



# Evidence-based funding of new imaging applications and technologies by Medicare in Australia: How it happens and how it can be improved

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Conflict of interest: Adelaide Health Technology Assessment (AHTA) staff conduct independent evaluations of technologies submitted to the Medical Services Advisory Committee (MSAC) and also developed the 2021 guidance for public funding applications to MSAC. MSAC and the Australian Government Department of Health had no involvement in the conception, writing or analyses conducted for this manuscript. Analyses were based solely on data in the public domain.

[Correction added on 10 May 2022, after first online publication: CAUL funding statement has been added.]

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## Introduction

In Australia, public funding of new health technologies follows an evidence-based process known as health technology assessment (HTA). HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.<sup>1</sup>

The Medical Services Advisory Committee (MSAC) is responsible for appraising new non-drug health technologies, such as medical imaging, that are proposed for

## Abstract

**Background:** The Medical Services Advisory Committee (MSAC) is responsible for the assessment of medical imaging tests proposed for public funding. A number of factors related to the clinical or cost effectiveness of an imaging service may impact on the funding decision.

**Objective:** To determine what evidentiary and economic factors impact most on MSAC recommendations for the funding of imaging tests.

**Methods:** Information was extracted on health technology assessments (HTAs) of medical imaging tests published on the MSAC website, with a funding decision between 2006 to July 2021. Imaging tests with diagnostic, staging or screening indications were eligible. Data were extracted in test-indication pairs and included data on evidence quality, quantity, consistency of findings, cost-effectiveness and financial impact. Multivariate logistic regression analysis was performed with adjustments for clustered data.

**Results:** Overall, 42 imaging test applications to MSAC were included, representing 91 clinical indications. Most were diagnostic tests. The most common evidentiary concerns reported by MSAC were limited evidence (36%), low quality evidence (26%), and applicability of the data (22%). The reference standard for diagnostic accuracy was imperfect or not appropriate in 25% of the indications. In regression analyses, uncertainty about cost-effectiveness of an imaging service predicted most negative funding decisions.

**Conclusions:** The single biggest contributor to a negative funding decision by MSAC was uncertainty about the cost-effectiveness of the imaging service. This was likely driven by uncertainty regarding the impact on patient health. HTAs that are able to demonstrate the clinical utility of a new imaging service are more likely to publicly funded.

**Key words:** Advisory Committees; Australia; cost-benefit analysis; radiology; technology assessment, biomedical.

public funding. This independent, non-statutory group provides advice to the Minister for Health on whether medical services involving these health technologies should be subsidised by the tax-payer and listed on the Medicare Benefits Schedule. MSAC consists of a diverse group of medical professionals, consumer representatives and health economists.

There are four main steps in the MSAC HTA process<sup>2</sup>:

- 1 The Australian Government Department of Health (DoH) receives an application for consideration to determine if it should be progressed further.

Applications can be made by the medical profession, medical industry and others with an interest in seeking Australian government funding for a new medical service or change to an existing service. Each application may contain more than one clinical indication for the imaging test.

- 2 A PICO Confirmation document to guide the subsequent formal assessment is developed by an HTA agency – usually University-based - contracted by DoH. The PICO Confirmation outlines the likely use of the imaging service in the form of a clinical management algorithm and definition of the appropriate target population(s) (P), intervention (I), comparator(s) (C) and patient relevant health outcomes (O) from using the imaging service. This PICO Confirmation is based on information in the application form, along with input from stakeholders and the applicant. This PICO Confirmation is made available for public consultation and sent to the applicants and key stakeholders for input and then is reviewed, potentially modified and confirmed by the PICO Advisory Sub-Committee (PASC).
- 3 An HTA report is developed to determine the safety, clinical effectiveness, cost effectiveness, and financial impact of the imaging service under consideration. This can be prepared either by a DoH contracted HTA agency or by the Applicant (or a consultancy group on behalf of the Applicant). If the HTA report is developed by the Applicant, a HTA agency is contracted by the DoH to provide a commentary on the HTA. The Evaluation Sub-Committee (ESC), consisting of clinicians and health economists, assesses and comments on the technical content of the HTA report and provides advice to MSAC.
- 4 MSAC considers the HTA report and ESC advice. Following this review, MSAC advises the Minister for Health whether the imaging service should receive funding or not. The MSAC commentary after review of the HTA report and justification for its funding recommendation is published in a Public Summary Document (PSD). MSAC can (i) recommend funding, including the circumstances of that funding, (ii) defer their decision to a later date, or (iii) reject funding with or without a recommendation for further research.

