPC 2001) outlines additional attributes of the health care system that are valued by society. By not investigating changes to these alternative health care system attributes in the decision making process, the recommendation is not a true reflection of public preferences. For INR POCT there are four particular attributes which INR POCT provides in comparison to usual care.

- The responsiveness of the health care system to patients needs: this evidenced by the patient’s preferred use of POCT over usual care.
- Ease of accessibility: patients can undertake the tests and obtain the results at their local GP and are not required to travel to a pathology testing centre.
- Continuity of care: patients care is uninterrupted with the test being both performed and evaluated at the GP.
- Sustainability: GPs build capacity in POCT that could be applied to future similar technologies, or used for alternative indications.

Brown et al (2007) conducted a review of ethical and psychosocial issues relating to long-term oral anticoagulation therapy. This provided decision-makers with a more balanced view,
particularly after noting that the review found most patients preferred POCT to standard laboratory testing.

4.2 CARDIAC RADIOFREQUENCY CATHETER ABLATION

Radiofrequency catheter ablation (RFCA) is a procedure used to treat (and potentially cure) a specific kind of arrhythmia (tachycardia). Tachycardia is a relatively common affliction associated with significant morbidity (including stroke and cardiac failure) and in some cases mortality. When successful, RFCA is curative, eliminating the need for lifelong drugs to control arrhythmia (antiarrhythmic drugs (AADs)) or can prevent patients having to progress to more powerful but more toxic pharmaceutical agents with often short term effectiveness. There has been technological advances in RFCA over time. Medical technology industry advice suggests that 2D systems, which are the predominant form of treatment, have been superseded by 3D systems for complex tachycardias. The 3D systems are relatively expensive and more expensive than 2D. Cardiac RFCA has not been assessed for cost effectiveness in Australia, but has been covered by existing MBS items since 1995. International studies have indicated RFCA (including with 3D systems) is cost effective for specific indications, although there are some limitations to the evidence on efficacy.

This case study briefly outlines the epidemiology of tachycardia, details the cardiac RFCA procedure and outlines its efficacy and cost effectiveness and discusses the reimbursement arrangements for catheters and provision of the procedure in Australia.

4.2.1 TACHYCARDIA

Tachycardia is an abnormally accelerated heart rate caused by faults in the electrical impulses controlling the heart beat. While it may be symptom free, it can also cause chest pain, shortness of breath, weakness or difficulty exercising, dizziness and fatigue. There are various types of tachycardia but atrial fibrillation (AF) is the most common. The prevalence of AF was just under 1% of 1.89 million health plan members aged 20 years or more in California, and prevalence rates increase with older age (Go et al, 2001). In the US, AF was diagnosed in 4.8% of women and in 6.2% of men aged 65 years or older (Furberg et al, 1994). Age-adjusted incidence of AF in the Framingham study increased significantly from the 1960s to the 1980s, and has increased further from 1980 to 2000, possibly due in part to the population increase in obesity and obstructive sleep apnoea (Medi et al 2007). The prevalence and incidence of other types of tachycardia are not as well documented.

TREATMENT

Individuals with tachycardias can experience episodes of sinus rhythm interspersed with episodes of tachycardia. These episodes can be very symptomatic and lead to complications. In order to diagnose tachycardias electrophysiological studies may be performed. Once diagnosed, conventional treatment is lifelong use of AADs to control heart rhythm or rate. Electrical cardioversion may also be used for rhythm control. If AADs become ineffective, or patients cannot tolerate them, RFCA may be undertaken (Rodgers et al 2008, NICE 2006 and FDA 2009). Some studies have also begun exploring RFCA as a first line treatment in some patients. In life threatening circumstances, a cardiovertor defibrillator may be implanted. All strategies are normally combined with anti-blood clotting agents to reduce the risk of stroke.
**THE COSTS OF AF**

The direct cost of health care for AF in the UK in 2000 was projected to be £459 million — 0.97% of all National Health Service (NHS) expenditure, of which 50% was for admission to hospital and 20% for drugs (Stewart et al 2004). In addition to NHS expenditure, nursing home costs accounted for an additional £111 million.

In a prospective cohort study with a sample of 1,000 AF patients in the US, Reynolds et al (2007) estimated that the costs of AF per patient in 2002 averaged USD$4,700 per year during the first few years of diagnosis. Their study did not include out of pocket patient costs or indirect costs.

**Australian hospital costs of AF and flutter**

There were just over 45,600 separations with a principal diagnosis of AF and flutter, and 9,776 separations for paroxysmal tachycardia in all Australian hospitals in 2006-07. Most would have been hospitalised for chest pain, arrhythmia, heart failure or other symptoms or health outcomes of AF. The separation rate for AF and flutter has increased over time since 1998-99, while separation rates for paroxysmal tachycardia rose until 2005-06 (Table 4-3).

**TABLE 4-3: SEPARATIONS WITH A PRINCIPAL DIAGNOSIS OF AF AND FLUTTER, OR PAROXYSMAL TACHYCARDIA(A)**

<table>
<thead>
<tr>
<th>Year</th>
<th>AF and flutter</th>
<th>Paroxysmal tachycardia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number separations</td>
<td>Separations per 100,000 people</td>
</tr>
<tr>
<td>1998-99</td>
<td>27,245</td>
<td>144.0</td>
</tr>
<tr>
<td>1999-00</td>
<td>31,110</td>
<td>162.4</td>
</tr>
<tr>
<td>2000-01</td>
<td>33,249</td>
<td>171.3</td>
</tr>
<tr>
<td>2001-02</td>
<td>36,157</td>
<td>184.0</td>
</tr>
<tr>
<td>2002-03</td>
<td>36,656</td>
<td>184.2</td>
</tr>
<tr>
<td>2003-04</td>
<td>36,191</td>
<td>179.8</td>
</tr>
<tr>
<td>2004-05</td>
<td>38,296</td>
<td>187.8</td>
</tr>
<tr>
<td>2005-06</td>
<td>41,510</td>
<td>200.6</td>
</tr>
<tr>
<td>2006-07</td>
<td>45,619</td>
<td>216.5</td>
</tr>
</tbody>
</table>

(A) The International Classification of Diseases Code for AF and flutter is I48 and for paroxysmal tachycardia is I47.21


ARDRG codes22 provide an indication of the cost to hospitals of treating AF and flutter. There were around 49,000 separations for the associated ARDRG codes — 61% of which were for public patients (Table 4-4). The cost per separation for more complex cases in 2006-07 was around $5,000 and for less complex cases was close to $2,000 (Table 4-4). In


22 The ARDRG classification system categorises acute admitted patient episodes of care into groups with similar conditions and similar expected use of hospital resources based on information in the hospital morbidity record such as the diagnoses, procedures and demographic characteristics of the patient.
An improved HTA economic evaluation framework for Australia

2006-07, a very approximate cost to hospitals of AF and flutter was around $115.5 million (calculated as the number of separations for the relevant ARDRGs factored down for the proportion of separations that were for AF ie, 4561/48951).

TABLE 4-4: SEPARATIONS FOR RELEVANT ARDRG CODES, 2006-07(A)

<table>
<thead>
<tr>
<th>Code</th>
<th>Total</th>
<th>Public hospital</th>
<th>Private hospital</th>
<th>Public patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>F71A</td>
<td>8,927</td>
<td>7,340</td>
<td>1,587</td>
<td>5,776</td>
</tr>
<tr>
<td>F71B</td>
<td>40,024</td>
<td>29,517</td>
<td>10,507</td>
<td>24,192</td>
</tr>
<tr>
<td>Total</td>
<td>48,951</td>
<td>36,857</td>
<td>12,094</td>
<td>29,968</td>
</tr>
<tr>
<td>%</td>
<td>100%</td>
<td>75.3%</td>
<td>24.7%</td>
<td>61.2%</td>
</tr>
</tbody>
</table>

(A) The Australian Refined Diagnosis Related Group (ARDRG) codes associated with I48 (AF and Flutter) are F71A (Non-Major Arrhythmia and Conduction Disorders W Catastrophic or Severe CC) F71B (Non-Major Arrhythmia and Conduction Disorders W/O Catastrophic or Severe CC). (B) While these costs are for public hospitals, the cost per separation for public hospitals from the National Hospital Cost Data Collection (NHCDC) often provides better coverage of costs than private sector unit costs from the NHCDC so the public sector estimates are generally preferable.


4.2.2 CARDIAC RFCA

Cardiac RFCA is a means of destroying the heart tissue which transmits faulty electrical pulses in patients with certain types of tachycardia (including atrial fibrillation (AF)). The problematic tissue is located using a catheter (a narrow, flexible wire), which is inserted into a blood vessel and threaded into the heart. The catheter is guided with a fluoroscope, (a type of x-ray). Once the site of the problem is located, the tissue is then destroyed using heat (radiofrequency ablation) (US Department of Health and Human Services 2009; US Heart Rhythm Society 2009; NICE 2006). In Australia, cardiac RFCA procedures are undertaken on admitted patients in hospital.

There are two types of RFA catheter technology available in Australia, using different hardware platforms and techniques. The latest technology provides three dimensional (3D) mapping systems which improve the ability of the clinician to navigate around the body and locate the problematic tissue. Examples of output from the two different technologies are in Figure 4-2 and Figure 4-3. 3D systems offer potentially improved efficacy over 2D systems including through fewer adverse events and reductions in exposure to fluoroscopic radiation (Willems et al 200023). Industry advised that 3D systems are required to treat more complicated arrhythmias such as AF. As the incidence and prevalence of AF is likely to increase (see Medei et al 2007, Section 4.2.1 and Table 4-3), the need for 3D systems will likely rise accordingly. Consistent with their potentially greater efficacy, 3D catheters are more expensive than 2D catheters. Per procedure, 3D catheters cost in the order of $6,000–

23 Willems et al (2000) compared 3D mapping with conventional RFA in 80 patients with recurrent paroxysm of AF refractory to drugs. Patients were prospectively and randomly assigned to treatment groups. There were 40 patients in each group, each with eight females. The average age in the conventional group was 65 years and in the 3D mapping group was 62 years. The study demonstrated that electroanatomic mapping and conventional ablation are both highly effective for treatment of AF. However, the overall fluoroscopy time can be reduced markedly with 3D mapping without prolonging the procedure time required for successful ablation. The average fluoroscopy time in the conventional treatment group was 29.2 (± 9.4) minutes compared with 7.7 (± 2.8) minutes in the 3D mapping group. During a mean follow up period of 8.5 months, three patients in each study group experienced recurrence of AF.
$8,000. There is a need for training clinicians to use 3D systems to ensure the efficacy benefits are realised.

