

An evaluation of methods used in health technology assessments produced for the Medical Services Advisory Committee

Emily S Petherick, Elmer V Villanueva, Jo Dumville, Emma J Bryan and Shyamali Dharmage

Medical technologies are believed to be a major driver of increased health expenditure and are therefore an object of cost containment, which requires a systematic approach to evaluating and introducing new medical technologies and procedures.

Australia implemented one of the world's first health technology assessment (HTA) programs in 1982.¹⁻³ The government body now responsible for the management of Australia's HTA program is the Medical Services Advisory Committee (MSAC). The MSAC comprises 22 members from specialist health care, health administration, consumer and academic health (epidemiologists, health economists, etc) who work together to fulfil the MSAC's terms of reference.⁴

- Advise the federal Minister for Health and Ageing on the strength of evidence pertaining to new or emerging medical technologies and procedures in relation to their safety, effectiveness (clinical), and cost-effectiveness, and under what circumstances public funding should be supported;
- Advise the Minister on which new medical technologies and procedures should be funded on an interim basis, to allow further data to be assembled to determine their safety, effectiveness and cost-effectiveness;
- Advise the Minister on references relating to new or existing medical technologies and procedures; and
- Undertake HTA work referred by the Australian Health Ministers' Advisory Council.

Further details including current membership and administrative arrangements are available on the MSAC website (<http://www.msac.gov.au>).

Although there is an expanding body of literature examining evaluation methods or the results of their application,^{3,5} little is known of the methods used to provide the evidence that informs policy when introducing new medical technologies to the Medicare Benefits Schedule (MBS) or of the quality of methods used to undertake HTAs for the MSAC. Here, we examine the methods used to produce the section of MSAC HTA reports that reviews effectiveness of the technology or procedure.

ABSTRACT

Objective: To examine the methods used in health technology assessments (HTAs) produced for the Medical Services Advisory Committee (MSAC) reviewing the effectiveness of a technology or procedure.

Design and setting: Data were extracted from the effectiveness section of HTA application assessment reports published between 1 January 1998 and 17 July 2006 and available on the MSAC website. Only HTAs of effectiveness interventions were examined, as the methods used to undertake such reviews are well established.

Main outcome measures: Variables reflecting methods used in the HTAs to evaluate the effectiveness of health technologies or procedures.

Results: Of 56 MSAC HTA reports available, 31 met the inclusion criteria. Considerable variability was shown to exist between the various indicators of quality and the methodology used within the HTAs. Reports did not describe potential conflicts of interest of participants. The majority of reports (19/31) did not formally state the research question that the assessment was attempting to answer. Just over half of the reports (18/31) provided details of validity assessment of the included studies.

Conclusions: Minimum and consistent standards of methodology and reporting are required in Australian HTAs, using international recommendations of best practice to increase the transparency and applicability of these reports.

MJA 2007; 187: 289-292

For editorial comment, see page 262. See also pages 283 and 286

METHODS

The MSAC process

New medical technologies and procedures are brought to the attention of the MSAC in two ways: (i) a sponsor (eg, a manufacturer, a craft group such as a medical college, or a consumer group) can submit an application to the MSAC for consideration (an "application"); or (ii) the Department of Health and Ageing can refer a particular technology to the MSAC (a "reference"). All technologies considered by the MSAC for listing on the MBS must have prior approval for marketing by the Therapeutic Goods Administration, if such approval is required for the technology in question. Evaluation of pharmaceuticals is administered by a separate body, the Pharmaceutical Benefits Advisory Committee.

An HTA commissioned by the MSAC takes the form of a systematic review. The review itself is undertaken by an independent group contracted by the MSAC under the guidance of an advisory panel formed by the MSAC, whose membership may comprise any combination of clinical experts (nominated by relevant clinical colleges), consumers of the technology, epidemiologists and health economists. On comple-

tion of the review, the MSAC can make one of three recommendations to the Minister for Health and Ageing: to fund the technology or procedure without restriction; to provide interim funding and have further evaluation take place at some future point; or to not fund the technology or procedure. This process provides a formal means by which new and emerging technologies and procedures may gain entry to the MBS. Once a technology or procedure has been listed on the MBS, a proportion of its cost will be met by government reimbursement.³

Under the current MSAC arrangements, there are no formal minimum requirements for evidence of safety, effectiveness or cost-effectiveness for a technology or procedure to be funded. Although the MSAC attempts to evaluate new technologies and procedures using an evidence-based approach, in many cases there is insufficient high-level evidence available to provide an unequivocal picture of the evidence in the form required by policymakers.