If funding is rejected or deferred, MSAC provides advice on the most appropriate resubmission process. When there are uncertainties around benefits, costs, and utilisation of the service, they may also recommend a compulsory review period following funding approval (interim funding). This includes advice on the expected timeframe for the review, the data requirements, and the organisation responsible for submitting the data.

The minimum time possible to complete the MSAC HTA process from application submission to first decision by MSAC is around 16 months and is determined, to

some extent, by the scheduling of the PASC, ESC and MSAC meetings as these committees meet three times per year.

MSAC bases its decision on the best available evidence provided by the HTA report, clinical experts and stakeholders such as patient groups. The methods used in HTA in Australia (and most other high income countries) involves a systematic review of the best quality evidence concerning the technology, relative to the comparator it is most likely to replace or supplement, to determine whether the technology is comparatively safe and effective. An economic model is developed to determine whether the technology is good value for money when used in the Australian health system. A financial impact analysis is also conducted so that the total cost to government is clearly understood.

MSAC's preference is for there to be direct evidence of the technology's impact on patient health outcomes (eg. survival, physical functioning, quality of life), where available, compared to the technology currently being used for those patients/clinical indications. This is the same, whether they are evaluating an intervention, or an investigative test. When no or limited direct evidence is identified by the systematic review, a HTA for an investigative test may use a linked evidence approach (LEA). This approach estimates the impact of the test on patient health outcomes by linking evidence across the test to treatment pathway. This evidence typically includes test accuracy (analytical or clinical validity), change in management and health outcomes (clinical utility) resulting from the change in management. The population, intervention, comparator and health outcomes described in the evidence base should be aligned as much as possible with the PICO confirmation and proposed MBS item descriptor for the medical service. This means that MSAC has greater surety that the findings from the evidence base will likely be observed in the Australian target population should the service be Medicare funded.

As for other investigative tests, demonstrating the value of imaging tests in HTA is problematic because the impact on patient health outcomes is indirect. There are issues around evidence quantity, quality and relevance and these factors increase uncertainty about how much clinical benefit is obtained by the patient that is attributable to the use of the new imaging technique, over and above what would be obtained with the standard imaging or diagnostic technique. This flows through to the subsequent economic assessment with the potential to influence the outcome of application for funding on the MBS.

The aim of our research was to determine what evidentiary and economic factors in HTAs of imaging technologies impact the most on MSAC recommendations for the funding of imaging services involving these technologies. In addition we were interested in seeing what factors predicted a subsequent positive funding decision following the initial rejection of an application.

## Methods

### Data source

We reviewed all publicly available HTA reports, and PSDs for medical imaging tests published on the MSAC website from 2006 to July 2021. These time points were selected to avoid periods where the methodological guidance for MSAC applicants changed. Major changes to the MSAC Guidelines for applicants were introduced in 2005 and again in mid-2021.<sup>2,3</sup> Imaging test indications were included in the analysis if the funding decision by MSAC occurred between 2006 and 2021, the PSD was publicly available on the MSAC website at the time that the search was carried out (July 2021), and concerned the assessment of an imaging test used for diagnosis, staging or screening, as defined previously.<sup>4</sup> Resubmitted applications were excluded from the primary analysis as the decision-making by MSAC described in the PSD would be confounded by the initial appraisal that was undertaken.

### Data extraction

The unit of analysis was test evaluation per clinical indication, as tests were often proposed for multiple purposes and several suggested uses may have been included within the same HTA report. Test characteristics, population and decision year were recorded for each assessment. Data for pre-specified variables potentially impacting on the MSAC decision for listing on the MBS were extracted for each imaging test indication from the available HTA report or PSD. These potential predictors included: test purpose (add-on test, replacement test, or triage test) as defined by Bossuyt *et al.*<sup>5</sup>; test accuracy; comparator; reference standard; methodological approach as defined in Merlin *et al.*<sup>4</sup>; quality of the evidence base available for assessment in the report (including binary assessments of evidence quality, quantity of data, directness of evidence (direct/indirect); applicability of evidence; consistency of findings); value for money (cost-effectiveness); and net annual financial impact. A positive funding decision was the dependent variable.

### Data analysis

Data were extracted by all three authors, cross-checked and collated using Microsoft Excel 16. Summary statistics were calculated and compared. Logistic regression models, adjusted for clustered data (as an HTA report may include multiple clinical indications), were tested using Stata Version 15 and fitted to determine whether the quality of evidence, cost-effectiveness of the proposed test or the other prespecified independent variables predicted positive MSAC funding decisions. Model fit and selection were determined using regression diagnostics,

the Wald statistical test and Akaike and Bayesian information criterion (AIC and BIC) measures.