**FIGURE 4-2 INFORMATION FROM 2D SYSTEMS FOR CARDIAC RFCA**

Determine location by (2D) fluoroscopic position and electrogram information

Source: Australian industry
Based on a systematic review of the literature which identified six randomised controlled trials and two non-randomised studies, Rodgers et al (2008) concluded that RFCA was efficacious for the treatment of AF with the majority of patients remaining free from arrhythmia at 12 months post procedure. Further, a small amount of moderate-quality randomised evidence suggested that RFCA was more effective than long term AADs in patients with drug-refractory paroxysmal AF and complications were rare. There did not appear to be a significant link between RFCA and mortality, although existing trials were not powered to assess this outcome.

3D cardiac mapping was approved by the US Food and Drug Administration (FDA) in the 1990s. In February 2009, the FDA approved 3D catheters for RFCA in patients with AF for whom drug treatment has failed to adequately control the symptoms of the condition. 3D catheters were previously approved to treat other arrhythmias such as atrial flutter (in 2004) and ventricular tachyarrhythmia (in 2006). The most recent approval was based on a prospective randomised study of 167 patients at 19 medical centres (15 in the US and four outside the US) showing the 3D RFA catheters were effective in eliminating symptomatic recurrence of AF episodes for one year in 0.627 (SD 0.048) RFA patients versus 0.172 (SD 0.049) of the patients on drugs. The 95% confidence interval for the difference between the
two groups was (0.3 13, 0.584) with a median difference of 0.457. As a condition of its approval, the FDA required the manufacturer establish a physician training program and conduct postmarket studies to collect data on long-term safety and effectiveness (including incidence of stroke, mortality, cardiac arrest, major bleeding, and pulmonary vein stenosis), and the effect of physicians’ experience in operating the device on procedural safety.

**COST EFFECTIVENESS**

Two high quality studies found RFCA to be cost effective when compared with AADs (Chan et al 2006, Rodgers et al 2008), although both studies underestimated the potential benefits of the procedure. Both studies produced high quality results despite a lack of evidence on long term efficacy of RFCA, including uncertainties surrounding the utilities for estimating the impact of RFCA on QALYs.

Rodger et al (2008) undertook a systematic literature review of existing cost effectiveness evidence of RFCA and found only one high quality study — a cost effectiveness evaluation by Chan et al (2006) of left atrial catheter ablation (LACA) as a first line treatment relative to medical therapy for reduction in the risk of stroke. Chan et al (2006) concluded that while LACA is unlikely to be cost-effective in patients with AF at low risk of stroke, it may be cost effective in moderate risk patients if sufficiently high LACA efficacy rates in restoring sinus rhythm translate into lower morbidity. However,

- the efficacy of RFA was underestimated because the benefits of symptom alleviation were excluded; and
- RFA was only analysed as a first line treatment so the broader use of RFA was excluded (Rodgers et al 2008).

Rodgers et al (2008) undertook a high quality cost effectiveness analysis of RFCA (without long term AAD use) compared with long term AAD treatment alone in adults with AF refractory to at least one AAD. They found that if the quality of life benefits of RFCA for paroxysmal AF are maintained over the remaining lifetime of the patient, RFCA is cost effective, with ICERs well below thresholds and the results robust to sensitivity analysis. If the quality of life benefits are maintained only for five years, however, the results depend on the modelling assumptions. The authors recommended further research into efficacy, noting the results of the forthcoming CABANA trial would provide some answers. They argued that UK data collection was warranted and suggested a UK registry of catheter ablation procedures be established. Alternatively, the authors suggested criteria for a randomised clinical trial comparing RFCA with AAD therapy for the treatment of AF. The analysis by Rodgers et al (2008) was limited to the costs to the UK National Health Service (NHS) — nursing home costs, productivity losses and informal care costs were excluded. Due to inadequate evidence, the authors were not able to consider other forms of tachycardia for which RFCA may be used as treatment (eg, persistent AF and flutter). The Rodgers et al (2008) assessment was for 3D systems.

**4.2.3 REIMBURSEMENT ARRANGEMENTS FOR RFA CATHETERS**

RFCA has been performed in Australia since the early 1990s and was listed on the Medicare Benefits Schedule (MBS) in 1995.
The industry made an application to MSAC in December 2002 for assessment of the 3D devices, but the application was rejected because the existing MBS item numbers were considered sufficient to encompass ablation with any type of catheter — 2D or 3D. The only public reference to this decision by MSAC is a statement on the MSAC website, “deemed ineligible”, so it is not possible to determine what MSAC took into account in its decision. Given that a cost effectiveness analysis of RFCA had not previously been undertaken in Australia the following key issues should have indicated a need for one:

- the expensive nature of the catheters and their substantial potential benefits compared with alternative therapeutic strategies (including drugs); and
- the relatively high prevalence of AF and the potential for an increase in the number of people affected both due to demographic ageing as well as the underlying causes of disease (see Medei et al 2007 above), indicating a broad potential for Australians to benefit from the procedure.

If evidence of efficacy was limited and did not allow a full evaluation at that time (2002), an early economic evaluation could have:

- guided the nature of research required (as for example Rodgers et al 2008 do). Specifically, an early economic evaluation could have identified those determinants of cost-effectiveness with the highest costs of uncertainty and hence where additional information would have the most value (Hartz and John 2009);
- recommended temporary reimbursement while efficacy data were collected.

Alternatives for ensuring data are collected systematically and independently include:

- Establishment of a broad based cardiac procedure registry to collect systematic information on patient quality of life outcomes, as well as revisions and adverse events. Notably, it is not possible to isolate the performance of the device from the nature of the associated procedure or other elements of the care provided, so the registry needs to be set up to collect information about the procedure and associated care. Specifically, it is important to annotate the reasons for device failures which may stem from the nature of the care provided rather than the device itself.
- A recommendation arising from the economic evaluation for collection of evidence ‘in the field’ related to the specific device (in this case, the RFCA catheters — both 2D and 3D). This approach was adopted by the Ontario Health Technology Advisory Committee (OHTAC). OHTAC recommends government funding to collect evidence if the basis for a decision is too uncertain. To
illustrate, in relation to implantable cardioverter defibrillators (ICDs) for primary prevention of sudden cardiac death (SCD), the OHTAC (2005) recommended that:

i) A set number of ICDs be funded for a two year period so a field evaluation could be undertaken to investigate the patients who would most benefit from ICDs in the primary prevention of SCD.

ii) Hospitals which were funded to provide ICD services be expected to participate in the field evaluation and to collect and report ICD data to the database.

The Prostheses List

RFA catheters were originally listed on Schedule 5 but were deleted from the Prostheses List (PL) in 2002. Since the catheter is not implanted for a ‘long period of time’, it is not considered a prosthesis, even though it is of the same magnitude in price. The guidelines for listing of prostheses state:

Where the intention is to implant a catheter for a long period of time it is reasonable that it be covered under the Criteria for Listing. Where, however, the intention is for a catheter to be in situ for a short duration before being removed, or replaced, then these catheters do not meet the Criteria for Listing (Australian Government Department of Health and Ageing 2008:45).

For devices, listing on the PL is important and has implications for access by private patients to procedures. While private health insurers are required to provide funding for devices on the PL, there is no requirement for funding of devices not on the PL. Further, the MBS covers only payments to clinicians for conducting procedures and does not cover payments for the necessary devices. Thus, while clinicians, pharmaceuticals and prostheses all have certainty of funding once listed on the relevant schedule (the MBS for clinicians, the pharmaceutical benefits schedule (PBS) for drugs or the PL for prostheses), devices are treated differently. Further, prostheses are not treated in the same way as drugs or procedures. Cost effectiveness is a requirement for listing on the MBS and the PBS. On the other hand, the criteria for listing on the PL is historically based and rather arbitrary. Prostheses and devices are subject to cost effectiveness analysis only indirectly via analysis of the associated procedure. As discussed in Section 1.3, few procedures are evaluated, however.

Another feature of the fragmented funding systems and the differential treatment of devices is that the devices industry sees little benefit in incurring the costs associated with an application to MSAC when MBS items already exist (not to be confused with any payment as there is no cost recovery at the moment). This is because where a procedure is already listed, a cost effectiveness assessment has no impact on the funding of the device.

Recent changes to the PL and prostheses funding arrangements were made in response to high growth in prostheses expenditure. In this context, policy responses often aim to contain costs, without considering the associated impact on benefits. Given the fragmented nature of the system, containing expenditure in one health funding stream can lead to increased costs in another (eg, procedures may be replaced by pharmaceuticals) or patients may simply miss out on potentially beneficial health interventions. Introducing cost effectiveness analysis as an explicit requirement of listing both devices and prostheses would have been one way of ensuring that cost increases were linked with associated benefits.
Uncertainty of funding for devices — particularly where they are expensive — can restrict access by patients to cost effective health interventions, and promote use of less beneficial alternatives (which are not necessarily cheaper eg, pharmaceuticals). Immediately after delisting of catheters for RFCA, reimbursement of the costs of RFCA for private patients was not guaranteed. Hospitals needed to renegotiate funding contracts for private patients to ensure catheters were covered as part of the procedure. Industry advice suggests that while some cardiac ablation catheters for private patients are covered by contracts negotiated between hospitals and private health insurers, the majority (70% or so) are either funded via ex-gratia agreements or are not funded by private health insurance at all (personal communication with the industry, April 2009). The consequence of this type of funding uncertainty is that clinicians and hospitals will either use the cheapest catheter available (in this case the 2D catheter) on private patients — despite the potential cost effectiveness of the 3D catheter — or a proportion of private patients may seek RFCA from public hospitals, potentially contributing to longer public hospital waiting lists. Patients indicated for RFCA are generally refractory to AADs and so may potentially be suffering the symptoms of tachycardia and the risks of significant morbidity whilst waiting for treatment.

4.2.4 CURRENT PROVISION OF CARDIAC ABLATION IN AUSTRALIA

The previous section demonstrated that access by private patients to a cost effective procedure (RFCA with 3D systems) may be constrained in Australia given current funding arrangements for the devices and their relatively high cost. However, it is not possible to investigate and track access to RFCA using current publicly available Australian health data sets.

The investigation of publicly available data sets outlined in this section demonstrates the inconsistencies between the publicly available AIHW and Medicare Australia data, and the particular problems identifying the number of procedures on public patients. In addition, currently available data sets do not enable tracking of the type of devices used (eg, 2D or 3D catheter).

AIHW HOSPITAL PROCEDURES DATA (ALL PATIENTS)

According to the national hospital morbidity database managed by the Australian Institute of Health and Welfare (AIHW), in 2006-07, 1,027 RFA procedures were undertaken in Australian hospitals (Table 4-5) including:

- 654 “Ablation of arrhythmia circuit of focus involving on atrial chamber” (Australian Classification of Health Interventions procedure code 38287-00); and
- 373 “Ablation of arrhythmia circuit or focus involving both atrial chambers” (Australian Classification of Health Interventions procedure code 38290-00).27

RFA procedures on public patients accounted for around 16% of procedures recorded in the national hospital morbidity data base. Procedure rates were highest among those aged 50 to 84 years (Figure 4-4). Procedure rates have increased over time (Table 4-6).

