

Medical Services Advisory Committee

Report of a review of the
Medical Services Advisory Committee

May 2005

© Commonwealth of Australia 2005

ISBN (Printed) 0 642 82762 1

ISBN (Online) 0 642 82763 X

First printed

Paper-based publications

This work is copyright. Apart from any use as permitted under the Copyright Act 1968, no part may be reproduced by any process without prior written permission from the Commonwealth available from the Department of Communications, Information Technology and the Arts. Requests and inquiries concerning reproduction and rights should be addressed to the Commonwealth Copyright Administration, Intellectual Property Branch, Department of Communications, Information Technology and the Arts, GPO Box 2154, Canberra ACT 2601 or posted at <http://www.dcita.gov.au/cca>.

Internet sites

This work is copyright. You may download, display, print and reproduce this material in unaltered form only (retaining this notice) for your personal, non-commercial use or use within your organisation. Apart from any use as permitted under the Copyright Act 1968, all other rights are reserved. Requests for further authorisation should be directed to the Commonwealth Copyright Administration, Intellectual Property Branch, Department of Communications, Information Technology and the Arts, GPO Box 2154, Canberra ACT 2601 or posted at <http://www.dcita.gov.au/cca>.

Electronic copies of the Report of the Review can be obtained from the Medical Service Advisory Committee's Internet site at:

<http://www.msac.gov.au>

Printed copies of the Report of the Review can be obtained from:

The Secretary
Medical Services Advisory Committee
Department of Health and Ageing
Mail Drop 106
GPO Box 9848
Canberra ACT 2601

Enquiries about the content of the Report of the Review should be directed to the above address.

The Medical Services Advisory Committee (MSAC) is an independent Committee which has been established to provide advice to the Minister for Health and Ageing on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform government decisions about which medical services should attract funding under Medicare.

These guidelines were prepared by the Medical Services Advisory Committee.

Publication approval number: 3724

Table of contents

Executive Summary	2
1. Introduction.....	3
Background to the review	3
Terms of reference	3
Conduct of the review	3
Structure of the report	4
Overview of responses.....	4
Recommendations beyond MSAC's terms of reference.....	5
Health technology assessment in Australia.....	6
National Health Technology Advisory Panel	6
Australian Health Technology Advisory Committee	7
Medical Services Advisory Committee	7
Productivity Commission study: Impacts of medical technology in Australia.....	8
2. Clear reasons for decisions	9
Background.....	9
What the review found.....	10
Response	11
3. Consistent use of evidence.....	13
Background.....	13
What the review found.....	13
Response	14
4. Timely decisions	17
Background.....	17
What the review found.....	17
Response	19
5. Including others in MSAC processes.....	22
Background.....	22
What the review found.....	23
Response	24
6. Information and communication.....	28
Background.....	28
What the review found.....	29
Response	30
7. Actions agreed	32
8. Conclusion	36
9. Appendices.....	38
A. Terms of reference of past advisory bodies	39
B. Chronology: Health Technology Assessment in Australia.....	40
C. Submissions received.....	41
D. References.....	43
E. Abbreviations	44

Executive Summary

Process

In May 2004, the Medical Services Advisory Committee (MSAC) decided to review its procedures and methods to identify where there might be opportunities to improve the ways it provides advice on new medical technologies.

The Committee received thirty submissions, mainly from professional medical bodies and medical industry groups. In November 2004, the Committee agreed to begin implementing a number of steps which were consistent with ideas being put forward in many submissions, and which were relatively straightforward.

Results

With a few exceptions, the ideas contained in submissions and coming forward from members themselves were very consistent. The report has been structured around the five main themes that have emerged:

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

MSAC has responded by agreeing to a series of 37 actions that it is able to undertake within its terms of reference. The Committee will inform the Minister for Health and Ageing of those issues arising from submission that go beyond the Committee's terms of reference.

Next steps

Some actions have already commenced. Several require a change to procedure but have no additional cost. The rate at which some other actions can occur will depend on what resources are available. MSAC will monitor and report on the implementation of these actions.

1. Introduction

Background to the review

Having operated for six years, the Medical Services Advisory Committee (MSAC) decided in May 2004 to review its procedures and methods to identify where there might be opportunities to improve the ways it provides advice on new medical technologies.

Terms of reference

In August 2004, MSAC endorsed the following terms of reference for the review:

1. Identify areas where the Medical Services Advisory Committee (MSAC) could improve its capacity to fulfil its terms of reference. These should include, but not be restricted to:
 - 1.1. Committee processes and governance;
 - 1.2. stakeholder relationships and communication;
 - 1.3. methods used to evaluate applications; and
 - 1.4. form and content of reports.
2. Identify responses to any of these issues:
 - 2.1. that can be achieved within MSAC's terms of reference and commenced before the completion of the review;
 - 2.2. that can be achieved within MSAC's terms of reference in the longer term, and that might require additional resources; and
 - 2.3. that would require changes to MSAC's terms of reference to enable it to provide better advice to government on the safety, effectiveness and cost-effectiveness of medical technologies.

Conduct of the review

A working group of six MSAC members drew up draft terms of reference for the review, and a process for consultation.

In August, 2004, the chair of MSAC wrote to past applicants to MSAC and to all past and present members of the Committee, informing them of the review and inviting them to provide input. In addition, a notice was placed on the MSAC web site inviting contributions from anyone who wished to contribute. A list of organizations and individuals who provided written submissions is at Appendix C.

MSAC considered an interim report on the review at its meeting in November 2004. The Committee agreed that a number of clear themes had emerged from the submissions received, and that some specific actions that were straightforward and non-contentious could be agreed at that point, rather than await the completion of the review.

A further report on a more comprehensive analysis of all submissions, as well as ideas put forward by MSAC members themselves, was considered at the Committee's meeting of March 2005. Members of the Committee then formed five focus groups, with each group considering the proposals contained in the submissions in respect of five emerging themes.

Following its meeting in May 2005, MSAC endorsed this final report on the review, including a series of actions it has agreed to undertake.

Structure of the report

The issues, ideas and proposals contained in the submissions cover many areas, and do not always fit neatly under the headings suggested in the review's terms of reference. Therefore, the body of the report has been structured to reflect the slightly different set of themes emerging from the submissions themselves:

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

Each chapter within the body of the report includes a summary and discussion of the ideas put forward in submissions to the review. Quotations from submissions are included to illustrate the range of views that have been put forward. These are not intended to represent all views contained in submissions, nor all of the views put forward by the individual organisations that are quoted.

A further chapter contains a list of all the actions the Committee has agreed to undertake in response.

Overview of responses

The Committee is grateful that so many organisations and individuals made the effort to make submissions to the review. Many submissions, particularly from organisations that had not achieved the result they had been expecting from the MSAC process, were critical of various aspects of the Committee's work but, without exception, all submissions provided constructive ideas about how processes might be improved. Each

of the subsequent chapters to this report included quotations from submissions that describe what stakeholders feel need attention. We have included here just a few quotations from submissions that complimented MSAC on some aspects of its work..

It is noteworthy that none of the submissions suggested that there should not be an evidence-based mechanism for determining which medical technologies should be recommended for reimbursement.