## Results

### Characteristics

There were 494 HTA applications listed on the MSAC website as of July 2021. Of these, 42 imaging test applications received a funding decision from MSAC between 2006 and July 2021 and were eligible for inclusion in our data set. There were no publicly available imaging test HTA reports or PSDs for the years 2019 to July 2021 on the MSAC website. The most frequent imaging test application assessed by MSAC for MBS listing was magnetic resonance imaging with 12 clinical indications considered in total. Other imaging applications assessed over this period were for computed tomography,  $n = 4$ ; optical coherence tomography ( $n = 4$ ), positron emission tomography ( $n = 8$ ), capsule endoscopy ( $n = 2$ ), dual-energy x-ray absorptiometry ( $n = 2$ ), endoscopic ultrasound ( $n = 3$ ), and other types of imaging technologies ( $n = 7$ ). Overall, these applications included 91 clinical indications relevant to our evaluation.

The main purpose of the imaging tests per indication is given in Figure 1. The median number of clinical indications per MSAC application was 2 (range 1–11). In most cases, the use of these imaging tests for the clinical indication were either in addition to ( $n = 36$ ), or as a replacement ( $n = 29$ ) for, current imaging or diagnostic procedures. Nine imaging test indications were for triage purposes. The "Other" category ( $n = 13$ ) included imaging tests with multiple purposes. Four applications with single clinical indications were for codependent imaging tests.

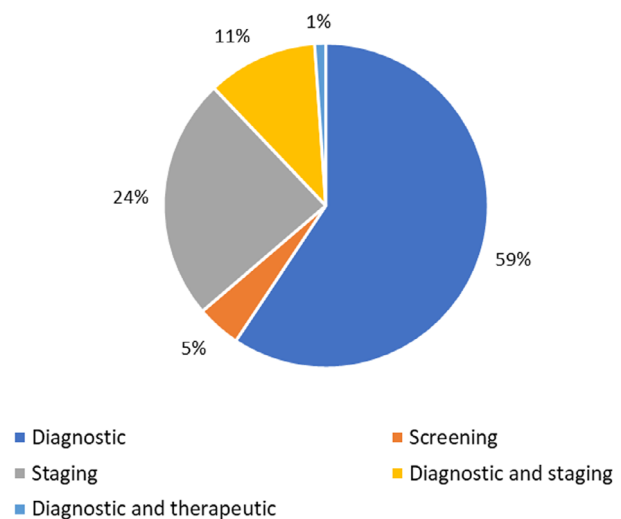


Fig. 1. Imaging test purpose.

### Methodological approach used for clinical evidence

Only a small proportion of assessment reports for imaging test indications relied on direct evidence alone. Around three quarters of all assessment reports utilised a full LEA in addition to providing direct evidence, if it was available (Fig. 2).

### Evidence provided in assessment reports or PSDs

Generally, MSAC's concerns for each imaging test were reported in the PSDs and advice was provided regarding the type of additional evidence required in a resubmitted application. The most frequently reported evidentiary concerns were: limited evidence, low quality evidence, and applicability of the data (Fig. 3). Other problems encountered included whether the HTA report had captured all relevant data, and uncertainties around whether the proposed algorithm represented current clinical practice and relevant clinical guidelines.

The reference standard used to determine test accuracy in the HTA reports was acceptable for almost half (48%) of the included imaging test indications but was considered imperfect or not appropriate by MSAC for almost a quarter (25%). There were no comments by MSAC regarding the appropriateness of the reference standard in the PSDs for the remaining indications.

### MBS funding recommendations

Of the 91 imaging test indications assessed by MSAC, 51 (56%) indications received a positive funding recommendation for MBS listing. This outcome is an aggregate of the following categories: recommended for new funding ( $n = 40$ ), interim funding recommendation ( $n = 1$ ), and no change to the existing funding arrangements ( $n = 10$ ). The remaining 40 (44%) clinical indications were not recommended for MBS funding. Funding decisions over time are shown in Figure 4 and by test type in Figure 5.