---

### Table 4-5: Cardiac RFA Procedure\(^{(A)}\), 2006-07

<table>
<thead>
<tr>
<th>Total separations</th>
<th>Public hospital</th>
<th>Private hospital</th>
<th>Public patient</th>
<th>Total procedures</th>
<th>Procedures for public patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,025</td>
<td>184</td>
<td>841</td>
<td>165</td>
<td>1,027</td>
<td>165</td>
</tr>
</tbody>
</table>

\(^{(A)}\) Procedure codes 38287-00 and 38290-00.


### Figure 4-4: Cardiac RFA Procedures, 2006-07

```
Age group (years)
10-14 20-24 30-34 40-44 50-54 60-64 70-74 80-84
```


### Table 4-6: Cardiac RFA Procedures

<table>
<thead>
<tr>
<th>Year</th>
<th>Rate per 100,000 people</th>
<th>Total procedures</th>
<th>38287</th>
<th>38290</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002-03</td>
<td>3.7</td>
<td>744</td>
<td>485</td>
<td>259</td>
</tr>
<tr>
<td>2003-04</td>
<td>4.5</td>
<td>902</td>
<td>625</td>
<td>277</td>
</tr>
<tr>
<td>2004-05</td>
<td>4.0</td>
<td>811</td>
<td>526</td>
<td>285</td>
</tr>
<tr>
<td>2005-06</td>
<td>4.6</td>
<td>944</td>
<td>575</td>
<td>369</td>
</tr>
<tr>
<td>2006-07</td>
<td>4.9</td>
<td>1,027</td>
<td>654</td>
<td>373</td>
</tr>
</tbody>
</table>

MEDICARE AUSTRALIA DATA (PRIVATE PATIENTS)

Subsidised ablation services for private patients are covered by the Medicare Benefits Schedule (MBS). The MBS item codes, descriptions and fees are in Table 4-7.

<table>
<thead>
<tr>
<th>MBS item number</th>
<th>Description</th>
<th>March 2009 fee ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>38287</td>
<td>Ablation of arrhythmia circuit or focus or isolation procedure involving 1 atrial chamber</td>
<td>1,938.60</td>
</tr>
<tr>
<td>38290</td>
<td>Ablation of arrhythmia circuits or foci, or isolation procedure involving both atrial chambers and including curative procedures for atrial fibrillation</td>
<td>2,468.50</td>
</tr>
<tr>
<td>38293</td>
<td>Ventricular arrhythmia with mapping and ablation, including all associated electrophysiological studies performed on the same day</td>
<td>2,649.50</td>
</tr>
</tbody>
</table>


There were 3,648 cardiac ablation services funded by Medicare in 2007-08 — 67% of which were item number 38287 (Table 4-8).

<table>
<thead>
<tr>
<th>Year</th>
<th>38287</th>
<th>38290</th>
<th>38293</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>95-96</td>
<td>327</td>
<td>51</td>
<td>15</td>
<td>393</td>
</tr>
<tr>
<td>96-97</td>
<td>487</td>
<td>56</td>
<td>24</td>
<td>567</td>
</tr>
<tr>
<td>97-98</td>
<td>738</td>
<td>55</td>
<td>26</td>
<td>819</td>
</tr>
<tr>
<td>98-99</td>
<td>868</td>
<td>52</td>
<td>49</td>
<td>969</td>
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<td>99-00</td>
<td>1,001</td>
<td>53</td>
<td>45</td>
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<td>00-01</td>
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<td>1,480</td>
<td>279</td>
<td>62</td>
<td>1,821</td>
</tr>
<tr>
<td>02-03</td>
<td>1,556</td>
<td>384</td>
<td>94</td>
<td>2,034</td>
</tr>
<tr>
<td>03-04</td>
<td>1,761</td>
<td>408</td>
<td>86</td>
<td>2,255</td>
</tr>
<tr>
<td>04-05</td>
<td>1,946</td>
<td>511</td>
<td>113</td>
<td>2,570</td>
</tr>
<tr>
<td>05-06</td>
<td>2,061</td>
<td>840</td>
<td>132</td>
<td>3,033</td>
</tr>
<tr>
<td>06-07</td>
<td>2,193</td>
<td>1,099</td>
<td>124</td>
<td>3,416</td>
</tr>
<tr>
<td>07-08</td>
<td>2,435</td>
<td>1,054</td>
<td>159</td>
<td>3,648</td>
</tr>
</tbody>
</table>

Source: Medicare Australia statistics online website, accessed April 2009

Most MBS ablation procedures were undertaken on people aged 55 to 75 years old, and usage rates were higher among males\(^{28}\) (Figure 4-5, Figure 4-6). Because use rates are highest in older age groups and because of demographic ageing, MBS average use rates have increased over time (Figure 4-7). In 2007-08, Medicare expenditure on cardiac ablation was $5.7 million ($3.5 million on 38287, $1.9 million on 38290, and $310,437 on 38293).

\(^{28}\) Higher use rates among males was also found in the US (Gerstenfeld et al 2007).
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**Figure 4-5: Female use of ablation, 2007-08**

Source: Medicare Australia statistics online website, accessed April 2009

**Figure 4-6: Male use of ablation, 2007-08**

Source: Medicare Australia statistics online website, accessed April 2009
While publicly available data from the AIHW national hospital morbidity database suggests there were 1,027 RFA procedures in 2006-07, Medicare Australia data suggests there were 3,416 procedures on private patients in the same year. This represents a significant anomaly. *A priori*, the AIHW estimate should be higher than that of Medicare Australia since the Medicare data reflect only private patients, while the AIHW data reflect both public and private. While there was incomplete coverage in the National Hospital Morbidity Database of private free standing day hospitals in the ACT and NT and one public mothercraft establishment in the ACT did not provide data (AIHW 2008), this is unlikely to fully explain the anomaly. There may also have been differences in the way procedures are recorded for entry in the National Hospital Morbidity Database and the way procedures are charged to Medicare.

The total number of cardiac RFA procedures is thus unclear, and the proportion conducted on public patients is unknown. Apart from the consequent uncertainties surrounding estimates of procedure costs, it is also difficult to analyse important issues relating to access and equity.

Such anomalies occur frequently. It is extremely difficult to reconcile Australian health data sets because of their establishment along funding lines. This is an important restriction on the quality of HTA in Australia. Linking health data sets would vastly improve the information available for HTA (and health research more generally).

Another problem is that it is not possible to determine which catheter was used to undertake RFGA. A procedure registry which included as part of its collection patient quality of life information would substantially improve the evidence available on the efficacy, access to and use of devices.
4.2.5 **CONCLUSIONS**

Even where evidence of efficacy is limited, an economic evaluation can identify those determinants of cost-effectiveness with the highest costs of uncertainty and hence where additional information would have the most value. In such instances, it is worth considering temporary reimbursement of both the procedure and device while data are collected, as well as providing support for the collection of data. This is more important for devices than for other therapies since evidence on the efficacy of devices is often incomplete because of the nature of the market for devices.

Procedure registries which collect information on the nature of care provided, patient quality of life outcomes as well as adverse events represent one option for building an evidence base for devices. Notably, since performance of the device is not separable from the attendant care, the information collected by a procedure registry needs to be structured accordingly. Another approach is a recommendation for temporary funding in order to collect data on a specific type of device. This approach has been adopted in Canada.

Linking health data sets would also contribute to evidence available on the efficacy of health interventions in Australia and their costs, as well as alleviating some of the inconsistencies and interpretation problems inherent in current health data sets because of their establishment along funding lines. Inadequate health data sets constitute a significant limitation on the ability to conduct HTA in Australia.

While clinicians, pharmaceuticals and prostheses all have certainty of funding once listed on the relevant schedule (the MBS for clinicians, the pharmaceutical benefits schedule (PBS) for drugs or the PL for prostheses), other devices are treated differently. Further, prostheses are not treated in the same way as drugs or procedures. Cost effectiveness is a requirement for listing on the MBS and the PBS. On the other hand, the criteria for listing on the PL is historically based and rather arbitrary. Prostheses and other devices are subject to cost effectiveness analysis only indirectly via analysis of the associated procedure.

Uncertainty of funding for devices — particularly where they are expensive — can restrict access by patients to cost effective health interventions, and promote use of less cost effective alternatives.

4.3 **REMOTE MONITORING SYSTEMS FOR PATIENTS WITH IMPLANTED CARDIAC DEVICES**

Implantable cardiac devices such as standard permanent pacemakers, implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy (CRT) are critical devices in the management of cardiac conditions. They regulate the heart beat through cardiac electrical impulses in order to avoid disruptions to a regular heart beat, known as cardiac arrhythmia. This includes bradyarrhythmia, which is a dangerously slow heart rate, and tachyarrhythmia, which is an abnormal fast heart rate.

However, cardiac arrhythmias require constant clinical monitoring to reduce the risk of heart failure, stroke, or sudden cardiac death. This is especially the case for high risk patients, such as those with structural heart disease. Currently this is being undertaken by patients visiting clinics regularly to check their device functions properly. Additional visits are required if the device malfunctions or new symptoms are experienced by the patient.
This case study investigates an application undertaken by Biotronik Australia Pty Ltd for the approval of funding for remote monitoring systems for patients with implantable cardiac devices (MSAC 2008). Remote monitoring allows supervision of device functions and cardiac health and diagnostic testing to be conducted at home rather than visiting a clinic. This has the potential to reduce risks associated with arrhythmias and device malfunction, and reduces the number of clinical attendances without a reduction in the frequency of patient assessments (Colechin et al 2009). Over 200,000 patients worldwide are now utilising remote monitoring of cardiac devices to facilitate the recognition of abnormal device behaviour and verify the patient’s physiological response (Jung et al 2008).

MSAC rejected the application based on ‘insufficient’ evidence. It noted:

- There is a lack of clinical evidence regarding patient outcomes and resource cost savings associated with remote monitoring systems. Therefore, an economic analysis of remote monitoring systems for patients with implanted cardiac devices is not presented in this assessment. (MSAC 2008, pp. xiii)

- More data are required to determine whether cost savings derived from use of remote monitoring systems exceed the cost of data analysis, or whether the net cost of remote monitoring is value for money in terms of the benefits provided by the service (such as cardiac events and deaths avoided). (MSAC 2008, pp. xiii).

MSAC found the procedure is safe but that clinical effectiveness was not demonstrated. Consequently a formal economic evaluation was not performed and MSAC did not support public funding for the use of remote monitoring systems for patients with implantable cardiac devices.