The Australian National Health and Medical Research Council (NHMRC) has provided much of the methodology for evaluating new technologies, with formalised levels of evidence that reflect susceptibility to bias within particular study designs

RESEARCH

1 Data extracted from 31 health technology assessment (HTA) reports produced for the Medical Services Advisory Committee, 1999–2005,* based on criteria developed by Busse et al⁷

Data extracted from HTA report	1999 (n = 6)	2000 (n = 5)	2001 (n = 6)	2002 (n = 6)	2003 (n = 6)	2005 (n = 2)
Basic information related to the HTA (ie, reporting of authorship, conflicts of interest)						
Did the HTA report the authorship? Yes/No	Yes 1 No 5	Yes 5	Yes 6	Yes 6	Yes 6	Yes 2
Did the HTA report provide details of conflict of interest? Yes/No	No 6	No 5	No 6	No 6	No 6	No 2
General methodological aspects of the HTA (ie, clarity of research question, sources of information used, selection criteria for information)						
Did the HTA report the research question in a clear manner (eg, using the PICO format or similar)? Yes/No/Unclear	No 6	No 4 Unclear 1	Yes 3 No 2 Unclear 1	Yes 1 No 5	Yes 4 No 2	Yes 2
Were selection criteria for study inclusion reported? Yes/No/Unclear	Yes 4 No 1 Unclear 1	Yes 4 Unclear 1	Yes 6	Yes 6	Yes 5 Unclear 1	Yes 2
Did the authors provide details of resources searched? Yes/No	Yes 6	Yes 5	Yes 6	Yes 6	Yes 6	Yes 2
Was the search strategy reported? Yes/No/Unclear	Yes 6	Yes 5	Yes 6	Yes 6	Yes 6	Yes 2
Was more than one reviewer involved in the review process? Yes/No/Not reported	Not reported 6	Yes 1 Not reported 4	Yes 4 Not reported 2	Yes 1 Not reported 5	Yes 3 No 3	Yes 2
Efficacy/effectiveness (ie, sources of data, selection criteria, assessment of validity/quality of data)						
Did the authors provide details of how they assessed the included studies for validity/quality beyond providing details of the study type? Yes/No/Unclear. If yes, what methods were used?	Yes 1 No 4 Unclear 1	Yes 2 Unclear 3	Yes 4 Unclear 2	Yes 3 Unclear 3	Yes 6	Yes 2
Was more than one reviewer involved in the extraction of data? Yes/No/Not reported	Not reported 6	Yes 1 Not reported 4	Yes 2 Not reported 4	Yes 1 Not reported 5	Yes 2 No 2 Not reported 2	Yes 2

PICO = patients/interventions/comparisons/outcomes. *None of the evaluated HTAs were published in 1998, 2004 or 2006. ◆

and by which the validity of primary studies can be assessed.⁶

Study sample

The MSAC website was searched on 17 July 2006; all HTA application assessment reports published since 1 January 1998 and accessible in full text on the website on that date were considered for inclusion in this study.

Inclusion and exclusion criteria

To be eligible for inclusion in this evaluation, HTAs had to:

- be accessible in full text on the MSAC website;
- have a published recommendation regarding the decision to either fund or not fund the technology or procedure through the MBS;
- review the effectiveness of a treatment; and
- be based on an application.

HTAs were excluded if:

- the full text of the HTA was not available on the MSAC website;
- the HTA contained commercial-in-confidence information that prevented publication in full on the MSAC website;
- the HTA did not review the effectiveness of a treatment; or
- the HTA was based on a reference from the Department of Health and Ageing rather than an application.

Non-treatment-based applications were excluded because of the current lack of consensus on methods to appraise systematic reviews with a non-treatment-based focus. This included HTAs with a main focus on aetiology, prognosis, diagnosis, screening, or management. Reports produced as the result of a reference were excluded as they were predominantly focused on diagnostic tests and, because they are commissioned in a different man-

ner, there is no applicant as there is with application reports. As these comprise a distinct group of reports, we did not include them in this evaluation.