### Factors associated with recommendations for MBS funding

Table 1 provides the results of the logistic regression analyses to determine the biggest predictors of MSAC funding decisions. The results indicate that Model 1 was the most comprehensive predictor of new funding decisions by MSAC (pseudo  $R^2 = 44.56\%$ ). In this model new funding decisions for imaging tests were associated with clinical evidence that was of good quality and with consistent findings that were applicable to the target population, and where there was information on the cost-effectiveness and financial impact of the imaging test. However, when comparing with other models it was apparent that the clinical evidence and financial impact information did not provide much explanatory power, only an additional 2–4%, over the impact of the cost-effectiveness data. Uncertainty about the cost-

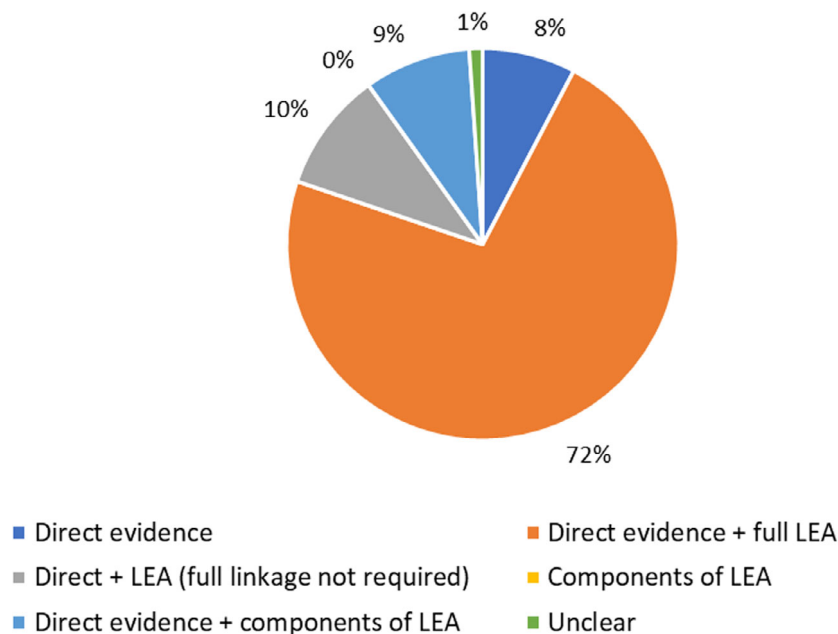


Fig. 2. Methodological approach used in the HTA report for each indication. LEA, linked evidence approach.

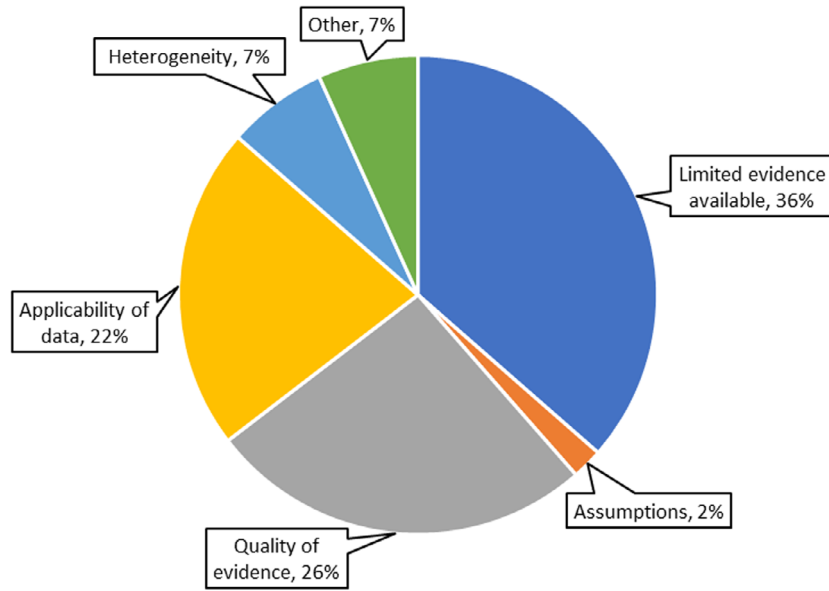


Fig. 3. Problems reported by MSAC during assessment of the clinical evidence.