However, this case study argues that rather than rejecting an application based on ‘insufficient’ evidence, an economic evaluation should have been performed that used the available evidence but incorporated uncertainty through a decision analytic model and probabilistic sensitivity analysis. If economic evaluation outcomes were sensitive to assumptions, the economic evaluation should have investigated the need for conditional funding based on further research by comparing the expected benefits with costs that were informed by the decision analytic model. A recommendation should have been made only after undertaking a thorough economic evaluation, rather than basing the decision on an incomplete (and potentially biased) assessment.

As an economic evaluation did not take place within the MSAC assessment, a critique based on the improved economic framework could not be undertaken. Instead, an outline of the evaluation that could have taken place under the improved economic evaluation framework is presented.

This case study also highlights the need to undertake an independent and external review of economic evaluation methodology and results. This should be completed by individuals who are trained in health economics and can fully appreciate the many technical and methodological considerations.

4.3.1 STUDY FRAME

The research question established by MSAC was to determine to what extent the monitoring of pacemakers, implantable cardioverter defibrillators, and cardiac resynchronisation therapy
was safe, effective (including diagnostic performance and the impact of diagnosis on changes in clinical management and outcomes), and cost-effective.

However, remote monitoring of cardiac devices also provides additional non-health benefits that should be included in the study frame. These include greater accessibility to health care (especially for those in rural locations or with reduced mobility), greater responsiveness (more patient oriented), increased capability through ongoing training associated with home monitoring in general, and increased sustainability through infrastructure development.

As one of the undisputable benefits associated with remote monitoring of cardiac devices is greater accessibility to health care for those who find it difficult to attend clinics, the study frame should have explicitly noted differences in target group characteristics and the special considerations associated with these specific sub groups.

4.3.2 PERSPECTIVE OF THE ANALYSIS

Any economic evaluation should adopt a societal perspective to account for the changes in costs and benefits to all Australians as well as the transfer of costs (for example, between patients and government).

In using a societal perspective, the economic evaluation would account for the reduction in costs assumed by the patient, particularly the costs associated with travelling for additional clinical visits. Furthermore, it could distinguish between the direct costs to the government (health care costs such as remote monitoring device costs, physician costs and costs of adverse cardiac events) and the indirect costs incurred by others in society, such as informal carer costs (travel and lost work/leisure time) associated with additional clinic visits.

4.3.3 SELECTING THE COMPARATOR

Patients with implanted cardiac devices require regular, scheduled consultations with specialists which, in the absence of remote monitoring devices, are undertaken in clinics. As such, the comparator for remote monitoring devices is routine monitoring in a specialist outpatient clinic (i.e. the remote monitoring capability is switched off). Consequently, the comparator is a care pathway associated with a cardiac device.

As there is likely to be variation on the care pathway across health care system jurisdictions, these should be investigated. One way to achieve this would be to directly consult those who work within cardiac device management.

4.3.4 DETERMINING WHICH EVIDENCE TO INCLUDE

According to the MSAC application report there was ‘insufficient’ evidence for an economic evaluation to take place. However, the MSAC evaluation only included TGA approved devices and excluded non-TGA approved devices in making the decision not to proceed. The only reason why devices should be excluded from the analysis is if the devices had gone through the TGA process and been rejected.

There is no indication that this was the case. According to Biotronik (pers. comm. 06 May 2009), none of the devices in any of the studies had been submitted to and rejected by TGA. Looking at the summary of non-TGA approved devices presented in Table 17 of the assessment report (MSAC 2008), there seems to be some relatively high quality studies that have been undertaken. These should not have been excluded from the evaluation.
Furthermore, consideration should be given to any economic evaluations undertaken by international HTA agencies. Medicare in the USA and the German government had both approved reimbursement for the use of home monitoring of cardiac devices before the assessment was undertaken, and this should have been recognised within the assessment report.

In the absence of high level data, an economic evaluation should have proceeded using the clinical evidence available. Evidence should have been critically appraised and limitations should be explicitly stated. Where limitations existed, the economic evaluation should have made assumptions and accounted for any perceived inadequacies through established methods, such as decision analytic modelling, sensitivity analysis, and scenario analysis. Economic evaluations should allow for lower levels of evidence and international evidence. Thus, the MSAC assessment should not have excluded observational studies like Lazarus (2007), Nielson et al (2008) and Brugada (2006) which include large numbers of patients. It should have also included results from the REFORM trial or recognise potential results from IMPACT trial (Elsner et al 2006).

A good example of incorporating uncertainty within an economic evaluation related to remote monitoring of cardiac devices was undertaken by Colechin et al (2009). They used a Markov model to estimate future treatment pathways, outcomes, and costs to patients. The Markov model consisted of the following health states for a patient with a cardiac device:

- the patient has prior atrial fibrillation that is stable;
- the patient experiences a stroke whilst being monitored;
- the patient does not die from the stroke but remains in a post stroke state; and
- death occurs due to a stroke or from other causes.

Outcomes were measured in QALYs by multiplying QALY weights derived from the literature by the estimated amount of time spent in each state.

Similar to MSAC, Colechin et al (2009) notes that there is a limited amount of high quality evidence on the effectiveness of remote monitoring. However, rather than concluding an economic evaluation cannot be performed, Colechin et al (2009) made some assumptions within the modelling exercise, including:

- no difference in effectiveness between remote and traditional monitoring but remote monitoring was assumed to impact on the level of resources required for monitoring;
- remote monitoring reduces the rate of stroke by 1%, 2%, 5%, 10% and 20%; and
- remote monitoring reduces the rate of stroke and the probability of death following stroke.

As a consequence the economic evaluation provided decision makers with an indication on how effective remote monitoring needs to be before it becomes cost effective when compared to a cost effectiveness threshold.

### 4.3.5 Selecting an Economic Evaluation Tool

As evidence suggests remote monitoring is expected to have an effect on total health outcomes through the reduction in risk of adverse cardiac events a CUA would be appropriate. This approach was also adopted by Colechin et al (2009). To investigate the differences in health and resource use between remote monitoring and its comparator,
Colechin et al (2009) used quality-adjusted life-years (QALYs) to measure changes in health outcomes. This determined the reduction in the incidence of cardiac events compared to routine monitoring required for the latter to fall below the incremental cost-effectiveness threshold.

However, as the use of a CUA only includes changes to health in the ICER denominator, changes to non-health benefits associated with the health care system should also be incorporated. If these cannot be quantified then a qualitative assessment should be undertaken and accompany any discussion relating to the ICER.

### 4.3.6 IDENTIFYING AND MEASURING BENEFITS

The benefits from remote monitoring can be classified as either health or other health care system benefits. Health care system benefits include reduction in unit costs of cardiac devices due to increased service time, reduction in costs for their clinical follow-ups and other direct costs (see below for more detail on direct costs).

The improved health outcomes associated with remote monitoring of cardiac devices may include:
- lower mortality rates;
- reduced number of hospitalisations;
- improved quality of life
- avoided cardiac events such as strokes and cardiac decompensation;
- increased survival rates;
- shorter hospital stays
- reduced anxiety associated with possible failure of the implanted device; and
- reduced emergency admissions.

Clark et al (2007) performed a meta-analysis of remote monitoring programs for patients suffering from congestive heart failure and found a statistically significant positive effect of remote monitoring on clinical outcomes, hospitalisation rates, quality of life, and healthcare costs.

### 4.3.7 IDENTIFYING AND MEASURING COSTS

As evidence suggests there are possibly reduced risks associated with the use of remote monitoring of cardiac devices, direct health care system costs that would need to be investigated include the direct costs associated with the remote monitoring device itself and the direct costs associated with any adverse events that are avoided. Some of these are:
- remote monitoring device cost;
- clinical follow-up visits;
- GP visits;
- nurse specialist visits;
- specialists outpatient examinations (cardiology);
- angiography;
An improved HTA economic evaluation framework for Australia

- percutaneous coronary interventions (PCIs);
- cardiac artery bypass graft (CABG) surgery
- rehabilitation costs associated with coronary events;
- hospital costs; and
- any other costs associated with adverse events.

There is also likely to be significant changes to indirect costs associated with the use of remote monitoring cardiac devices. Some of these would include:

- time savings for clinicians;
- time savings for patients that would have otherwise been spent in a clinic (remote data transmission is significantly shorter than the duration of an in-office visit and in the case of the Biotronik system, the transmission is completely automatic with no intervention by the patient);
- reduced loss of leisure time or work time for patients and informal carers; and
- reduced travel costs for patients and their informal carers.

As remote monitoring is expected to reduce time associated with monitoring for cardiologists and electrophysiologists, the reduction in opportunity cost should also be measured. This could be proxied using the current MBS fee for data analysis.

4.3.8 Time Horizon

To reflect the differences in the use of health care resources between remote monitoring and routine monitoring the time horizon should equal the lifespan of the implantable cardiac device.

However, if the clinical evidence suggests there is a difference in health outcomes between technologies, the time frame should be long enough to capture these differences. As the risk of heart failure, stroke, or sudden cardiac death may be reduced using a remote cardiac monitoring device then the time horizon is likely to expand the expected life span of the patient.

4.3.9 Discounting

As the discount rate recommended by MSAC is five per cent then this rate would have to be used within the analysis. However, if further evidence suggests that significant benefits from reduced risk to adverse events are obtainable using remote monitoring, then the time horizon may be long. Consequently the discount rate would have to be tested within the sensitivity analysis, for example using three per cent and seven per cent.

4.3.10 Dealing with Uncertainty

Uncertainty surrounding inputs into the decision analytic model should be investigated using a probabilistic sensitivity analysis. Within this type of analysis, benefit and cost parameters, and probabilities associated with health states would have a distribution placed around them and a Monte Carlo simulation would be conducted.
Distribution bounds should incorporate all possible ranges of each parameter. Consideration should be given to any likely trends in parameters, for example, a decrease in the price of cardiac monitoring devices as technology becomes cheaper.

In using a probabilistic sensitivity analysis, uncertainty surrounding cost effectiveness ratios could be determined, along with sensitivities associated with individual parameters.

In addition, known variability in inputs could also be tested. For example, as one significant benefit for rural individuals using remote monitoring would be the time and travel costs saved in not having to attend clinics, the economic evaluation could specifically test the results using a rural sample only.

4.3.11 REVIEW OF ECONOMIC EVALUATION RESULTS

There is no suggestion within MSAC’s assessment report that a review of the assessment was undertaken. Although the evidence search within the assessment seems thorough, a review may have re-considered the exclusion of non-listed TGA devices.

As an economic evaluation did not take place due to ‘insufficient’ evidence, the methodology (or lack thereof) should have been reviewed by an independent, and external, reviewer with skills in health technology evaluation. The review may have suggested a methodology that could have tested assumptions regarding remote monitoring effectiveness (such as decision analytic modelling used by Colechin et al (2009)), thereby enabling a more thorough investigation of the likely cost effectiveness.