Data extraction

Data were extracted from the HTA reports by two investigators using a standardised data extraction form. The extracted covariates were predominantly based on the criteria developed by Busse et al to assess the quality of HTA reports,⁷ however, we restricted our data extraction to the section of each HTA report dealing with effectiveness of the technology or procedure. Details of the data extracted are shown in Box 1. For most of the covariates, we simply assessed whether the variable had been reported in the HTA (*yes, no or unclear*). Disagreements between the reviewers were resolved by consensus, with a third reviewer available (although not required) for adjudication.

Statistical analysis

Descriptive analyses were performed on the HTAs to determine the frequency with which each categorical variable was reported. Data entry was performed in Excel (Microsoft, Redmond, Wash, USA) and statistics were calculated using SPSS version 14.0 (SPSS Inc, Chicago, Ill, USA).

RESULTS

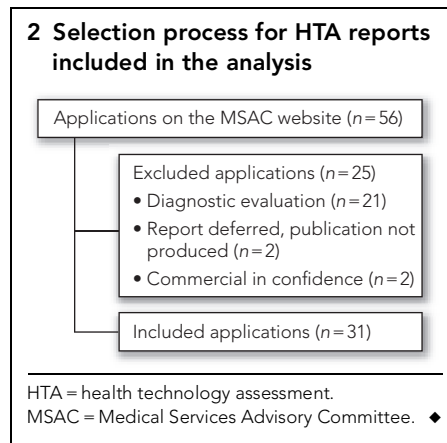
Of the 56 available HTA reports of applications to the MSAC, 31 met the inclusion criteria. Box 2 summarises the selection process for HTAs and the reasons for exclusion. Of the 31 included HTAs, six were published in 1999, five in 2000, six in 2001, six in 2002, six in 2003 and two in 2005. Results of the data extraction are shown in Box 1. Sixteen of the 31 technologies or procedures assessed in these HTAs were recommended for funding, either on a permanent or interim basis.

Authorship and conflict of interest

Declarations of conflict of interest of any party involved in the assessment process — either MSAC committee members or report authors — were not recorded in any of the HTA reports. The MSAC requires that potential conflicts of interest be declared, however no information was presented detailing policies for dealing with conflicts of interest if they existed. All HTA reports published since 2000 (25/31) included specific details of the authors. All reports contained contact details for the MSAC, enabling contact if further details were required.

Descriptions of methods used

The majority of HTAs (19/31) did not formally report the research question that the assessment was attempting to answer. This did, however, seem to improve over time, with no HTAs reporting the research question in 1999, but over half (4/6) doing so by 2003. Most HTAs (27/31) did publish, as a minimum, the inclusion criteria of study types that were to be included in the report. All HTAs included some detail of search terms used to search databases for relevant literature. The number of reviewers who extracted data was not reported in 21 HTAs. In eight HTAs, it was explicitly stated that more than one reviewer was involved in extracting data and assessing the inclusion of studies, and in the remaining two reports only one reviewer extracted data. Twelve HTAs provided a diagram of the study inclusion process, showing the number of studies



located and the number of studies that were subsequently included and excluded.

Searching for evidence

MEDLINE was searched for relevant literature for all published HTAs. Other common sources searched were the Cochrane Library (24/31), EMBASE (21/31), PreMEDLINE (15/31), and Current Contents (16/31). Additional databases were searched for most reports (30/31), with the number of additional databases ranging from one to nine. Other websites and specialist sources of information were searched in 23 HTAs. Common sources searched included the website databases of the International Society for Technology Assessment in Health Care and the International Network of Agencies for Health Technology Assessment. Other sources, including specialist websites, trial registries, other health technology assessment agency websites and grey literature, were searched in 13 HTAs.

Results of the search for evidence

The type of evidence included in the effectiveness section of the HTA reports was classified according to a modified version of the NHMRC designation of levels of evidence⁶ in most reports. Level I evidence (a systematic review) was included in eight HTAs. Level II evidence (randomised controlled trials) was included in 12 HTAs, with the number of randomised controlled trials included in each of these ranging from one to 16. Level III-1 evidence (pseudo-randomised controlled trials) was only included in three HTAs, and level III-2 evidence (comparative studies with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group) was also rare, being included in only four HTAs. Level IV evidence (case series, either post-test or pre-test/post-test) was included in

half of all HTAs (16/31). Interestingly, the level of evidence of some included studies was not reported in five HTAs.