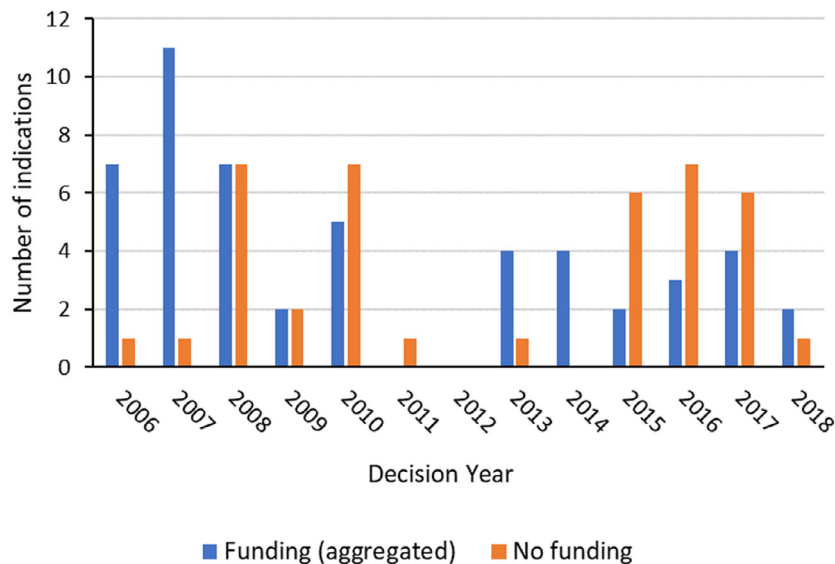
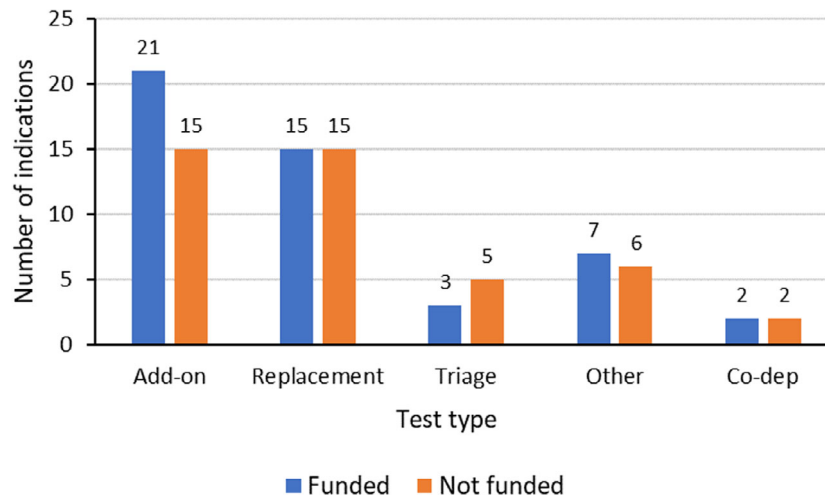


Fig. 4. MSAC funding outcomes for imaging tests over time. There were no publicly available imaging test HTA reports or PSDs fitting our inclusion criteria for the years 2012, 2019 to July 2021.

effectiveness or certainty about *lack* of cost-effectiveness (Model 4) was the single factor that predicted the majority of negative funding decisions (pseudo  $R^2 = 40.65\%$ ).

Four applications were resubmitted between 2006 and 2018. Of these, three (MSAC Applications 1195, 1357, and 1372) were approved upon resubmission to MSAC. The time from initial rejection to final approval at an MSAC meeting was 67, 48, and 32 months, respectively, although it is unclear when the resubmission was

submitted. The fourth application was unsuccessful despite being resubmitted twice. Qualitative assessment of the resubmitted applications confirmed that approval on resubmission was more likely when applicants considered advice provided by MSAC in the PSDs and were able to address their concerns. MSAC concerns included the diagnostic accuracy of the technology, quality and quantity of the evidence, evidence for change in management leading to improvement in health outcomes, and item descriptors. Low evidence quality impacted on the



**Fig. 5.** Funding outcomes by imaging test type. Co-dep, codependent technology.

economic assessment of cost-effectiveness. Successful resubmissions included additional evidence published after MSAC's decision on the initial submission, suggesting that additional appropriate evidence was a pivotal driver of a successful application. The MSAC application that was not approved on resubmission was unable to address these concerns despite an interval of 78 months between the initial and final decision by MSAC. Evidence quality and the strength of evidence on diagnostic accuracy and clinical utility was still a major concern for MSAC in the second resubmission.

## Discussion

Our review of imaging tests assessed by MSAC for the period 2006 to July 2021 highlighted, unsurprisingly, that a narrative linkage of evidence across the test-treatment pathway, in addition to the inclusion of any direct evidence available, was the most common methodological approach used in the HTA reports. Despite this, the PSDs reported that MSAC had concerns about the evidence base supporting the assessment of imaging technologies in many HTA reports, focussing mainly on quantity and quality of the clinical evidence. However, despite stating these concerns, the factors that had the greatest impact on funding decisions was whether the imaging service was not cost-effective (dominated) or whether there were uncertainties about the cost-effectiveness of the imaging service. Uncertainty in a health economic model is usually caused by parameter uncertainty, methodological uncertainty or structural uncertainty.