‘In general the College considers the MSAC approach to be an excellent process to evaluate new diagnostic and other technologies from an effectiveness, quality, safety and cost perspective prior to acceptance for funding by the Commonwealth Government.’ (RCPA)

‘... the small number of issues that have been addressed by MSAC that come to my personal attention ... have in fact been handled extremely well.’ (RANZCOG)

‘Transparency’ was a recurring theme in many submissions, though it was used as a shorthand way to describe a few different issues. In some contexts it referred to a lack of clear understanding of MSAC processes. In other contexts, it referred to an organisation’s wish to be more directly involved in the Committee’s decision-making, or to a perceived disjuncture between MSAC’s assessment reports and the related recommendations. Therefore, issues of ‘transparency’ are dealt with in several places, under several headings, throughout the report.

Recommendations beyond MSAC’s terms of reference

Some submissions included recommendations that MSAC can acknowledge but not respond to, because they extend beyond the Committee’s terms of reference, and hence are the prerogative of the Minister for Health and Ageing. These recommendations are as follows:

- **Committee membership:** some submissions recommended that the membership of the Committee be expanded to include representatives of various groups of stakeholders including, for example, the medical devices industry, private health insurers, and a second consumer representative. Another suggested that there be explicit criteria for appointing members.
- **Input to recommendations:** one submission suggested that the medical professions have input to MSAC’s recommendations before they proceed to the Minister.
- **Appeals mechanism:** some submissions suggested that there be an independent review mechanism through which to appeal MSAC decisions.
- **Implementation issues:** some submissions urged MSAC to have regard for matters to do with the implementation of its recommendations, such as the listing of new or

altered MBS items, the time that elapses between MSAC recommendations and changes to the MBS, and to take into account the broader effect of implementing its recommendations – questions that extend beyond considerations of safety, quality and effectiveness.

Health technology assessment in Australia

Other than for pharmaceuticals, the first formal system of medical technology evaluation arose following the report of the Committee on Applications and Costs of Modern Technology (1978). The report viewed health technology assessment as ‘one of several long-term measures to improve the effectiveness of technological services in the health system’ (Hailey 1994, p.36).

‘The major goal of any assessment program should be not simply to reduce costs but should be to ensure that funds spent on developing and using technologies provide, on balance, a positive health benefit. But the diversity of technologies and their different modes of diffusion make a uniform approach to technology assessment very difficult’ (Report of the Committee on Applications and Costs of Modern Technology in Medical Practice, 1978).

The Superspecialty Services SubCommittee of the Australian Health Ministers’ Advisory Council (AHMAC) was established in 1981 to advise on regulating the diffusion of highly specialised and costly technologies for comparatively rare conditions. The subCommittee prepared nine guidelines between 1982 and 1990 (Sax 1990, pp.131-132; Hailey 1994, p.39).

National Health Technology Advisory Panel

In mid-1982, the federal Minister for Health established the National Health Technology Advisory Panel (NHTAP) as a non-statutory advisory Committee to provide advice to Australia’s health authorities on medical technology of national importance and/or of high cost. The membership comprised representatives of the medical profession, hospitals, the health insurance industry, manufacturing industry and the States (nominated by their respective organizations), as well as three people appointed by the Minister as experts in health economics, biomedical engineering and medical evaluation. The Committee’s first report was on magnetic resonance imaging.

A permanent secretariat, the Health Technology Unit, was created in the Department of Health in 1984-85, and transferred to the new Australian Institute of Health from 1987. As well as providing secretariat support to the Committee, the Health Technology Unit also undertook most of the Committee’s research. The panel produced 41 reports, which did not always include an economic analysis.

Most assessments were carried out at the request of the Commonwealth Department of Health and AHMAC, or originated from the Committee's own decisions (NHTAP 1989, pp.15-20; Hailey 1994, pp.36-38).

Australian Health Technology Advisory Committee

In 1990, NHTAP and the Superspecialty Services SubCommittee of AHMAC were subsumed by the new Australian Health Technology Advisory Committee (AHTAC), on the recommendation of AHMAC. The objective was 'to establish stronger links between AHMAC and NHMRC and to involve NHMRC more closely in advising health authorities on health services and technology (Hailey 1994, p.39). The Committee reported both to the NHMRC's Health Care Committee and to AHMAC. AHTAC's brief was to evaluate health technologies and highly specialised services looking at safety, efficacy, effectiveness, cost, equity, access and social impact, and to advise government, the health professions and the community on those issues (AHTAC 1997, p.14). It consisted of experts in health economics, health services planning, research and industry; as well as nominees of AHMAC, the Consumer' Health Forum and the Commonwealth Department of Health, and a representative of the New Zealand Ministry of Health.

A survey of government agencies and other users found that the recipients of AHTAC's assessment reports found them to be generally useful and relevant, though there was no systematic relationship between reports' recommendations and funding or reimbursement decisions. From time to time a particular assessment might have influenced the subsequent listing of a new technology on the Medicare Benefits Schedule (MBS), but decisions were routinely taken on the basis of assessments by the Health Department of submissions from professional groups (Hailey 1994, p.33).

Medical Services Advisory Committee

The Australian Government Minister for Health and Family Services established MSAC (originally as the *Medicare Services Advisory Committee*) in April 1998 to strengthen arrangements for assessing new technologies and procedures before they are considered for reimbursement under the Medicare Benefits Schedule (MBS) (Commonwealth of Australia 1997, p.65).

The Committee'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 either 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.

The fourth term of reference was added in August 1999 to allow the Committee to undertake work referred from AHMAC which before MSAC's establishment had been conducted by AHTAC.

Productivity Commission study: Impacts of medical technology in Australia

In August 2004, the Treasurer directed the Productivity Commission to undertake a study detailing and explaining the advances in medical technology on public and private healthcare expenditure, and the associated costs and benefits for the Australian community.

In April 2005, the Commission published a progress report, 'Impacts of Medical Technology in Australia,' in which it observed that there is scope to better coordinate health technology assessment processes, and that better processes could help to target new technologies to patient groups most likely to benefit (Productivity Commission 2005, pp.xxvi, 242). The final report is due to be presented to the Government in August 2005.

2. Clear reasons for decisions

Background

The main forum for the Medical Services Advisory Committee's (MSAC's) decision-making is the Committee's quarterly meeting, at which members formulate their advice to the Minister for Health and Ageing or in response to matters referred by the States and Territories through AHMAC. However, this is just the final stage of a process that draws on information contained in applications, the advice of experts, and an analysis of all relevant published (and sometimes unpublished) evidence.

In the case of applications, once an application has been assessed by the Department of Health and Ageing as being in respect of a service eligible for reimbursement under Medicare, the MSAC executive directs which medical craft groups it wishes to have represented in the Advisory Panel, and on occasion will also identify individuals they consider would have an important contribution to make to the assessment.

As the Advisory Panel is being formed, contracted evaluators are assigned to the assessment and having carefully considered the application, prepare preliminary material which the chair of the panel, the evaluators and the department use as a basis for drafting an assessment protocol to present to the first meeting of the panel.

At the Advisory Panel's first meeting, members develop the fundamental scope of the assessment, including the clinical pathways both of the technology under review and its comparator, the indications and patient groups, and the health outcomes by which the technology will be assessed. Until recently, applicants were contacted at this point only if there was a significant difference of view between the applicant (as revealed in the application) and the Advisory Panel on matters affecting the scope of the assessment.