4.3.12 OTHER CONSIDERATIONS

EQUITY

All equity assumptions and implications should be explored and highlighted separately within the economic evaluation. In regards to remote monitoring of cardiac devices, inequities in access to specialised physicians/cardiologists should be explored. For example, patients who live a significant distance from their clinic or patients with substantial mobility limitations would derive the greatest benefit from remote monitoring. Similarly, Zartner et al (2007) highlighted the benefits of home monitoring for young children as they are more susceptible to lead or pulse generator failure, and are unable to describe specific symptoms needed for diagnosis.

PATIENT PREFERENCES

In general, individuals have a diversity of preferences within society, and these heterogeneous preferences extend to health technology. It is more than likely that preferences will vary regarding the use of remote monitoring devices. Some individuals would prefer an increased frequency of monitoring and a reduced need to attend clinics. For example, Masella et al (2008) found that 78% of participants in their study claimed to prefer remote monitoring to a clinic visit. However, others may not trust the technology and prefer face-to-face consultations. Consequently different preferences should be explored as part of the economic evaluation.
5. CONCLUSIONS

The objectives of this study was to review the current MSAC process and economic framework, review international HTA economic frameworks (focusing on the UK, Europe, and Canada), and develop an improved economic framework for the evaluation of procedures and devices in Australia.

The current MSAC process and economic evaluation framework seems inadequate for the current and future needs of HTA in Australia. There are shortcomings associated with current scope, methods, activity levels and timeframes for assessment. Consequently, there are only a small proportion of medical procedures and devices currently being used in Australia that have been directly and demonstrably assessed for cost effectiveness.

The analytical basis for decision making, including financial analysis methods as well as economic evaluation methods, needs to be refined. Economic evaluation is the most appropriate method for guiding the allocation of scarce health resources towards cost effective health technologies. However, it needs to be conducted using systematic and coordinated processes, and resourced appropriately.

Significant development has taken place in the international HTA sphere. In the UK and Canada significant resources have been allocated to the continual development and refinement of HTA assessment processes and economic evaluation frameworks. In Europe, the EUnetHTA was established as a European network for HTA by bringing together the recommendations of a series of European Union (EU) funded projects from 1993 to 2002 on increasing co-ordination of HTAs across the EU states (EUnetHTA 2008). The objective of the EUnetHTA project was to provide a robust, multifaceted input to decision making.

In developing the improved economic evaluation framework in this study, particular attention was given to those areas deemed inadequate within the current framework to meet the future needs of HTA in Australia. These are summarised below:

- While the current MSAC economic evaluation framework claims to adopt a broad health care system perspective, some studies only address direct health care system benefits and costs. Consideration of costs other those incurred by governments is especially rare in financial analyses. Using a narrow perspective in an economic evaluation may exclude important benefits and costs, leading to bias in health care policy. To avoid this outcome, a full societal perspective should be used.

- New technology should be compared with the existing treatment approach it will replace (which may mean more than one comparator) and the most cost-effective existing treatment approach, which are not necessarily the same. Failure to identify the appropriate comparator(s) may render the economic evaluation irrelevant.

- An economic evaluation should include the best available evidence from which a robust decision can be made. However, levels of evidence developed by the NHMRC are more easily applied to the evaluation of pharmaceuticals rather than procedures and devices.

- The limitations in generating high level evidence means a complete dataset on clinical evidence for procedures and devices is more than likely to come from a wider set of study designs. Consequently, the designated NHMRC evidence levels represent an
An improved HTA economic evaluation framework for Australia

impractical tool to measure the quality of evidence for the assessment of procedures and devices.

- There should be no specific cut-off point in the level of evidence acceptable. Evidence should be critically appraised and limitations should be explicitly stated. The type of evidence used should be determined on a case by case basis, taking into consideration the quantity and quality of evidence available. Where limitations exist, economic evaluations should make assumptions and account for any perceived inadequacies through established methods, such as decision analytic modelling, sensitivity analysis, and scenario analysis.

- The chosen tool used for economic assessment should depend on the characteristics of the new technology and comparator(s) under assessment. The types of benefits and costs associated with the technologies, the type of evidence available, and the uncertainty surrounding estimates should be the main driver of choice.

- Choosing the correct economic evaluation tool is paramount. Unlike the evaluation of pharmaceuticals where the use of a CUA is considered the gold standard, the economic evaluation of non-pharmaceutical health technologies requires greater flexibility. This is to accommodate lower levels of evidence and the benefits and costs associated with changes to health and non-health outcomes. Consequently, the use of a CUA, and the requirement to derive QALYs, is unlikely to be the most appropriate approach in evaluating new technologies that are expected to deliver significant non-health benefits.

- Currently, the health technology assessment process focuses on three broad health care system attributes, including safety, effectiveness, and technical efficiency. However, there are several other attributes of the health care system also valued by society but are not currently included in an economic evaluation. As current and future users of the health care system value these non-health attributes, an economic evaluation should take into consideration these values if allocative efficiency, and subsequent improvements in welfare, are to be achieved.

- Costs of a new health care technology can be broadly classified into direct health care system costs and indirect costs associated with treatment and the condition. Furthermore there is the opportunity cost of shifting resources away from additional areas of the health care system, or economy. All of these costs should be measured if expected to change as a result of a new technology.

- Health economic evaluation guidelines currently being used in Australia (for example, NHMRC 2001; MSAC 2005; PBAC 2008) recommend a five per cent discount rate. However, it is unclear whether this rate reflects Australia’s true societal preferences. The choice of a discount rate is not just a theoretical exercise because it will have significant impacts on economic evaluation outcomes. Any recommended discount rate made within an MSAC economic framework should be theoretically defensible, based on solid research, and updated regularly as social preferences change.

- Rejection of applications based on ‘insufficient’ evidence should be avoided. Instead, a thorough economic evaluation should take place that incorporates uncertainty in evidence. Decision analytic modelling should be a standard tool used in MSAC economic evaluations when complex and uncertain decisions need to be made. In addition, based on a decision analytic model, recommendations should be explicitly made within the economic evaluation on whether conditional funding with additional research should be undertaken.
Sensitivity analysis in HTA economic evaluations have generally consisted of straightforward approaches that recalculate results from systematically changing one or two parameters, or each input is set to their most optimistic and pessimistic values. However, simple sensitivity analyses such as a one-way sensitivity analysis is likely to underestimate the uncertainty associated with results, while an extreme scenario analysis is likely to overestimate the risk. Instead probabilistic sensitivity analysis should be used.

There is limited review (if any) of economic evaluations within the MSAC process. Best practice in health technology assessment commands an independent, and external, review of economic evaluation methodology and results is undertaken before a final recommendation is made. Critical assessment of an economic evaluation should be undertaken by individuals who are trained in health economics and can fully appreciate the many technical and methodological considerations within an economic evaluation.

An economic evaluation should be one tool used in formulating a recommendation, but not the only tool. There are other important considerations that cannot be measured through economic evaluation tools, such as equity and political concerns.

Social preferences for health care technology should be included in the assessment process. Disregard for social preferences will represent disconnect between resource allocation and social welfare.
APPENDIX A: CRITERIA FOR INCLUSION ON THE PL

The Prosthesis List (PL) Guidelines specify the following criteria for products to be listed (Australian Government Department of Health and Ageing 2008).

Products meeting all of the following criteria are eligible for consideration for inclusion on the PL:

1. The product must be included on the Australian Register of Therapeutic Goods;
2. The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment;
3. A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist);
4. The product should:
   (a) be surgically implanted in the patient and be purposely designed in order to:
      (i) replace an anatomical body part;
      (ii) combat a pathological process; or
      (iii) modulate a physiological process;
   (b) be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted;
   (c) be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted;
5. The product has been compared to alternate products on the PL or alternate treatments and:
   (a) assessed as being, at least, of similar clinical effectiveness; and
   (b) the cost of the product is relative to its clinical effectiveness.

Catheters

The PL as established by legislation in 2005 derives from a long-established system for funding of surgically implanted devices by Registered Health Benefits Organisations. The term “Surgically Implanted Prosthesis” has been used in the past to distinguish the listed products from such devices as artificial limbs, which while meeting the ordinary dictionary meaning of prostheses, are not part of these arrangements. Commonly used surgical products such as sutures, drains, urinary catheters and dressings are also not encompassed by these arrangements. The new criteria have been developed in this same context. That is, it is not the intention that the criteria apply to the latter categories of products. In relation to catheters, it is the intent of these criteria to include catheters for long term use (Australian Government Department of Health and Ageing 2008:45).

For example, where the intention is to implant a catheter for a long period of time it is reasonable that it be covered under the Criteria for Listing. Where, however, the intention is
for a catheter to be in situ for a short duration before being removed, or replaced, these catheters do not meet the Criteria for Listing. For example, a cuffed catheter is intended for long term use (Australian Government Department of Health and Ageing 2008:45).

The Australian Government has commenced work on criteria for a new part of the PL to cover clinically effective and cost effective devices that are not surgically implanted (letter from the Minister for Health and Ageing to the Medical Technology Association of Australia, 23 September 2008).
## APPENDIX B: SELECTED MSAC ASSESSMENT SUMMARIES