Parameter uncertainty can be addressed by conducting sensitivity analyses about different model inputs (for example, varying the likely costs) and determining those inputs that the model is most sensitive to. Methodological uncertainty is less likely to be an issue as most

HTA health economists follow best practice guidance on the types of models to use to address a decision problem. Structural uncertainty is, however, more difficult to address. This type of uncertainty falls into four general themes: (i) inclusion of relevant comparators; (ii) inclusion of relevant events; (iii) alternative statistical estimation methods; and (iv) clinical uncertainty.<sup>6</sup> The first three of these themes can be addressed by ensuring the model appropriately characterises the way the imaging service will be used in clinical practice and captures all of the important health events for people with the clinical indication being targeted by the service. The biggest problem is the clinical uncertainty and that is because clinical utility – or the impact of the service on a patient's health outcomes – is not often measured in studies of imaging technologies. This means that unless an Applicant has conducted their own studies on the clinical utility of the imaging service, they must rely on the available scientific literature, knowing that the available evidence base is sorely lacking.

A review by Winkelmann *et al.* (2019) analysed the current use of HTAs in radiology in Germany and discussed challenges associated with HTA.<sup>7</sup> Imaging devices have a relatively short lifecycle due to constant modification and innovation making the collection of long-term data and demonstration of incremental benefit difficult. As randomised controlled trials are not required for regulatory approval in the European Union (EU), manufacturers focus on carrying out studies that demonstrate technical advantages and features of their imaging device over existing technology, rather than focusing on its clinical utility. While technical parameters determine the quality of images obtained during diagnostic imaging, the technical and clinical expertise of the clinician interpreting these images impacts on clinical utility. Differences in treatment during follow-up, even within a single disease, affects the estimated value of the diagnostic



**Table 1.** Logistic regression analysis models

Variable	Model 1		Model 2		Model 3		Model 4	
	$\beta$ [SE]	Robust OR [95% CI]	$\beta$ [SE]	Robust OR [95% CI]	$\beta$ [SE]	Robust OR [95% CI]	$\beta$ [SE]	Robust OR [95% CI]
Constant	3.489 [1.107]	32.751 [3.742, 286.639]	2.447 [0.622]	11.556 [3.413, 39.126]	0.247 [0.337]	1.280 [0.661, 2.479]	2.485 [0.637]	12.000 [3.441, 41.854]
Evidence quality								
Poor quality	-0.281 [0.888]	0.755 [0.135, 4.237]						
Limited data	0.217 [0.837]	1.242 [0.241, 6.407]						
Applicability	-0.234 [0.862]	0.791 [0.149, 4.288]						
Heterogeneity	-0.805 [0.923]	0.447 [0.073, 2.729]						
Cost-effectiveness results*	<b>-0.810 [0.182]</b>	<b>0.445 [0.312, 0.635]</b>						
Uncertain/unknown or imaging test dominated			<b>-3.822 [0.858]</b>	<b>0.022 [0.004, 0.121]</b>				<b>-3.801 [0.828]</b>
Uncertain					<b>-3.137 [1.029]</b>	<b>0.043 [0.006, 0.326]</b>		
Net annual financial impact* >\$5million or unknown	0.191 [0.185]	1.211 [0.843, 1.740]						
Cost savings					<b>2.392 [1.005]</b>	<b>10.938 [1.525, 78.461]</b>		
No. of observations	91		91		91		91	
Log pseudolikelihood	-34.9396		-37.3642		-46.6701		-37.4078	
Wald $\chi^2$ , df, P value	<b><math>\chi^2 = 23.13</math>, df = 6, P = 0.0008</b>		<b><math>\chi^2 = 21.36</math>, df = 2, P &lt; 0.0001</b>		<b><math>\chi^2 = 18.15</math>, df = 2, P = 0.0001</b>		<b><math>\chi^2 = 21.08</math>, df = 1, P &lt; 0.0001</b>	
Pseudo $R^2$	44.56%		40.72%		25.95%		40.65%	
AIC	0.922		0.887		1.092		0.866	
AIC*n	83.879		80.728		99.340		78.816	
BIC	-309.033		-322.227		-303.615		-326.651	
BIC'	-29.109		-42.304		-23.692		-46.727	

\*Cost-effectiveness and financial impact data were categorised into 7 and 6 categories, respectively. For cost-effectiveness results categories were coded as: 0 cost saving/dominant; 1 < \$25,000/QALY; 2 \$25-\$50,000/QALY; 3 >\$50,000/QALY; 4 less costly, less effective; 5 Dominated; 6 Uncertain; 7 Not available/other. Data for net annual financial impact results were categorised as: 0 <\$500 K; 1 \$500 K-\$1 M; 2 \$1 M-\$2 M; 3 \$2 M-\$5 M; 4 >\$5 M; 5 Net Savings; and 6 NA/unknown.