The evaluators produce a draft report, based on the assessment protocol, and including evidence of the safety of the technology, and of its clinical effectiveness: whether there is evidence that it achieves results as compared with the alternative approach. If the assessment indicates that there is evidence that the technology is effective, then they will also include an economic analysis to demonstrate whether the technology also represents value for money.

The Advisory Panel meets again to provide advice on the interpretation of the evidence, and to indicate also where members consider the published evidence might usefully be supplemented with expert opinion, based on the experience of the members and their professions. For particularly complex assessments, further meetings of the Advisory Panel might be required.

Once the Advisory Panel is satisfied that the report contains clear and defensible conclusions about the safety, effectiveness and cost effectiveness of the technology, the

applicant receives a copy and is invited to provide comment. The report can be amended in response to the applicant's comments, but in any event, MSAC receives the comments, any response the evaluators might have to the applicant's comments, as well as comment provided by the medical adviser to the Medicare Benefits Branch within the department.

In addition to receiving this material, the Committee hears a critique of the report from one of its members who has had no part in the assessment up to that point. On the basis of all of these elements, MSAC comes to a view about the safety, effectiveness and cost-effectiveness of the technology under review and whether it will advise that Minister that public funding should be supported, and agrees the precise wording of a recommendation to that effect. The Committee will include in the recommendation more detail where it considers it important that it convey some additional qualification or rationale for the decision. If the Committee considers that the report does not provide a sufficiently sound basis for its advice, then it will ask that the evaluators and the Advisory Panel do more work, and will postpone a decision until a subsequent meeting.

The Committee's recommendation is conveyed to the Minister for Health and Ageing. After the Minister has signed off on the Committee's advice, the final report and recommendation are conveyed to the applicant and then published.

Until recently, in the case of references to MSAC from the department or AHMAC, the research protocol and draft assessment report were not routinely provided to parties beyond the Advisory Panel for comment.

What the review found

Many of the submissions to the MSAC Review asserted that the relationship between the published evidence and clinical opinion on the one hand, and conclusions and recommendations on the other, is not always made clear.

MSAC reports were criticised in some submissions for being too brief and for lacking depth and consistency. Other commented that reports did not include sufficient detail on the way evidence and expert opinion was weighted in order to reach conclusions.

Some submissions suggested that the views of expert clinicians should carry more weight, and be reflected in assessment reports.

'... it isn't clear how MSAC comes to its decisions.' (Guidant)

'... the recommendations do not follow from the narrative and contradict the expert clinical view.' (AMA)

'Full reasons for decisions about recommendations should be published to ensure confidence in the decision-making process.' (ASA)

'For the sake of transparency, relevant sections of MSAC minutes should be made available to affected suppliers.' (MIAA)

'... it is important that where there are dissenting technical views of medical specialists who are members of any MSAC Supporting Committees, such views are both acknowledged and taken into consideration in the final recommendations to the Minister.' (ANZAPNM)

'The issues which lead to recommendations, where these add to or significantly depart from the results of the literature review, need to be explicit and justified in some way.' (RANZCR)

'The form and content of reports is ... very thorough and clear.' (GESA)

'The transparency of the connection between the evidence base and the reimbursement decision is commendable – surpassing many other reimbursement agencies.' (htanalysts)

Response

MSAC concluded that there are several steps it could take to make the reasons for its decisions clearer. In particular, the Committee agreed that it would develop a larger range of standard recommendations that would cover the majority of circumstances it faces when assessing a new technology. For circumstances where the standard wording still does not cover factors that were material to the Committee's decision, the Committee agreed that there would be a less structured preamble to the recommendation describing those factors.

MSAC decided to include in its reports sections set aside specifically for consumer and expert medical opinion, where such opinion might diverge from the published evidence, Reports' conclusions will indicate the extent to which these considerations affected final decisions.

To make the reasons for decisions clearer, MSAC agreed that full minutes of its quarterly meetings will be routinely available on the Committee's web site, once the Minister has considered any recommendations contained within them. This will replace abbreviated

version of the minutes that has been available on the web site until now. The Committee also decided in future to publish 'plain English' summaries of each of its reports, and to actively distribute them to all interested parties.

MSAC was concerned that the role of Advisory Panels, and of expert opinion generally, in informing the Committee's decision-making, is not always well understood, even by some of the key stakeholders. MSAC agreed that this needs to be spelt spelled out more clearly in guidelines and other information disseminated by or for the Committee.

After careful consideration, the Committee decided not to include in reports applicants' responses or evaluators' rejoinders to those responses. However, the Committee did agree that, if the applicant disputed a particular aspect of the report, the report would include a statement in the report to that effect. The Committee also decided not to publish any raw data that is used in analyses.

Actions agreed:

The actions MSAC have agreed to undertake are described in Chapter 7. The actions that relate to this theme are presented below.

- Publish minutes of MSAC meetings on the Committee's web site.
- Introduce a wider range of standard recommendations that cater particularly to decisions based on different levels of evidence, that articulate more clearly the bases on which decisions are reached.
- Produce a more standard template for MSAC reports, including sections that summarise expert opinion and a consumer perspective, to the extent that they might diverge from the published evidence.
- Indicate in reports that an applicant has disputed elements of the report.
- Publish with each assessment report a concise, 'plain English' summary of the basis for the recommendation, and distribute to interested organisations.
- Include in the "executive summary" and as a preamble to recommendations, a description of the factors that led the Committee to make a particular recommendation, including its assessment of the weight of evidence and opinions underlying its decision, and any relevant contextual issues.
- Include strong qualitative elements that make clear patient and community benefits, in addition to any patient benefit measures used to estimate cost-effectiveness.

3. Consistent use of evidence

Background

The Medical Services Advisory Committee (MSAC) publishes guidelines which include information on the level, quality and strength of evidence it seeks so as to provide the most reliable advice it can, to the Minister. The Committee will always seek the best evidence that is available, while also having regard for the opinions of expert clinicians.

However, MSAC deals with a very wide variety of technologies and procedures, ranging from pathology tests and diagnostic imaging, to new surgical procedures, to medical devices. Therefore, the nature of the evidence available will vary accordingly. In addition, the number of patients to whom the technology or procedure will apply might be very small making it difficult to accumulate quantities of evidence that would be ideal. In short, there are several factors that mean that it is both impractical and inappropriate for the Committee to apply a single, rigid rule to the nature of the evidence it considers acceptable for decision-making.

What the review found

Some submissions to the MSAC Review included claims that the Committee has not applied a consistent approach to requiring particular levels of evidence.

At the same time, MSAC was urged to adopt a more flexible approach to attaining evidence where ethical or practical difficulties made the collection of evidence particularly problematic, or where it is appropriate to have regard for other dimensions of evidence, such as its relevance, quality and the size of the effect.

Some submissions highlighted the particular methodological issues to do with assessing diagnostic technologies, and sought clarification of MSAC's approach to such technologies.

The issue was raised of decision making that uses commercial-in-confidence data, with the consequence that the published report cannot reveal the full extent of evidence that led to that particular decision.