### Table B1: Analysis of One Page Summaries of MSAC Decisions 2007 and 2008

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<thead>
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<th>Date</th>
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<th>Economic analysis</th>
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<tr>
<td>Nov 2006</td>
<td>To assess the safety, effectiveness and cost-effectiveness of double-balloon enteroscopy (DBE) for obscure gastrointestinal bleeding or suspected small bowel disease relative to laparotomy with or without intra-operative enteroscopy.</td>
<td>No formal CEA. As there was no comparative evidence on DBE, it was not possible to determine if the procedure was as effective as, or more effective than, the comparators. As a consequence, a financial incidence analysis was performed which indicated that although performing DBE would be more costly to the Commonwealth relative to the comparators, there were likely to be savings to the Australian healthcare system overall.</td>
<td>Double-balloon enteroscopy (DBE) is a safe, minimally invasive technique. While there is no direct comparative data, DBE is likely to be safer to perform than the most appropriate alternative. DBE is effective in allowing endoscopic assessment and some treatment of the entire small intestine. Although more costly to Medicare than intra-operative enteroscopy, DBE is potentially cost saving for the entire health funding system. <strong>MSAC recommends public funding</strong> for DBE for the diagnosis and treatment of patients with obscure gastrointestinal bleeding. The Minister for Health and Ageing accepted this recommendation on 5 February 2007.</td>
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<td>March 2007</td>
<td>To assess the safety, effectiveness and cost-effectiveness of repetitive transcranial magnetic stimulation (rTMS) for major depression, compared to electroconvulsive therapy (ECT).</td>
<td>The costs and consequences of rTMS vary in magnitude and direction by patient (who would otherwise have ECT and/or be hospitalised), site (multi-day or same-day admission, outpatient or private clinic) and sector (public or private). The added cost per additional responder (3 months depression-free) is estimated to be $1,952. The expected net increase in responders and financial and resource implications (additional $12.9M to the MBS and $11.2M to health system overall) depends upon the mix of patients who have rTMS and uptake by patients currently treated in the community. It is unlikely that the entire estimated additional MBS rebateable private clinic consultations will be met within capacity. This will reduce the additional cost to the MBS but may be at a cost of displaced services.</td>
<td>MSAC has considered the safety, effectiveness and cost-effectiveness of rTMS for moderate to severe refractory treatment resistant depression compared with ECT. MSAC finds evidence that rTMS is safe and less invasive than ECT. MSAC finds limited evidence that rTMS may be less effective than ECT. The financial and resource implications will depend upon the mix of patients who have rTMS, including uptake amongst patients who would otherwise not have ECT. At present, MSAC finds there is insufficient evidence to support public funding. The Minister for Health and Ageing endorsed this recommendation on 4 June 2007.</td>
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<td>May 2007</td>
<td>To evaluate the safety, effectiveness and cost-effectiveness of endoscopic ultrasound guided fine-needle aspiration (EUS-FNA) for the staging of non-small cell lung cancer (NSCLC) and the diagnosis of mediastinal masses of unknown origin.</td>
<td>The economic analysis demonstrated that EUS-FNA was cost saving when compared with mediastinoscopy. EUS-FNA and mediastinoscopy were comparable in terms of patients’ mean life expectancies. Evidence was insufficient to conduct an economic analysis of EUS-FNA for diagnosis of mediastinal masses of unknown origin.</td>
<td>MSAC recommended that EUS-FNA be publicly funded for pre-treatment staging of patients with presumed or known NSCLC and in the diagnosis of mediastinal masses. This recommendation was endorsed by the Minister for Health and Ageing 27 August 2007.</td>
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<td>Nov 2007</td>
<td>To assess the safety, effectiveness and cost-effectiveness of multi slice computed tomography coronary angiography (MSCTCA) in the visualisation of coronary arteries for the following four clinical indications: (1) Evaluation of patients with symptoms consistent with coronary ischaemia (2) Exclusion of coronary artery anomaly or fistula (3) Evaluation of coronary arteries in patient with cardiomyopathy (4) Evaluation of coronary arteries in patients undergoing non-coronary cardiothoracic surgery</td>
<td>Indication 1 = Cost utility analysis. For a substitution scenario (every patient at low to intermediate pretest risk of coronary artery disease (CAD) would receive MSCTCA before being referred to invasive coronary angiography (CA) conditional on the MSCTCA result) the weighted average was calculated across the point estimates of ICERs for between 10% and 90% pre test risk of CAD. The result suggests approx $28,367/QALY. However, uncertainty around distribution of patients across the different pre test risk levels of CAD. Financial incidence analysis suggests likely additional costs of approx $10.2M to Medicare, plus other costs of $0.2 million. Economic analysis not possible for Indications 2 and 3 because of lack of evidence. Indication 4 = Cost minimisation analysis found that MSCTCA is less costly than CA when used to evaluate the coronary arteries of patients undergoing valve surgery. These patients form a large subgroup of those patients undergoing non-coronary cardiothoracic surgery. The base case analysis indicated that use of MSCTCA±CA compared to CA alone in this population results in savings to the public hospital system of approx $8.4M per year and costs to Medicare of approx $1.6M per year. Thus the result is a net saving of $6.8M per year to the Australia society.</td>
<td>Indication 1 = Public funding supported for specific indication Indication 2 = Limited evidence of effectiveness because condition is rare and there has been no appropriate comparator. Public funding supported for specific indication Indication 3 = No evidence to assess effectiveness. Public funding no supported. Indication 4 = Public funding supported. The Minister for Health and Ageing accepted this recommendation 11 April 2008.</td>
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<td>Dec 2007</td>
<td>To assess the safety, effectiveness and cost-effectiveness of the Acticon artificial bowel sphincters (ABS) in the management of severe faecal incontinence relative to colostomy, dynamic graciloplasty or conservative management.</td>
<td>No formal CEA. Lack of appropriate incremental effectiveness data prevented a formal economic evaluation being performed. The cost per procedure costs was compared, and likely total annual cost to Australian Health System estimated. Cost of complications not included.</td>
<td>MSAC finds that there is no evidence comparing the Acticon ABS with colostomy and limited evidence comparing it with conservative management and dynamic graciloplasty. MSAC finds that the evidence suggests that Acticon ABS implantation is not as safe as conservative management and that it is likely to be at least as safe as dynamic graciloplasty. MSAC finds that the evidence indicates that the Acticon ABS is more clinically effective than both conservative management and dynamic graciloplasty. MSAC finds that relative cost effectiveness of the Acticon ABS and the comparators could not be assessed due to lack of data. The comparison of the estimated total costs indicates that the cost to the health system for the Acticon ABS is less than for dynamic graciloplasty. <strong>MSAC recommends that public funding is supported</strong> for this procedure. The Minister for Health and Ageing endorsed this recommendation on 11 April 2008.</td>
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<td>March 2008</td>
<td>To assess the safety, effectiveness and cost-effectiveness of argon plasma coagulation (APC) for the following indications of the gastrointestinal (GI) tract: (1) ablation of dysplastic Barrett’s oesophagus; (2) haemostasis of bleeding ulcers; (3) haemostasis of gastric antral vascular ectasia (GAVE); (4) haemostasis of radiation proctitis; (5) haemostasis of bleeding angiodysplasia; (6) coagulation of post-polypectomy bleeding; (7) ablation of tumorous growth through oesophageal metal stents.</td>
<td>Economic evaluation was possible for (1) and (2). For (1), The incremental cost per patient of receiving APC rather than multipolar electrocoagulation for the treatment of Barrett’s oesophagus is $283. The total additional cost to the health care system of treating Barrett’s oesophagus patients with APC is $1,633,000 per annum. For (2) The incremental cost per patient of receiving APC rather than heater probe treatment for bleeding peptic ulcer is $343. Based on an estimated 13.2% improvement in effectiveness (permanent haemostasis), the incremental cost-effectiveness per additional patient with permanent haemostasis is $2,606.</td>
<td>MSAC considers that APC is at least as effective and as cost-effective as other local methods of treatment of bleeding in peptic ulcer disease. There are insufficient data to demonstrate effectiveness and cost-effectiveness for (3), (4), (5), (6), (7). MSAC considers that the incidence of these conditions is insufficient to allow the collection of these data. MSAC recommends that public funding is supported for endoscopic APC as an option for the treatment of peptic ulcer disease and other less common causes of gastro-intestinal bleeding including (4), (5), (6), (3), (7). The Minister for Health and Ageing endorsed this recommendation on 20 May 2008.</td>
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<td>March 2008</td>
<td>To evaluate the safety, effectiveness and cost-effectiveness of endobronchial ultrasound (EBUS)-guided transbronchial sampling procedures for non-small cell lung cancer (NSCLC) staging, diagnosis of mediastinal/hilar masses, depth diagnosis of endobronchial cancers and the diagnosis of peripheral lung lesions.</td>
<td>No description of method provided. The economic analyses demonstrated that the use of EBUS-guided procedures was cost saving for assessment of NSCLC and mediastinal/hilar masses, and for diagnosis of peripheral lung lesions when compared with current practices. Lack of clinical data meant that an economic analysis was not conducted for depth diagnosis of endobronchial cancers.</td>
<td><strong>MSAC recommended that public funding should be supported</strong> for EBUS-guided procedures for the staging of non-small cell lung cancer, and the investigation of mediastinal/hilar masses and peripheral lung lesions, but should not be supported for EBUS-guided procedures to evaluate endobronchial cancer. This recommendation was endorsed by the Minister for Health and Ageing on 20 May 2008.</td>
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<td>June 2008</td>
<td>To assess the safety, effectiveness and cost-effectiveness of MRI for staging newly diagnosed rectal carcinoma, restaging rectal carcinoma after neoadjuvant therapy and diagnosis/staging of patients suspected of having carcinoma recurrence. MRI is proposed as an alternative to endorectal US (ERUS) and an addition to multislice CT (MSCT).</td>
<td>No formal CEA. There was insufficient data on the accuracy of MRI plus MSCT compared to MSCT alone to warrant a CEA. A financial analysis found that the addition of MRI to MSCT would result in additional staging costs to the Australian government ($1.1 million per year) and society ($1.2 million per year). However, these costs would likely be offset by a decreased rate of neoadjuvant therapy use through visualisation of the circumferential resection margin.</td>
<td>Safe, effective and likely to be cost effective for initial staging of rectal cancer so public funding supported. <strong>Insufficient evidence to support public funding</strong> for restaging and diagnosis of recurrence of rectal cancer. The Minister for Health and Ageing noted MSAC’s advice on 28 August 2008.</td>
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<td>Oct 2008</td>
<td>To evaluate the safety, effectiveness and cost-effectiveness of remote monitoring systems for patients with pacemakers, implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy (CRT) devices.</td>
<td>No formal CEA. An economic evaluation could not be performed because of the lack of appropriate, comparative clinical evidence.</td>
<td>MSAC finds that the procedure is safe. MSAC finds that clinical effectiveness is not demonstrated. A formal economic assessment was therefore not performed. <strong>MSAC does not support public funding</strong> for the use of remote monitoring systems for patients with implanted cardiac devices. The Minister for Health and Ageing accepted this recommendation on the 28 August 2008.</td>
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<td>Nov 2008</td>
<td>To assess the safety, effectiveness and cost-effectiveness of deep brain stimulation (DBS) for dystonia and essential tremor, compared to no treatment.</td>
<td>No formal CEA. Due to limited effectiveness data the base case considered only the resource use. The DBS cost per patient is $91,250 for essential tremor and $136,278 for dystonia, with the annual total cost of DBS in Australia estimated to be $8.201 million.</td>
<td>DBS is relatively safe in the context of the clinical condition and the net benefit of the treatment. MSAC considers the treatment is sufficiently effective in these conditions. Robust information on cost effectiveness is unlikely to emerge but the total cost is acceptable. <strong>MSAC recommends public funding of DBS</strong> for primary and secondary dystonia and essential tremor in patients where other therapies are insufficient and the patient has severe disability including inability to feed or toilet independently. The Minister for Health and Ageing noted MSAC’s advice on 28 August 2008.</td>
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<td>To evaluate the safety, effectiveness, and cost considerations associated with intragastric balloons for the temporary management of morbid obesity in addition to conventional therapies (diet ± physical activity ± behavioural therapy ± drug therapy) versus conventional therapies alone; and used prior to obesity surgery, versus obesity surgery alone.</td>
<td>No formal CEA. There was insufficient information on which to base a cost-effectiveness analysis. Based on an estimated 4,903 – 8,000 intragastric balloons being inserted/removed per year, an additional $19,236,067 – $30,535,600 would potentially be incurred per annum by the Australian healthcare system. These costs would be in addition to the costs associated with conventional management of obesity.</td>
<td>The MSAC finds that intragastric balloons used for the temporary management of morbid obesity pose additional risks to patients when compared to the standard treatment for morbid obesity and that they do not provide additional clinical benefits over standard treatment. There may be a role for the temporary placement of intragastric balloons for the management of the super obese patient prior to bariatric surgery however, evidence to support this approach is limited. The MSAC finds that the use of intragastric balloons for the temporary management of morbid obesity is less cost-effective than standard treatment for morbid obesity. The MSAC recommends that public funding is not supported for this procedure. The Minister for Health and Ageing endorsed this recommendation on the 20th May 2008.</td>
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<td>March 2008</td>
<td>To assess the safety, effectiveness and cost-effectiveness of endovenous laser therapy (ELT) for varicose veins, compared with conventional surgery (i.e. saphenous junction ligation with or without vein stripping).</td>
<td>A cost-analysis was conducted based on the assumption of no significant differences between treatments in primary clinical outcomes. Receiving ELT rather than conventional surgery for unilateral varicose vein treatment was associated with an estimated cost saving of $171 per patient. A predicted short-term increase in treatment demand (50 per cent above current levels in the first year, decreasing to 10 per cent in the third year) may impact the Australian health care system by an additional $18.9M in the first year after ELT is approved.</td>
<td>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. The Minister for Health and Ageing endorsed this recommendation on 20 May 2008.</td>
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<td>Nov 2008</td>
<td>To evaluate the safety, effectiveness and cost-effectiveness of urinary metabolic profiling (UMP) for the detection of metabolic disorders with the following indications: 1. Asymptomatic newborns with a positive screening result suggestive of metabolic disorder. 2. Individuals with a clinical presentation suggestive of a metabolic disorder. 3. At-risk family members of patients with specific genetic metabolic disorder.</td>
<td>No formal CEA. Given the lack of high quality comparative evidence of effectiveness, a cost effectiveness analysis could not be conducted and a budget impact analysis was performed. Whilst it is likely that downstream costs incurred by alternative investigations or delayed diagnosis are avoided by the use of urinary metabolic profiling, these could not be formally costed. The annual number of UMP procedures was forecast to be approximately 11,150 with a cost of $1.1 to $2.1 m.</td>
<td>The evidence was limited by three factors: • the rarity of the various metabolic disorders such that conventional high quality comparative diagnostic test studies are not possible • the large number of metabolic disorders that can be diagnosed by urinary metabolic profiling • that urinary metabolic profiling has been standard practice in Australia for many years. MSAC finds that urinary metabolic profiling is either as safe or safer than alternative investigations to diagnose metabolic disorders. MSAC finds that urinary metabolic profiling is effective in diagnosing metabolic disorders and is likely to be more effective than alternative investigations in allowing a timely diagnosis, especially in patients with undifferentiated presentations where a metabolic disorder is suspected or needs to be excluded. MSAC considers it is likely that urinary metabolic profiling in carefully selected patients is cost-effective. The current funding arrangements adequately capture the target population. MSAC advises that current public funding arrangements within the health care system should continue to be supported for this procedure. The Minister for Health and Ageing noted this advice on 8 December 2008</td>
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| Feb 2009 | To assess the safety, effectiveness and cost-effectiveness of sacral nerve stimulation (SNS) for the treatment of refractory detrusor overactivity, non-obstructive urinary retention and painful bladder syndrome. | No methodology provided.  
Detrusor overactivity = Using years of complete dryness as the primary outcome measure, the cost per patient per year of additional dryness was estimated to be $9,866. This was robust to univariate sensitivity analysis.  
Non-obstructive urinary retention = For this indication, a successful result was defined as either a) elimination of catheterisation or b) at least a 50 per cent reduction in catheter volume per catheterisation. The cost per year over the seven year time horizon of these successful results was estimated to be $7,129. This was robust to univariate sensitivity analysis.  
Painful bladder syndrome = As there was no clinical evidence for painful bladder syndrome which could be used in an economic evaluation, a costing analysis was undertaken. The incremental cost associated with SNS in this population was $11,300 per patient.  
Financial implications = It is estimated that 200 people per year will be eligible for SNS. Expert clinical opinion suggests that 90 per cent of patients would present with detrusor overactivity and 10 per cent with non-obstructive urinary retention. Should this be the case, the total net cost would be $2.481 million per annum. This consists of costs incurred by the healthcare system, which sum to $2.600 million, minus the cost reduction associated with reduced use of disposables by the individual ($119,000). | MSAC finds there is evidence for the safety of sacral nerve stimulation in adults with detrusor overactivity, non-obstructive urinary retention and painful bladder syndrome refractory to conservative, non-surgical intervention.  
MSAC finds sacral nerve stimulation in adults with detrusor overactivity and non-obstructive urinary retention refractory to conservative, non-surgical intervention is more expensive than, but more effective than clinical non-surgical management.  
MSAC finds there is insufficient evidence to assess the effectiveness of sacral nerve stimulation in adults with painful bladder syndrome refractory to conservative, non-surgical intervention.  
MSAC recognises the social and quality of life issues associated with these conditions.  
MSAC advises that public funding should be supported for the procedure of sacral nerve stimulation in adults with detrusor overactivity and non-obstructive urinary retention refractory to conservative, non-surgical intervention. MSAC advises that public funding should not be supported for the use of sacral nerve stimulation for treatment of patients with painful bladder syndrome.  
The Minister for Health and Ageing noted MSAC’s advice on 08 December 2008. |
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<td>Nov 2008</td>
<td>To assess the safety, effectiveness and cost-effectiveness of optical coherence tomography (OCT): a) compared with fundus fluorescein angiography (FFA) or clinical observation in the diagnosis of macular diseases; b) in addition to FFA and clinical examination in the monitoring of patients with macular diseases; c) in addition to computerised perimetry and clinical examination in the diagnosis of glaucoma; and d) in addition to computerised perimetry and clinical examination in monitoring of patients with glaucoma.</td>
<td>No formal CEA. A modelled economic evaluation was not undertaken. The total annual cost of OCT for macular diseases is estimated to range between $6.1 million (using FFA utilisation to estimate potential OCT utilisation) and $21.7 million (epidemiological utilisation estimates). The total annual cost for glaucoma is estimated to range between $8.3 and $13.8 million (epidemiological utilisation estimates).</td>
<td>The MSAC finds that OCT is a safe procedure. MSAC finds that there is currently insufficient evidence to recommend public funding for the assessment of macular disease or glaucoma.</td>
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<td>Nov 2008</td>
<td>To assess the safety, effectiveness and cost-effectiveness of vagus nerve stimulation (VNS) in addition to anti-epileptic drug (AED) therapy relative to AED therapy alone in all patients, and with or without the ketogenic diet in children. This assessment considered VNS therapy only in patients with medically refractory epilepsy, who had previously failed or were unsuitable for intracranial surgery.</td>
<td>No formal CEA. The high risk of selection bias and concerns regarding the generalisability of the comparative data resulted in uncertainty surrounding the net benefit of VNS plus AED therapy. As a consequence, a formal cost-effectiveness analysis was not performed. The financial implications associated with providing VNS plus AED therapy indicate that the total healthcare costs would be an additional cost of $652,000 annually. This is based on the assumption that 30 patients would receive a VNS implant each year. Potential leakage could see this estimate significantly increase to $1,630,000 per year. The greatest cost associated with VNS therapy is the cost of the device itself. It should be noted that this financial analysis does not consider the likely substantive downstream costs associated with battery depletion which would require the implantation of a new pulse generator. These costs cannot be accurately estimated on the basis of the data available.</td>
<td>MSAC finds the procedure is reasonably safe in the context of the condition being treated. MSAC finds there is insufficient evidence of effectiveness and net benefit of vagal nerve stimulation therapy for patients with medically refractory epilepsy. Formal economic analysis was not conducted in view of the uncertainty of net clinical benefit. MSAC recommends that public funding arrangements for vagus nerve stimulation for epilepsy remain unchanged. The Minister for Health and Ageing noted this advice on 28 August, 2008.</td>
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* No month provided