AIC, Akaike Information Criterion; BIC, Bayesian Information Criterion; CI, confidence interval; dominated, not cost-effective; DF, degrees of freedom; heterogeneity, inconsistent findings; OR, odds ratio; SE, standard error;  $\beta$ , regression coefficient. Shaded cells indicate that these specific variables were not included in the regression model. Bold values indicate the variable is a significant univariate predictor of MSAC funding decisions.

method used. It is also difficult to obtain patient-relevant outcome data for diagnostic radiology to calculate utility values for use in an economic evaluation.

Historically, both regulators and reimbursement bodies have focused on processes for the assessment of drugs rather than medical devices. The infrastructure and methodology of regulatory approval and HTA of medical devices have recently come under increasing scrutiny. The quality and extent of the supportive evidence base for medical devices, amongst other challenges, were acknowledged following evaluation of HTA in both EU and non-EU jurisdictions.<sup>8–11</sup> Clinical evidence is not only required for establishing efficacy and safety but a comparison of clinical outcomes with the nominated comparator, usually standard of care, is a basic requirement for economic analyses, such as a cost-effectiveness analysis. However, the evidence base for device assessment relies upon low-level evidence such as observational studies. There are difficulties conducting randomised controlled trials because of ongoing incremental device modification and innovation, difficulties with obtaining adequate blinding, and the role of the “learning curve” in assessment of effectiveness. A systematic review of European Health Economic guidelines for HTA of medical devices found that there was limited consensus and specific guidance for clinical and economic evaluation.<sup>8</sup> Guidance was focused on the challenges rather than offering solutions. The low level of evidence available to demonstrate the effectiveness of a medical device was the most widely recognised challenge reported in 77% of the included guidance.

It is recognised that the regulatory processes for medical devices generate less clinical data than the corresponding process for drugs.<sup>11–13</sup> A lack of clinical evidence in response to the lower evidentiary requirements of medical device regulatory approval leads to difficulties when carrying out HTA, which can lead to delays in reimbursement and patient access.<sup>11,12</sup> The regulatory processes used for medical devices in some jurisdictions has contributed to poor evidence development, such as 510(k) clearance in the US based on claims of equivalence or reliance on a single controlled study for approval of higher-risk devices using the Pre-Market Approval (PMA) Letter. The FDA 510(k) clearance system for similarity in the USA or the substantial equivalence system used by the TGA in Australia may allow a device to be approved with limited data based on similarity to a predicate or a similar marketed device. While regulatory processes require a manufacturer to carry out structured post-market surveillance, such surveillance processes are often limited to passive reporting of adverse events. The increased requirement in EU medical device regulations (EU 2017/745–746) for evidence from clinical studies may aid HTA of medical devices across other jurisdictions, particularly now that there is a move towards some sharing of regulatory assessment across regulators in different countries,<sup>14</sup> although other evidentiary limitations affecting devices remain a challenge.

So, if there is limited evidence available on the clinical utility of an imaging test, can evidence of test accuracy, alone, suffice? Unfortunately test accuracy is only one dimension of the value or usefulness of an imaging test. Accuracy is an indirect predictor of the effect of the test on people’s health status.<sup>15</sup> Test accuracy and test performance, including sensitivity and specificity, may vary in different situations.<sup>16</sup> For imaging it can be affected by intra- and inter-rater/reader reliability, by the experience of the radiologist, and by the risk status of the patient (or pre-test probability of the clinical indication being observed). There is also no guarantee that the information provided by the new imaging test will change the clinical management of the patient any more than that already offered by the test being used as the benchmark or comparator. As a consequence, any impact on patient health outcomes might not be realised. A clinical trial, from test-to-treatment, that measures the health outcomes in patients (direct evidence) would capture all of these uncertainties. Without this evidence, the applicant needs to make explicit and address each of these uncertainties in the narrative linkage of evidence.

Other considerations that can affect the conduct of an HTA of an imaging service are: multiple clinical applications of medical imaging, rapid technological innovation in the field leading to outdated clinical comparisons, and impact of the operator “learning curve” effect on performance in the form of errors and adverse events.<sup>17,18</sup> These evidentiary issues reduce confidence in the evidence base, impacting on value demonstration, and ultimately feeding through to the analysis of cost-effectiveness.