Industry and craft groups felt that when preparing applications for assessment, it would be helpful to know what weight is given to particular elements of evidence in the decision making process.

'It is important that the evidence requirements for a new procedure are calibrated to the characteristics of the procedure.' (MIAA)

'We appreciate levels 1 and 2 evidence may be the standard required for pharmaceutical reviews, however, we are experiencing difficulty implementing measures which would enable us to achieve level 1 or 2 evidence with a new [diagnostic] procedure ...' (Given Imaging)

'... guidelines for undertaking economic evaluations need to be developed to specify MSAC's core needs and the minimum requirements and the recommended methods to meet these needs.' (NHMRC CTC)

'... it would be helpful to document the core needs and minimum requirements for MSAC decisions, for example under the headings of clinical need, expected utilization, safety, effectiveness and cost-effectiveness.' (NHMRC CTC)

'One area of major concern is the inconsistent approach and quality of the economic evaluations and financial impact estimations within the existing Assessment Reports.' (htanalysts)

'The recommendation regarding a clinical practice should be based on the synthesis of all aspects of best available evidence. It is not appropriate that a single dimension such as a requirement for a certain level of evidence, to be applied across the board.' (Prof Paul E. O'Brien)

'The cost of the MSAC process can be out of proportion to the potential saving.' (Prof Paul E. O'Brien)

Response

The Committee recognised that the levels of evidence that would normally be available for pharmaceuticals will often not be available (or appropriate) for the very diverse range of diagnostic and therapeutic technologies and procedures MSAC is asked to assess. The Committee found, on the basis of its experience to date, that a set of hard and fast rules on what levels of evidence will be considered acceptable in any conceivable circumstance would not be practical or helpful. It agreed that there are often practical as well as methodological issues that will guide the Committee in determining what quantity and quality of evidence it will regard as appropriate in different circumstances.

In view of these complexities, the Committee agreed to develop a set of broad principles and to analyse the Committee's decisions to date, to provide a body of material akin to 'case law' that would both help prospective applicants to understand what is required, and to inform future advice from the Committee.

MSAC noted that the assessment of diagnostic technologies presents particular methodological challenges, and that therefore the Committee has had developed guidelines for assessing these types of technologies. The guidelines are in use and available through the MSAC website.

MSAC also noted that when issues of methodological consistency arise, they are often in relation to the economic aspects of assessments. The Committee observed that it was timely that it had already begun a major project to examine and revise its guidelines for conducting economic analyses, and that this should help to ensure that future reports are more consistent in their use of evidence. The guidelines are being developed by a working group of the Committee, with the assistance of Monash University's Centre for Health Economics. They will provide consistent direction to applicants, evaluators, Advisory Panels and MSAC.

MSAC considered that there is scope to better inform Advisory Panel members (particularly those who are participating in the process for the first time) about the way the Committee uses evidence, and also to develop a standard format for research protocols, to ensure that there is a consistent approach to assessing technologies.

In response to a proposal contained in submissions that commercial-in-confidence material not be used, the Committee recognised that reports that draw on such information cannot provide a complete explanation of the conclusions it reaches but, on balance, considered that it would not be appropriate to preclude the use of commercial-in-confidence material, if such data provided a stronger basis for demonstrating the safety, effectiveness or cost effectiveness of a technology.

In response to a suggestion that overseas evidence should be used in assessment reports, the Committee observed that such evidence is already used where it is the best available and where it can be translated to the Australian setting. The Committee asked that this be made clear in future communications with stakeholders.

Again, in response to a view that MSAC should have regard for the effect of decisions on supplementary technologies - not just new or replacement technologies - when assessing diagnostic procedures, the Committee noted that this is already standard practice.

The Committee considered involving the member who is responsible for critiquing each report earlier in the process, specifically before the draft final report stage, so that their views could inform the version that is considered by MSAC. While it was conceded that this might help to shape the version that the Committee considers (and hence aid both consistency and timeliness), on balance it was felt that it is preferable that the critiquer remain completely independent of the assessment.

Actions agreed:

The actions MSAC have agreed to undertake are described in Chapter 7. The actions that relate to this theme are presented below.

- Develop a presentation and associated material that will provide clear, consistent direction to Advisory Panels about the roles and responsibilities of panel members, as well as the 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.
- Develop 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.

4. Timely decisions

Background

To date, Medical Services Advisory Committee (MSAC) assessments have taken an average of thirteen months to complete, though there has been considerable variation. There are several factors that affect the time it takes to complete a review, including:

- The formation of an advisory panel: this can be affected by the availability of individuals with the required experience and expertise, and the responsiveness of craft groups who are invited to nominate people to become advisory panel members;
- The complexity of the assessment: this will vary with the number of indications under review, the number of procedures the technology in question is being compared with (comparators), the volume of evidence that is available, and the extent to which economic modeling is required.
- Interaction during the review process with the applicant: applicants are now invited to comment on the draft research protocol or scoping document that guides the assessment. While this is designed to improve ‘transparency’, and particularly to ensure that the scope of the assessment is clear from the start, it can slightly impede the process. Also, there have been cases where applicants have asked that additional evidence be taken into account, which has caused the process to take longer than it otherwise would have.
- The Committee seeking further information: on occasion, MSAC has received assessment reports, but then asked that further work be undertaken if it considers that the report does not provide sufficient basis on which to come to an informed view. While this clearly improves the quality of the Committee’s work, it can add three months to the assessment process.

What the review found

Most submissions made reference to the time taken to complete assessments. There was a general view that changes could be made to the MSAC processes to improve efficiency and timeliness.

There were several suggestions that each assessment should run to a published schedule, and any delays should be explained. Such views were particularly prominent in submissions from industry and craft group representatives.

There was one suggestion that applicants should be able to pay a fee to receive priority, and therefore a faster result.

'MSAC should establish review turnaround times as a key performance indicator and report on its performance against this criterion regularly and publicly.' (AMA)

'There is an urgent need to streamline the process and for there to be a timetable similar to the PBS submissions so that there can be certainty that an application, if successful, will be listed on the MBS by a certain date.' (MIAA)

'A suggestion would be for new technology assessments to have a cost implementation filter applied; and technologies that are not going to be vastly expensive ... may not require the full exhaustive MSAC process.' (AAPP)

'... our members are concerned about the slowness of the process of evaluating data and making recommendations to the Minister. We believe reviews should be concluded in a timely fashion and should take no longer than 6-9 months to conclude.' (ANZAPNM)

'The processing time for MSAC evaluations is too long, particularly given the growth in new diagnostic and therapeutic techniques and devices.' (RANZCR)

'... time guidelines should at least be articulated so that performance against these can be measured.' (CYTYC)

'The MSAC process needs to be accountable to predetermined timelines.' (Novartis)

'There needs to be a mechanism whereby MSAC decisions can be reviewed in a timely manner so that decisions rendered obsolete by scientific and clinical advances can be revised promptly and inexpensively.' (Dorevitch Pathology)

'... the time taken for the review to be completed was excessive.' (Dr P.J. Graziotti)

Response

MSAC agreed that matters before it should be dealt with in as timely a manner as possible, it also wished to emphasise that there will often be a trade-off. Faster decision-making might, if not handled sensitively, be at the expense of consultation with applicants and clinical experts, or rigorous assessments.