**APPENDIX C: SELECTED MSAC ASSESSMENT REPORTS**

**TABLE C1: SACRAL NERVE STIMULATION FOR URINARY INDICATIONS**

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
</tr>
<tr>
<td><strong>Nature of analysis</strong></td>
</tr>
<tr>
<td><strong>Approach to CEA</strong></td>
</tr>
<tr>
<td><strong>Health outcome measure</strong></td>
</tr>
<tr>
<td><strong>Comparator</strong></td>
</tr>
<tr>
<td><strong>Modelling approach</strong></td>
</tr>
<tr>
<td><strong>Modelling horizon</strong></td>
</tr>
<tr>
<td><strong>Discount rate</strong></td>
</tr>
<tr>
<td><strong>Perspective</strong></td>
</tr>
<tr>
<td><strong>Scope of costs</strong></td>
</tr>
<tr>
<td><strong>GST</strong></td>
</tr>
<tr>
<td><strong>Approach to patient copayments</strong></td>
</tr>
<tr>
<td><strong>Indexing/inflation</strong></td>
</tr>
<tr>
<td><strong>Treatment of co morbidities/complications</strong></td>
</tr>
<tr>
<td><strong>Sensitivity analysis</strong></td>
</tr>
<tr>
<td><strong>Financial analysis</strong></td>
</tr>
<tr>
<td><strong>Economic analysis findings</strong></td>
</tr>
</tbody>
</table>
**TABLE C1: SACRAL NERVE STIMULATION FOR URINARY INDICATIONS CONTINUED**

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MSAC recommendation</strong></td>
</tr>
<tr>
<td>MSAC advises that public funding should be supported for the procedure of sacral nerve stimulation in adults with detrusor overactivity and non-obstructive urinary retention refractory to conservative, non-surgical intervention. MSAC advises that public funding should not be supported for the use of sacral nerve stimulation for treatment of patients with painful bladder syndrome.</td>
</tr>
</tbody>
</table>

* unclear why these were indexed to 2008 and other costs indexed to 2006.