Further methods used

Eighteen HTAs provided a validity assessment of included studies with explicit details of the methods used. The methods used were unclear in nine HTAs, and in the remainder of reports it was assumed no validity assessment had been undertaken. The most commonly reported method to assess the validity of included studies, used in five HTAs, was the *Cochrane handbook for systematic reviews of interventions*;⁸ other methods used in at least two reports were the Centre for Reviews and Dissemination handbook,⁹ Quality of Reporting of Meta-analyses (QUOROM) checklist¹⁰ and assessment methods proposed by Schulz et al¹¹ and Greenhalgh.¹² In total, at least seven different validity appraisal methods were used in these reports. In other cases it was difficult to determine whether formal validity assessments had been undertaken, as, although there were elements of validity assessment in the reports, the exact methods used were not reported. Both the descriptive elements and the results of included studies were presented in both tables and text in 30 HTAs. Due to a reported lack of appropriate studies, meta-analysis was performed in only three reports.

DISCUSSION

Our examination of 31 HTA reports produced for the MSAC between 1998 and 2006 found considerable variability in quality. Reports did not describe authors' potential conflicts of interest. Most reports did not formally state the research question, and just over half provided details of any validity assessments of included studies.

Conflict of interest is of concern because of the perception that it could lead to unreasonable bias in an HTA report.¹³ No information was provided within the published HTA reports, nor is there any documentation available publicly, which details how conflicts of interest are handled beyond the recording of such information by the MSAC.^{9,14} Other international HTA agencies have provided greater detail of how conflicts of interest are both identified and recorded.^{15,16}

The reported methods applied and information presented in the HTAs differed substantially, with a little over half of the HTAs describing the methods used to assess the validity of included studies; these reports

used at least seven different methods to do so. The reporting of methods used was poor, frequently omitting information required to clarify internal and external validity of the reports, as well as to facilitate replication. We did not contact authors of HTAs, so it remains unknown whether these omissions were due to inadequate reporting rather than methodological limitations.

In undertaking our study we used the criteria of Busse et al, which were published in 2002.⁷ Most of the HTAs we evaluated were conducted before these criteria were published, and indeed there is some evidence that reporting is improving, with an increase in the number of reports including details of the methods used over the time period examined. Optimal search strategies for primary studies to be included in the effectiveness and cost-effectiveness sections of HTAs have been suggested and may prove useful in future reports as a minimum standard to which report authors could adhere.¹⁷ Problems with reporting of systematic reviews and HTAs have been noted previously. A study by Olsen et al found that 29% of new Cochrane systematic reviews published in 1998 had major problems,¹⁸ and the authors specifically highlighted three areas of concern: that the evidence did not support the conclusions; that the conduct or reporting of reviews was unsatisfactory; and that reviews had stylistic concerns. A study conducted in Canada, which evaluated the conduct of reports from four HTA agencies in that country, found similar results to our study in that almost half of all reports failed to specify the methods used.¹⁹

The MSAC has produced its own guidance for evaluators undertaking HTAs,¹⁴ and this has recently been updated to include information on undertaking reviews of diagnostic and screening technologies.²⁰ Other organisations such as the Cochrane Collaboration and the QUOROM group have produced guidance on the undertaking and reporting of systematic reviews and meta-analyses.^{8,10}

While the MSAC does recommend interim funding in some instances, with a set time limit to allow further data collection, there is no mandatory requirement to publish these data. It therefore remains unclear what purpose this further data collection serves or if it facilitates the production of quality research evidence required for further appraisals of the technology or procedure.

CONCLUSIONS

Given the policy implications of HTAs produced by the MSAC, it is only right that they are produced to the highest quality standards. Statistical and methodological advances continue to take place in the field of systematic reviewing. There is an ongoing need to update the methods of conduct and reporting of HTAs in order to ensure that decisionmakers have access to the most scientifically rigorous information possible. The advantage of moving towards a system in which minimum reporting standards have been entrenched will be a reduction in variability of reports, raising their overall standards of quality and providing greater transparency of the decisions made.

ACKNOWLEDGEMENTS

We thank Ms Alexandra Rauli, Dr Alison Orrell and Professor Nicky Cullum for their positive encouragement and feedback on the manuscript.