The comparison is sometimes made between the timeframes applying to assessments by the Pharmaceutical Benefits Advisory Committee (PBAC) and by MSAC. While there are probably aspects of the PBAC process that MSAC could learn from, there are some major differences, particularly that applicants to the PBAC are required to submit a complete assessment which evaluators then scrutinize, whereas MSAC's assessments commence after the application is lodged.

On the proviso that it did not wish to compromise the quality of the advice it provides to the Minister, the Committee agreed that a number of steps could be taken to help speed up the assessment process. Most significantly, the Committee agreed that it is not always appropriate for every application to be the subject of a 'one size fits all' assessment process. In some cases, it will be clear that a shorter (but still rigorous) assessment is appropriate. The Committee also agreed that the process of appointment of members to advisory panels often takes too long, and should be fixed. The Committee was keen to provide information via the MSAC website on expected completion dates for each assessment, and for the time taken to complete assessments to be a recorded and used as a marker of the Committee's and the secretariat's performance.

In response to the suggestion in at least one submission that data provided by applicants are not considered as a starting point for each assessment, the Committee affirmed that it is current practice that data provided by the applicant is taken into account, and that it expects all Advisory Panel members routinely to receive copies of the application being assessed.

In response to a suggestion that MSAC, develop a process for receiving applications for 'classes' of tests and considering these as a group rather than individually, the Committee noted that this issue is most likely to arise in relation to emerging genetic tests, and that it is looking to work collaboratively with the Genetics Working Party of the Pathology Services Table Committee to find a sensible way to deal with these classes of tests.

MSAC did not consider that giving priority to applicants who paid a fee would be appropriate. To date, there has not been a need to delay the commencement of assessments arising from applications due to resource constraints, and if there ever were, then an applicant's capacity to pay a fee would not be regarded as an acceptable criterion for moving it to the top of a queue.

Actions agreed

The actions MSAC have agreed to undertake are described in Chapter 7. The actions that relate to this theme are presented below.

- Include an MSAC member with relevant clinical expertise in the preliminary teleconference stage of assessments.
- Develop an MSAC meeting cycle timetable, with earlier cut-offs for completion of review processes.
- 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.
- MSAC Executive to formally monitor the progress of each application, and report any delays to the Committee.
- Establish timeframes for Committee and Advisory Panel processes and use as key performance indicators.

5. Including others in MSAC processes

Background

The Medical Services Advisory Committee (MSAC) consists largely of doctors and health economists appointed by the Minister for Health and Ageing on the basis of their individual expertise, and their capacity to exercise independent judgement on the basis of evidence that is presented to the Committee. Exceptions are people nominated to represent consumers' interests, and a representative of the Australian Health Ministers' Advisory Council.

Contracted evaluators also have a direct role in the Committee's decision making in that they provide the research and modelling that underlie each assessment, although this is done within parameters determined by the relevant Advisory Panel.

Over the course of the assessment process, there are specific instances when MSAC or the Secretariat communicates with applicants. Organisations considering making an application to MSAC can meet first with the Secretariat both for the prospective applicants to describe their expectations of the process, and for the Secretariat to describe the process by which the Committee assesses each application. This is not a mandatory part of the application process, but it is strongly encouraged.

Once an application has been lodged, applicants are contacted, at a minimum, at the following points in the process:

- Once a research protocol has been drafted, if the Advisory Panel disagrees with the applicant's selection of a comparator or clinical pathway, or with any other element of the application that could influence the outcome of the assessment, then the Secretariat will convey to the applicant the Panel's views and seek a response, before the assessment proceeds further.
- Once the Advisory Panel has settled on a final draft report to submit to MSAC the applicant receives a copy, and is invited to provide comment within 28 days.
- The Secretariat informs the applicant of the Minister's decision in response to MSAC's recommendation, and provides to the applicant the final report when it is published.

The Advisory Panel provides the main mechanism for drawing others in to each individual assessment. The main purpose of these groups is to ensure that the scope of the assessment, as expressed in the protocol, is clear and appropriate including, for example, that the comparator, the clinical indications and the patient group are all consistent with clinical practice in Australia. Advisory Panels often provide comment on the quality of published evidence that forms the basis of assessments, and on how the evidence compares with their experience of clinical practice.

Members of Advisory Panels are appointed by the MSAC executive either directly, or on the recommendation of relevant colleges or craft groups. Individuals are appointed on the basis of their knowledge and/or experience of the technology under review or the technology it is intended to complement or replace.

At present, everyone involved in assessments is required to observe conditions of confidentiality. While participants can seek information that will help in the assessment, they are not permitted to divulge the group's internal discussions and decision making. Sometimes the Committee and panel will consider information that the applicant has provided on a confidential basis, for commercial reasons.

What the review found

Many of the submissions suggested that there should be more opportunities for other parties to participate in, or contribute to, the MSAC process. In particular, submissions suggested that MSAC should include representatives of a broader cross-section of key stakeholders including, for example, the medical devices industry and the health insurance industry.

Evaluators suggested that they be allowed to present their reports at MSAC meetings or, a minimum, to have a representative attend.

There was a general view that MSAC had made some decisions without considering the opinions of clinicians using the technology. Some submissions suggested that clinical experts be invited to speak to MSAC or Advisory Panels.

Several submissions referred to MSAC's assessment of technologies already in wide use and reimbursed under Medicare. (The issue doesn't fall neatly under any of the themes, but is included here because the proposed solutions involve broader involvement of others in the assessment process.) There were different perspectives. On the one hand, there was a view that MSAC should concentrate on assessing new technologies, or at the very least have regard for the effect on clinicians and patients of assessing diffused technologies. On the other hand, some contributors considered it incongruous that only new technologies should be scrutinised to determine whether they work and represent value for money, while many longstanding technologies which precede MSAC have not been so rigorously assessed.

'There should be less need for confidentiality agreements binding participants ...'
(AMA)

'MSAC should conduct its affairs in the public arena to the maximum extent possible.'
(AMA)

'This insistence on confidentiality simply prevents any open discussion on matters of clinical relevance and supposedly based on open research.'
(ASA)

'The confidentiality provisions have hampered communication with craft group representatives. It is not explicit as to how a medical member of the panel can seek appropriate input from colleagues.'
(RANZCR)

'A far more robust system of governance is required if withdrawal of public funding may result from MSAC decisions.'
(ANZHMG)

'... MSAC must move beyond its current focus on only 'new' services and technology.'
(ADIA)

'... there seem to be no declaration of actual or potential conflict of interest by the members of the MSAC Committees.'
(CYTYC)

'... the supporting Committee formed to assess this application was not truly representative of the relevant stakeholders.'
(Diagnostic Technology)

'... it might be valuable for the secretariat to conduct 'debriefing' meetings with unsuccessful applicants ...'
(htanalysts)

Response

Noting that timeliness is another theme emerging from submissions to the review, the Committee made the general observation that steps to include other parties in MSAC processes will often mean that processes will take longer.