Source: (MSAC 2008b)
**TABLE C 2: ENDOBRONCHIAL ULTRASOUND GUIDED PROCEDURES**

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
</tr>
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<td><strong>Approach to CEA</strong></td>
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<td><strong>Discount rate</strong></td>
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<tr>
<td><strong>Perspective</strong></td>
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<tr>
<td><strong>Scope of costs</strong></td>
</tr>
<tr>
<td><strong>Approach to patient copayments</strong></td>
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<tr>
<td><strong>Financial analysis</strong></td>
</tr>
<tr>
<td><strong>Sensitivity analysis</strong></td>
</tr>
<tr>
<td><strong>Economic analysis findings</strong></td>
</tr>
<tr>
<td><strong>MSAC recommendation</strong></td>
</tr>
</tbody>
</table>

Source: (MSAC 2008c)
### Table C3: Acticon Artificial Bowel Sphincter

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
</tr>
<tr>
<td><strong>Nature of analysis</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Perspective</strong></td>
</tr>
<tr>
<td><strong>Scope of costs</strong></td>
</tr>
<tr>
<td><strong>Sensitivity analysis</strong></td>
</tr>
<tr>
<td><strong>Financial analysis</strong></td>
</tr>
<tr>
<td><strong>Economic analysis findings</strong></td>
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<tr>
<td></td>
</tr>
<tr>
<td><strong>MSAC recommendation</strong></td>
</tr>
</tbody>
</table>

Source: (MSAC 2007a)
APPENDIX D: HTA REVIEWS IN AUSTRALIA

MSAC REVIEW

In May 2004, MSAC reviewed its procedures and methods to identify where there might be opportunities to improve: processes and governance; stakeholder relationships and communication; methods used to evaluate applications; and form and content of reports (MSAC 2005b). MSAC identified five main themes which emerged from submissions to the review:

- Clarity of reasons for decisions;
- Consistent use of evidence;
- Timely decisions;
- Including others in MSAC processes; and
- Information and communication.

Another issue identified and included as a sixth theme here was that the focus of MSAC was on new technologies, and that longstanding technologies which preceded MSAC were not so rigorously assessed. All of these themes and MSAC’s responses/conclusions are summarised in Table D 1.

PRODUCTIVITY COMMISSION (PC) REVIEW

The Productivity Commission (2005) identified the following key problems associated with HTA in Australia.

Fragmentation and duplication

The PC (2005) noted the fragmentation of HTA processes along jurisdictional and sectoral lines and the absence of a national comprehensive system for the review of new technologies once they have been approved for use by the TGA. For example, MSAC evaluates new health technologies and procedures for which funding is sought under the MBS. The MBS covers funding for professional services provided by doctors to private patients. Professional services to public patients on the other hand may be covered by State/Territory HTA processes. While this can allow flexibility across jurisdictions, it can lead to duplication of effort together with differences in access to services across regions.

The relationship between HTA and health funding arrangements

Funding systems in the health sector are generally aligned with budgetary responsibility which can lead to a focus on the implications of funding decisions for an individual budget holder, rather than broader and more long term considerations across budget holders and the community more generally that can arise from cost effective interventions. This ‘silo’ problem is reinforced by HTAs being undertaken by bodies which are also responsible for expenditure on the assessed technology.

Lack of transparency in HTA processes

The PC (2005) suggested HTA processes were not transparent and therefore lacking in accountability. While MSAC was more transparent than PBAC, information was disclosed
only when the assessment process was completed and there was no part in the process for public comment.

**Insufficient opportunities for community consultation during HTA**

A major gap identified in the MSAC process was the lack of consultation with patient/carer groups or the broader public. While community representatives are included on MSAC committees, they are often restricted in their ability to consult others because of confidentiality requirements.

**HTA of combined technologies**

The evaluation of combined technologies can be hampered by the organisation of HTA by technology type, for example, assessment of drugs, is separate from procedures and diagnostic tests. The procedure and any associated equipment or tests, or devices and any associated drugs are generally considered separately, rather than (more sensibly) in an integrated manner. This can impede access to cost effective technologies.

The need for a more integrated approach to HTA is increasing. As the PC (2005) argued:

> It is possible that the distinction between pharmaceuticals and medical devices will blur even further in the future. … If technology convergence continues, HTA agencies and committees will face an increasing number of ambiguous cases (PC 2005:207-208).

**Development of advice and clinical guidelines**

The development of clinical guidelines in Australia does not appear to be sufficiently linked to HTA processes. There is a disconnect between cost effectiveness findings and clinical practice.

**HTA of procedures and devices**

The Productivity Commission (2005) noted that HTA of procedures and devices is often more complex and associated with more uncertain outcomes than HTA of pharmaceuticals because:

- There is often a lack of high level scientific evidence on efficacy;
- The safety and effectiveness of devices depends not only on the device but also on the skill of the attending team of medical professionals;
- Physical infrastructure is often required for delivery of procedures/devices; and
- Product life cycles are often short.

In relation to medical procedures, the PC (2005) noted the following difficulties:

- Development of medical devices is characterised by a constant flow of incremental product improvements. Some MBS service descriptors may be broad enough to encompass new procedures and devices. Thus, some new procedures or devices that fit under an existing MBS item number may not have been assessed, or have been assessed only after the procedure is already being widely used. Further, if improvements to existing procedures are marginal they may not require full assessment by MSAC. There is no systematic process for consideration of new or improved technologies. While MSAC can re-assess existing MBS procedures, its ability to do so has been constrained by a lack of resources and by the type of references it has received. “Appropriate monitoring and review processes could help to
improve the overall cost effectiveness of medical technologies on the MBS and Prostheses Schedule” (PC 2005:266).

- High level evidence (Level I and II) may not be available for procedures or devices because:
  - It can be difficult to isolate the effects of the procedure or device from other elements of the care provided;
  - It is not always possible to blind patients to procedures/devices because of ethical and cost considerations.

Hence, the evidence available can be more prone to bias than that for pharmaceuticals and less easily generalised. MSAC is able to commission further work in order to assess new technologies more fully. It is also able to approve funding on an interim basis until new evidence is gathered.

- While MSAC accepts international assessments, the PC noted that these are unlikely to obviate the need for Australian evidence because of differences in the skill levels and experience of surgeons in Australia and other countries, differences in prices, relative efficiency, incentives and funding systems, and differences in social preferences.

- The MSAC assessment process ‘appears lengthy’.
### Table D1: Themes emerging from MSAC 2004 review and responses

<table>
<thead>
<tr>
<th>Theme from submissions</th>
<th>MSAC response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clear reasons for decisions.</strong></td>
<td>MSAC agreed to (among other things):</td>
</tr>
</tbody>
</table>
| Lack of clarity on reasons for decisions, including insufficient detail on the weight given to clinical opinion versus evidence. | - publish minutes of its meetings;  
- Introduce a wider range of standard recommendations that explain different levels of evidence and the bases on which decisions are reached;  
- Indicate where an applicant disputes elements of the report;  
- Include a plain English summary and a description of the factors that led the Committee to its recommendations including the weight of evidence and opinions underlying its decisions; Include strong qualitative elements that make clear patient and community benefits, in addition to any patient benefit measures used to estimate cost effectiveness. |
| **Consistent use of evidence**                                                            | MSAC agreed to:                                                                                                                                                                                                  |
| Some submissions claimed MSAC had an inconsistent approach to requiring particular levels of evidence. Others claimed MSAC needed to be more flexible because of the difficulties attaining evidence. Some submissions noted the methodology issues associated with assessment of diagnostic imaging. Lastly, submissions noted that commercial in confidence requirements for some data meant that evidence for decisions could not be revealed. | - Clarify the roles and responsibilities of advisory panel members, contracted evaluators and the department.  
- Investigate a process for monitoring the consistency of the content of reports.  
- Where commercial-in-confidence data are involved, state clearly in the MSAC report that the assessment is based in part on the analysis of data that the applicant has asked not to be published.  
- Develop a standard format for assessment protocols and guidelines on the relationship of evidence requirements to other factors such as the nature of the procedure or technology, the size of the target group, and access to alternative treatments.  
- Investigate a process of peer review for assessments. |
<table>
<thead>
<tr>
<th>Theme from submissions</th>
<th>MSAC response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Timely decisions</strong></td>
<td>Potential trade off between expanding consultation and faster assessments noted. Agreed to (among other things):</td>
</tr>
<tr>
<td>There was a general view that MSAC processes could be more efficient and timeliness could be improved.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Develop guidelines to allow for rigorous but abbreviated assessments where either: technologies are low cost and low risk; there is insufficient evidence on which to base an assessment; substantial, conclusive Level 1 evidence exists; or the Committee is assessing a technology for a second time to incorporate a small body of new evidence, and the parameters of the review (comparators, indications, patient group etc) have not changed.</td>
</tr>
<tr>
<td></td>
<td>▪ Establish timeframes for Committee and Advisory Panel processes and use as key performance indicators.</td>
</tr>
<tr>
<td></td>
<td>▪ As above, potential trade off between expanding consultation and faster assessments noted.</td>
</tr>
<tr>
<td></td>
<td>▪ Considered the most effective way to involve other parties in decision making was to make the Advisory Panel process work better and provide more opportunity for applicants to contribute to the assessment process, eg, provide applicants with a copy of the draft research protocol for comment.</td>
</tr>
<tr>
<td></td>
<td>▪ Agreed to update and clarify conflict of interest and confidentiality protocols.</td>
</tr>
<tr>
<td></td>
<td>▪ Agreed to invite medical and industry groups to make submissions for assessments arising from referrals.</td>
</tr>
<tr>
<td></td>
<td>▪ Noted cost attached to providing more frequent and regular communication, but benefits in the form of better quality applications, and more issues amongst stakeholders being resolved sooner likely to outweigh costs.</td>
</tr>
<tr>
<td><strong>Including others in MSAC processes</strong></td>
<td></td>
</tr>
<tr>
<td>Submissions suggested that MSAC should include representatives of a broader cross-section of key stakeholders including, for example, the medical devices industry, the health insurance industry and clinicians using the technology. Evaluators suggested that they be allowed to present their reports to MSAC</td>
<td></td>
</tr>
<tr>
<td><strong>Information and communication</strong></td>
<td></td>
</tr>
<tr>
<td>Stakeholders sought more information from MSAC at a number of different points in the assessment process</td>
<td></td>
</tr>
<tr>
<td><strong>Assessment of technologies already in wide use and reimbursed under Medicare</strong></td>
<td>Develop and publicise guidelines and criteria for referring to MSAC technologies already in use</td>
</tr>
</tbody>
</table>

Source: MSAC (2005b)
REFERENCES


- (2008a), Expenditure and prescriptions twelve months to 30 June 2007 Data and Modelling Section Pharmaceutical Policy and Analysis Branch.

- (2008b), Prostheses List Guide to listing and setting benefits for prostheses, December.

- (2007), Portfolio Budget Statement for 2007-08, Outcome 3.


- (2005a) Funding for new medical technologies and procedures: application and assessment guidelines September.


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- (2005a), Funding for new medical technologies and procedures: application and assessment guidelines, Department of Health and Ageing, Commonwealth of Australia, Canberra, September.


- (2005), IPG121 Radiofrequency ablation for atrial fibrillation in association with other cardiac surgery – guidance, May.


Ontario Health Technology Advisory Committee (OHTAC) (2005) Implantable Cardioverter Defibrillators for Primary Prevention of Sudden Cardiac Death, September.