Closer integration and harmonisation of regulatory and HTA processes across different jurisdictions combined with horizon scanning and early dialogue with industry about the evidentiary requirements for specific patient populations, comparators, and outcomes may improve the quality of the evidence available for submissions, facilitate access to new technologies and reduce the period required for assessment.<sup>19</sup> Other approaches discussed in the international literature include harmonisation and minimum standards for HTA, improved guidance, increased stakeholder participation and consultation, methods for evaluation of observational data that adequately allows assessment of bias affecting clinical outcomes, methods that can account for the impact of the “learning curve” on effectiveness data and coverage with evidence development agreements.<sup>11,12,19–22</sup> Several of these approaches have been incorporated in the recent revision to the MSAC Guidelines,<sup>2</sup> but cannot completely address the lack of good quality primary research.

### Key considerations for MSAC applications

So, what can an applicant do to make a more solid case for MSAC consideration? Some key considerations are as follows:



- 1 Use direct clinical evidence, and where that is not possible or the evidence is inadequate, use the LEA.
- 2 Use an HTA clinical expert that is familiar with the LEA, as well as an experienced modeller, whether by commissioning these experts or – if the applicant is a not-for-profit – by requesting DoH to contract them.
- 3 Follow the new MSAC Guidelines<sup>2</sup> as these provide comprehensive and explicit instruction on how to apply the LEA and how to present the evidence in a logical and coherent manner, including through the use of logic models. Guidance is also provided on how the economic model should be constructed.
  - a It should be noted that these new MSAC Guidelines include provision for a claim based on the “value of knowing”. Although evidence of clinical utility is preferred, when it cannot be established, MSAC may consider evidence supplied by the applicant on the non-health benefits and harms. The value of knowing “encompasses any consequence for the wellbeing of a patient beyond the changes in the health outcomes attributed to changes in the health care provided. These additional outcomes may or may not be able to be demonstrated with quantitative data”.<sup>2</sup>
- 4 Follow the PICO Confirmation as closely as possible and make sure the evidence for *each* linkage is also consistent with the designated population(s), intervention, comparator and outcomes.
- 5 Use an appropriate reference standard to establish imaging test accuracy. MSAC had concerns about the proposed reference standard for test accuracy for almost a quarter of the image test indications assessed. For some imaging tests there may be no appropriate reference standard, or the proposed imaging test may be considered the reference standard if already established in clinical practice. In the absence of a reference standard, evidence of concordance between the tests is required.
- 6 Consider the proposed use of the imaging service and whether it is likely to ‘leak’ to other clinical indications. The evidence requirements for assessment can vary according to whether a test is in addition to, or a replacement for, an existing test. An additional test leads to increased costs that require justification through better health outcomes or additional clinical benefits. A replacement test that is equivalent (non-inferior) in terms of accuracy may not require evidence of change in patient management or better health outcomes as it is assumed that these remain the same.
- 7 Consider the impacts of false positive and false negative test results, as well as indeterminate test results, and their impact on the selection of therapies for patients. Also consider their effect on subsequent tests, as well as the clinical consequences and

adverse effects associated with inappropriate or delayed treatment. These consequences should all be captured in the economic model.

### Limitations of this study

The content, format and availability of the HTA reports and accompanying PSDs on MSAC’s website varied across the period assessed. There was an assumption during data extraction that the absence of a negative comment in the PSD indicated that it was not a major concern in committee decision-making, which may not be correct. Although the PSD is based on the executive summary of the HTA report, not all pertinent information in the assessment report may be summarised in the PSD. In addition, other concerns and factors may affect the MBS listing of an imaging test beyond the HTA report.

In conclusion, an expert statement on value in radiology, representing the views of Radiology Societies in Europe, the USA, Canada, Australia, and New Zealand, was published in 2021.<sup>23</sup> The societies made recommendations on how to prevent radiology being viewed only as a costly adjunct to quality health care rather than a driver of it.<sup>24</sup> This included use of evidence-based treatment guidelines for imaging procedures and publishing “research reporting on radiology’s impact on therapeutic decisions, patient outcomes, and societal benefits”.<sup>23</sup> This type of research is exactly what is needed to increase MSAC’s certainty in decision-making. The single biggest contributor to a negative funding decision by MSAC in our study was uncertainty about the cost-effectiveness of the imaging service. An increased emphasis on demonstrating the value of radiology, through a formal assessment of its clinical utility, would ensure that there is better quality evidence to support HTA and increase the likelihood that new imaging services would be publicly funded in Australia.

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### Data availability statement

These data were derived from the imaging service MSAC applications and Public Summary Documents available in the public domain: <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/application-page>

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