The group considered that the most effective way to involve other parties in MSAC decision making is to make the Advisory Panel process work better. As part of its interim response to the review, the Committee decided to provide more opportunities for applicants to contribute to the assessment process. In particular, applicants now receive a copy of the draft research protocol after the first meeting of the Advisory Panel. Any comments the applicant might have on the draft documents are fed back to the Panel. The objective is to sort out any issues to do with the basic scope of the assessment at that early stage, rather than at the end of the process when it is usually too late. This does not always guarantee that the applicant and the Advisory Panel will be of one mind, but it does give the applicant

an additional opportunity to shape the assessment, and keeps them informed of where the Panel is heading.

While there was a fairly common concern to provide more opportunities for expert involvement, there was also a view that if any individual who was involved had a conflict of interest, that this should be declared. The Committee noted that MSAC members' conflicts of interest are routinely recorded in MSAC minutes, and that members abstain from voting on the Committee's decisions when there is such a conflict. However, MSAC also agreed that in future any conflicts of interest relating to Advisory Panel members should be recorded, including in assessment reports.

MSAC noted the medical devices industry's interest in having more frequent opportunities to exchange information, and agreed that there should be a more regular series of formal discussions between MSAC and the key industry and medical groups.

MSAC agreed that the confidentiality requirements that currently apply to Advisory Panel members particularly, should at least be clarified if not revised. There was a general view that these strictures should not prevent panel members from seeking advice from other experts, so long as they do not divulge the panels' discussions and conclusions.

On the issue of assessing existing technologies (mainly in response to references from the Department of Health and Ageing), MSAC noted that this function is clearly within its terms of reference. The Committee agreed though, that stakeholders should have more opportunities to contribute to assessments arising from references, than was once the case. Previously, for assessments where there was not an applicant, stakeholders' involvement extended only as far as the Advisory Panel. The Committee agreed that medical and industry groups should now be invited to make submissions for assessments arising from referrals, which would in turn enable the organisation to comment on draft assessment protocols and draft final reports.

The Committee also decided it would recommend to the Department that it consider developing criteria which would clarify the grounds on which an existing technology might be referred for assessment.

MSAC considered the proposal that a GP be included on all Advisory Panels, and concluded that this is already current practice, in every case where GPs are a part of the relevant clinical pathways under review. MSAC noted the suggestion that an evaluation group representative should be invited to attend meetings at which assessments they have contributed to are discussed, but observed that this is already an option that is open to the Committee's executive.

MSAC considered at length the value of having applicants meet with Advisory Panel members. On the one hand, the Committee acknowledged the argument that panel members might gain an understanding of the technology being assessed. On the other hand, MSAC recognized that the application itself provides a clear and consistent mechanism for applicants to describe what the technology does compared to current practice, and what

evidence there is to indicate that it is safe, effective and cost effective. The Committee foresaw that, even with the very best intentions, there would be potential for perceptions of bias to arise if better-resourced applicants were seen to have an advantage in ‘marketing’ their product to the panel. On balance, the Committee concluded that the current arrangement whereby information is received from applicants in a common format, and the panel is able to seek further information from the applicant if it wishes, is simple and fair.

Actions agreed:

The actions MSAC have agreed to undertake are described in Chapter 7. The actions that relate to this theme are presented below.

- Enhance and better publicise the role of Advisory Panels as follows:
 - Clarify and publicise that Advisory Panel members are able to seek advice beyond the panel, provided they do not divulge the panel’s discussions or conclusions;
 - Investigate ways to speed up the appointment of consumer representatives to Advisory Panels;
 - Chair to brief the consumer representative before the first Advisory Panel meeting;
 - Revise and disseminate Advisory Panel guidelines to reflect these changes.
- Record any conflicts of interest relating to Advisory Panel members and MSAC members in assessment reports.
- Invite applicants to recommend which types of clinicians should be represented on the Advisory Panel considering their application.
- Provide to applicants a copy of the assessment protocol.
- Provide to applicants a further copy of a draft assessment report if, following MSAC’s consideration, the report changes significantly.
- Provide to applicants a copy of the evaluators’ rejoinder to the applicant’s comments on draft assessment reports.
- Invite stakeholders to make submissions and comment on final draft reports in respect of assessments arising from referrals from the Department and, in respect of applications if the applicant clearly indicates that they wish it to occur.
- Develop and publicise guidelines and criteria for referring to MSAC technologies already in use.

6. Information and communication

Background

This theme clearly intersects with almost every aspect of the Medical Services Advisory Committee's (MSAC's) work. The Committee's effectiveness depends largely on how well it communicates its purpose, its methods and the results of its analyses to those with a stake in the process.

MSAC currently provides information in a number of ways, and at various stages of the assessment process.

The **web site** provides basic background information on the Committee's role, links to all published material, and a guide to submitting an application. Over the period July 2002 to October 2003, the website was visited on average 3,518 times per month.

The most substantial means of communication is the Committee's **assessment reports** on each of its individual reviews of medical technologies. They are available in hard copy and through the Committee's web site.

In addition, MSAC produces an **annual report**, which summarises the business concluded by the Committee in a particular year, and a **newsletter** which has been produced sporadically, most recently in July 2003.

From time to time, the MSAC Secretariat advises the International Network of Agencies for Health Technology Assessment (INAHTA) of new assessments and completed reports, and provides one-page summaries of completed reports.

The MSAC executive and other members of the Committee often provide papers and presentations at Australian and international conferences, including for example, the 2004 Health Technology Assessment International annual conference in Krakow, Poland.

From time to time, the MSAC Secretariat has addressed the medical devices industry at workshops organized by the Medical Industry Association of Australia.

What the review found

The review found that stakeholders would like more information from MSAC at a number of different points in the assessment process. Some stakeholders would like more frequent engagement with the medical devices industry, in order to explain the MSAC process.

A number of submissions referred to the MSAC website and suggested that it could be better used to keep stakeholders informed about MSAC matters in general, but particularly the status of applications in the process of being assessed. There was also suggestion that the MSAC Executive should meet from time to time with the key industry and medical groups.

There were several suggestions that the ‘pre-lodgement’ meetings that the secretariat offers should be a mandatory part of the process, so that prospective applicants are fully aware of what is required in an application, and what can and cannot be expected from the process. There were further suggestions that unsuccessful applicants be offered ‘debriefing’ meetings.

‘MSAC processes are black box to the profession.’ (AMA)

‘... there may need to be better communication of the overall objectives of the MSAC process ...’ (ADIA)

‘I am not aware of the availability of reports about MSAC reviews on reasons for funding or not to fund new technologies.’ (RACS)

‘... there is not a clear recognition of the role and terms of reference of this Committee and ... there should be a greater attempt to promulgate publicly the importance of this role.’ (RANZCOG)

‘It would be very useful to be able to track the status of an approval [application] on-line or to receive periodic reports.’ (Zeiss)

‘Regular updates [of the web site] may assist MSAC by reducing the frequency of direct telephone inquiries from application sponsors.’ (Given Imaging)

‘...awareness of MSAC and its impact on diagnostic and surgical practice in Australia remains very poor amongst clinicians and the related industry, never mind the general public.’ (Guidant)

‘Communications could be improved by updating the MSAC website more frequently and more completely ...’ (Guidant)

Response

MSAC agrees that the timely dissemination of accurate and relevant information can only benefit all parties concerned, including the Committee itself. MSAC notes also that some of the submissions to the review included responses that suggest that MSAC's purpose and processes are not well understood, even amongst groups with an obvious interest in the outcomes.