COMPETING INTERESTS

Emily Petherick, Elmer Villanueva and Emma Bryan were authors on several of the MSAC HTAs evaluated in this study. No funding was received to carry out this study.

AUTHOR DETAILS

Emily S Petherick, BSc(PhysEd), MPH, Research Fellow¹

Elmer V Villanueva, MD, ScM, Associate Professor²

Jo Dumville, MSc, PhD, Research Fellow¹

Emma J Bryan, BSc, PhD, Formerly, Research Officer³

Shyamali Dharmage, MD, PhD, Senior Research Fellow and Senior Lecturer⁴

1 Department of Health Sciences, University of York, York, UK.

2 Department of Rural and Indigenous Health, Monash University, Moe, VIC.

3 Monash Institute of Health Services Research, Monash University, Melbourne, VIC.

4 School of Population Health, University of Melbourne, Melbourne, VIC.

Correspondence: ep9@york.ac.uk

REFERENCES

- 1 Goodman C. An introduction to health technology assessment. Falls Church, Va: The Lewin Group, 1998.
- 2 Hailey D. Health care technology in Australia. *Health Policy* 1994; 30: 23-72.
- 3 Hailey DM. Health technology assessment in Australia: a need to re-focus. *J Qual Clin Pract* 1996; 16: 123-129.
- 4 Medical Services Advisory Committee. What is MSAC? <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/what-is-1> (accessed Mar 2007).

5 May C, Mort M, Williams T, et al. Health technology assessment in its local contexts: studies of telehealthcare. *Soc Sci Med* 2003; 57: 697-710.

6 National Health and Medical Research Council. How to use the evidence: assessment and application of scientific evidence. Canberra: NHMRC, 2000.

7 Busse R, Velasco M, Perleth M, et al. Best practice in undertaking and reporting health technology assessments. Working group 4 report. *Int J Technol Assess Health Care* 2002; 18: 361-422.

8 Higgins J, Green S, editors. Cochrane handbook for systematic reviews of interventions. Version 4.2.6. The Cochrane Library, Issue 4, 2006. Chichester, UK: John Wiley & Sons, Ltd.

9 Centre for Reviews and Dissemination. Undertaking systematic review of research on effectiveness: CRD's guidance for those carrying out or commissioning reviews. York: CRD, 2001. <http://www.york.ac.uk/inst/crd/report4.htm> (accessed Jul 2007).

10 Moher D, Cook DJ, Eastwood S, et al. Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement. Quality of Reporting of Meta-analyses. *Lancet* 1999; 354: 1896-1900.

11 Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA* 1995; 273: 408-412.

12 Greenhalgh T. Assessing the methodological quality of published papers. *BMJ* 1997; 315: 305-308.

13 Hailey D. Towards transparency in health technology assessment: a checklist for HTA reports. *Int J Technol Assess Health Care* 2003; 19: 1-7.

14 Medical Services Advisory Committee. Funding for new medical technologies and procedures: application and assessment guidelines. Canberra: MSAC, 2000.

15 Medical Advisory Secretariat, Ontario. Technologies for osteoarthritis of the knee. Integrated health technology policy assessment. October 2005. <https://ospace.scholarsportal.info/bitstream/1873/1875/1/259170.pdf> (accessed Jul 2007).

16 NHS Research & Development. The HTA programme. The principles underlying the work of the National Coordinating Centre for Health Technology assessment. March 2007. <http://www.nccta.org/sundry/probity.pdf> (accessed Jul 2007).

17 Centre for Reviews and Dissemination. Finding studies for systematic reviews: a checklist for researchers. York: CRD, 2006. <http://www.york.ac.uk/inst/crd/revsrch.doc> (accessed Jul 2007).

18 Olsen O, Middleton P, Ezzo J, et al. Quality of Cochrane reviews: assessment of sample from 1998. *BMJ* 2001; 323: 829-832.

19 Menon D, Topfer LA. Health technology assessment in Canada. A decade in review. *Int J Technol Assess Health Care* 2000; 16: 896-902.

20 Medical Services Advisory Committee. Guidelines for the assessment of diagnostic technologies. Canberra: MSAC, 2005.

(Received 2 Jan 2007, accepted 1 Aug 2007)

□