The Committee acknowledges that there is a cost attached to providing more frequent and regular communication, but believes that there would also be many benefits, for example, in the form of better quality applications, and more issues amongst stakeholders being resolved sooner and with less fuss.

The actions the Committee has agreed to implement include making better use of the existing website. The Committee noted that since its inception, it had participated in many seminars and discussions with industry and medical groups, but undertook to ensure that it continues to do so.

While the secretariat often meets with unsuccessful applicants, at the applicant's request, the Committee agreed to ask the secretariat to offer this facility routinely when it passes on the Minister's decision.

Actions agreed

The actions MSAC have agreed to undertake are described in Chapter 7. The actions that relate to this theme are presented below.

- Develop orientation package for new MSAC members.
- Brief members annually on Committee roles and responsibilities.
- Provide consumer-focused, 'plain English' summaries of all reports in a succinct format to all relevant colleges and consumer organisations in a format easily reproducible for their member publications.
- Require evaluators to publish report findings in academic journals.
- Hold regular workshops for potential applicants.
- Routinely invite unsuccessful applicants to attend a 'debriefing' meeting when the Minister's decision is conveyed.
- Invite peak bodies MIAA/AMA to inform organisations of referrals under way.
- Hold meetings with stakeholders (eg, AMA, MIAA) each triennium to explain the process and to receive feedback.

- Update the MSAC website more frequently and also include the following additional information:
 - criteria outlining what constitutes acceptable levels of evidence;
 - regular reports of the status of applications and review timelines and revision of timelines as necessary (include applications awaiting assessment);
 - roles and responsibilities of MSAC, HealthPACT, Horizon Scanning Unit, Advisory Panels, evaluators, applicants and other groups (eg, ASERNIP-S, the NHMRC).
 - an on-line newsletter.
 - links to related sites.

- Provide succinct and timely information regarding MSAC, its work and the process for applications to the medical colleges in a format easily reproducible for their member publications.

- Investigate how the UK National Institute of Clinical Excellence ensures that outcomes considered are relevant to patients and how it incorporates broader consumer issues into its assessments (in consultation with the Consumers' Health Forum of Australia).

7. Actions agreed

These actions are arranged according to the part of the assessment process that they refer to.

Advisory Panels

1. Include an MSAC member with relevant clinical expertise in the preliminary teleconference stage of assessments.
2. Develop a presentation and associated material that will provide clear, consistent direction to Advisory Panels about the roles and responsibilities of panel members, as well as the contracted evaluators and the department.
3. Enhance and better publicise the role of Advisory Panels as follows:
 - Clarify and publicise that Advisory Panel members are able to seek advice beyond the panel, provided they do not divulge the panel's discussions or conclusions;
 - Investigate ways to speed up the appointment of consumer representatives to Advisory Panels;
 - Chair to brief the consumer representative before the first Advisory Panel meeting;
 - Revise and disseminate Advisory Panel guidelines to reflect these changes.

Medical Services Advisory Committee meetings

4. Publish minutes of MSAC meetings on the Committee's web site.
5. Develop an MSAC meeting cycle timetable, with earlier cut-offs for completion of review processes.
6. Develop orientation package for new MSAC members.
7. Brief members annually on Committee roles and responsibilities.
8. Introduce a wider range of standard recommendations that cater particularly to decisions based on different levels of evidence, that articulate more clearly the bases on which decisions are reached.

MSAC Reports

9. Produce a more standard template for MSAC reports, including sections that summarise expert opinion and a consumer perspective, to the extent that they might diverge from the published evidence.

10. Record any conflicts of interest relating to Advisory Panel members and MSAC members in assessment reports.
11. Indicate in reports that an applicant has disputed elements of the report.
12. Publish with each assessment report a concise, 'plain English' summary of the basis for the recommendation, and distribute to interested organisations.
13. Include in the "executive summary" and as a preamble to recommendations, a description of the factors that led the Committee to make a particular recommendation, including its assessment of the weight of evidence and opinions underlying its decision, and any relevant contextual issues.
14. Include strong qualitative elements that make clear patient and community benefits, in addition to any patient benefit measures used to estimate cost-effectiveness.
15. Provide consumer-focused, 'plain English' summaries of all reports in a succinct format to all relevant colleges and consumer organisations in a format easily reproducible for their member publications.
16. Investigate a process for monitoring the consistency of the content of reports.
17. 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.
18. Require evaluators to publish report findings in academic journals.

Communication with and involvement of applicants and relevant stakeholders

19. Hold regular workshops for potential applicants.
20. Invite applicants to recommend which types of clinicians should be represented on the Advisory Panel considering their application.
21. Provide to applicants a copy of the assessment protocol.
22. Provide to applicants a further copy of a draft assessment report if, following MSAC's consideration, the report changes significantly.
23. Provide to applicants a copy of the evaluators' rejoinder to the applicant's comments on draft assessment reports.
24. Routinely invite unsuccessful applicants to attend a 'debriefing' meeting when the Minister's decision is conveyed.

25. Invite stakeholders to make submissions and comment on final draft reports in respect of assessments arising from referrals from the Department and, in respect of applications if the applicant clearly indicates that they wish it to occur.
26. Invite peak bodies MIAA/AMA to inform organisations of referrals under way.

Communication with stakeholders in general

27. Hold meetings with stakeholders (eg, AMA, MIAA) each triennium to explain the process and to receive feedback.
28. Update the MSAC website more frequently and also include the following additional information:
 - criteria outlining what constitutes acceptable levels of evidence;
 - regular reports of the status of applications and review timelines and revision of timelines as necessary (include applications awaiting assessment);
 - roles and responsibilities of MSAC, HealthPACT, Horizon Scanning Unit, Advisory Panels, evaluators, applicants and other groups (eg, ASERNIP-S, the NHMRC).
 - an on-line newsletter.
 - links to related sites.
29. Provide succinct and timely information regarding MSAC, its work and the process for applications to the medical colleges in a format easily reproducible for their member publications.

Assessment guidelines/procedures

30. Develop a standard format for assessment protocols.
31. Develop and publicise guidelines and criteria for referring to MSAC technologies already in use.
32. 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.
33. Develop 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.
34. Investigate a process of peer review for assessments.

35. Investigate how the UK National Institute of Clinical Excellence ensures that outcomes considered are relevant to patients and how it incorporates broader consumer issues into its assessments (in consultation with the Consumers' Health Forum of Australia).

Performance measurement

36. MSAC Executive to formally monitor the progress of each application, and report any delays to the Committee.
37. Establish timeframes for Committee and advisory panel processes and use as key performance indicators.

8. Conclusion

The Medical Services Advisory Committee's (MSAC's) review of its methods and processes has been valuable for a number of reasons. It has: generated a solid body of ideas and actions that will help to refine the way the Committee operates; revealed a general readiness by the medical professions and the medical industry to contribute constructively to advancing evidence-based health technology assessment in Australia; and demonstrated the Committee's own willingness to listen to the views of its stakeholders and to learn from its experience over these past six years.

The themes that have emerged from the submissions and from Committee members' own views have, with one or two exceptions, been remarkably consistent. In this context, it might be significant that a disproportionate number of submissions to the review were from organisations and individuals whose applications to MSAC had led to a negative recommendation. Disappointingly, some submissions revealed that there continue to be misconceptions about what MSAC is required to do, and how it goes about its work. MSAC will learn from this though, as is reflected in the actions which are designed to improve the ways it conveys information about what it does and why it does it.

The Committee has agreed to make a wide range of changes or adjustments to its processes in response to the review, a number of which are already underway.

- There will be changes to the ways Advisory Panels operate, with clear and consistent direction to members about their roles and their latitude to consult with their colleagues about the technologies under review. The Committee will work with the medical colleges to find ways to speed up the process of forming panels.
- MSAC is reviewing and revising its guidelines for undertaking the economic components of its assessments.
- MSAC, with the support of the Department of Health and Ageing, will work to provide more timely and targeted information about its methods and processes, and the outcomes of its assessments, to all the stakeholders it engages with.
- MSAC is already providing more opportunities for applicants and other stakeholders to engage at important points in the assessment process

With the support of the Department of Health and Ageing, MSAC will implement those actions that are consistent with responding to the Committee's terms of reference, and will inform the Minister for Health and Ageing of those proposals that the Committee is not empowered to respond to.

While this review has been a worthwhile and rewarding exercise, the challenge now is to make the changes that the Committee has agreed to, without interrupting the momentum of the Committee's work. The task of implementing these actions will fall very largely

on the Committee's secretariat within the Medicare Benefits Branch of the Department of Health and Ageing. The Committee has agreed to draw up a plan to implement these actions. It will regularly review progress against that plan, and provide an update twelve months from the release of this report.

9. Appendices

- A. Terms of reference of past advisory bodies
- B. Chronology: health technology assessment in Australia
- C. Submissions received
- D. References
- E. Abbreviations

A. Terms of reference of past advisory bodies

National Health Technology Advisory Panel (NHTAP)

- To establish and maintain a process for identifying emerging medical technologies.
- To examine significant existing medical technologies to determine whether their present application should be reassessed.
- To determine methods of and priorities for assessment, based on criteria such as safety, efficacy, appropriateness of use, cost and social impact.
- To recommend to the Minister for Health specific areas for research that would facilitate the assessment of medical technologies.
- To recommend whether payment of medical benefits for medical technologies should be restricted until assessment is carried out and review results of technology assessment to decide whether the implications of findings require action at federal or state level.
- To disseminate implications of findings for medical practice to all relevant parties.

AMHAC Superspecialty Services SubCommittee

Develop guidelines for superspecialty services, defines as highly specialized services for relatively rare diseases or which are unusually complex and costly. Guidelines should include the potential for integration, coordination, and rationalization of superspecialty services. Guidelines are submitted through AHMAC to the Australian Health Ministers' Conference for approval.

Australian Health Technology Advisory Committee (AHTAC)

- Identify, gather data on, and assess new and emerging health technologies and highly specialized services, including their safety, efficacy, effectiveness, cost, equity, accessibility, and social impact in the context of the Australian health care system.
- Assess and develop guidelines for established health technologies and highly specialized services in light of their history of use.
- Determine methods of and priorities for assessment of health technologies.
- Advise the Australia Health Ministers' Advisory Council (AHMAC) on requests relating to the assessment of technologies in the context of AHMAC's nationally funded centres policy.

B. Chronology: Health Technology Assessment in Australia

1978	Proposal for an expert national advisory panel on health technologies: report of the Committee on Applications and Costs of Modern Technology in Medical Practice (the Sax Report)
1981	Superspecialty Services SubCommittee of AHMAC established
1982	National Health Technology Advisory Panel (NHTAP) established
1983	NHTAP's first report produced, on MRI
1984	Permanent Secretariat to NHTAP established within the Department of Health
1987-88	NHTAP secretariat staff and chair transferred to the Australian Institute of Health
1989	Report of the Committee to Review the Role and Function of the National Health Technology Advisory Panel
1990	Australian Health Technology Advisory Committee (AHTAC) established (subsuming AHTAP and the Superspecialty Services SubCommittee)
1998	Medicare Services Advisory Committee established (replacing AHTAC)
1999	Fourth term of reference added (August), and name changed to Medical Services Advisory Committee
2004-05	Productivity Commission conducts an enquiry into the impact of advances in medical technology on health care expenditure in Australia

C. Submissions received

Professional groups

Australian Association of Pathology Practices Inc
Australian Diagnostic Imaging Association
Australian Medical Association
Australian and New Zealand College of Anaesthetists
Australian and New Zealand Hyperbaric Medicine Group
Australian Society of Anaesthetists
Gastroenterological Society of Australia
Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Royal Australasian College of Surgeons
Royal College of Pathologists of Australasia
Australian and New Zealand Association of Physicians in Nuclear Medicine
Royal Australian and New Zealand College of Radiologists

Industry

BUPA Australia
Carl Zeiss Pty Ltd
Cytoc
Diagnostic Technology Pty Ltd
Dorevitch Pathology
Given Imaging Pty Ltd
Guidant Australia Pty Ltd
Johnson & Johnson Medical Pty Ltd
Medical Industry Association of Australia
Novartis

State health authorities

Department of Health, South Australia
Queensland Health

Evaluators

htanalysts
M-TAG Pty Ltd
NHMRC Clinical Trials Centre

Individuals

Dr PJ Graziotti

Ms Rebecca James

Prof Paul O'Brien

Responses without submissions

ASERNIP-S

Prof Robert Stable

Prof David Weedon

D. References

Australian Health Technology Advisory Committee (AHTAC) 1997, *Review of Magnetic Resonance Imaging, a Report of the Australian Health Technology Advisory Committee*, Canberra, October.

Commonwealth of Australia 1997, *Budget Measures 1997-98, Budget Paper No.2*, Canberra.

Hailey, David 1994, 'Health care technology in Australia,' *Health Policy* 30, pp.23-72.

NHTAP Review Committee 1989, *Report of the Committee to Review the Role and Function of the National Health Technology Advisory Panel*, February.

Productivity Commission 2005, *Impacts of Medical Technology in Australia*, Progress Report, Melbourne, April.

Sax, Sydney 1990, *Health Care Choices and the Public Purse*, Allen & Unwin, North Sydney.

E. Abbreviations

AAPP	Australian Association of Pathology Practices
ADIA	Australian Diagnostic Imaging Association
AHMAC	Australian Health Ministers' Advisory Council
AHTAC	Australian Health Technology Advisory Committee
AMA	Australian Medical Association
ANZAPNM	Australian and New Zealand Association of Physicians in Nuclear Medicine
ANZHMG	Australian and New Zealand Hyperbaric Medicine Group
ASA	Australian Society of Anaesthetists
GESA	Gastroenterological Society of Australia
MBS	Medicare Benefits Schedule
MIAA	Medical Industry Association of Australia
MSAC	Medical Services Advisory Committee
NHTAP	National Health Technology Advisory Panel
NHMRC	National Health and Medical Research Council
NHMRC CTC	National Health and Medical Research Council Clinical Trials Centre
PBAC	Pharmaceutical Benefits Advisory Committee
RACS	Royal Australasian College of Surgeons
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RANZCR	Royal Australian and New Zealand College of Radiologists
RCPA	Royal College of Pathologists of Australasia