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Review of Economic Submissions to NICE Medical Technologies Evaluation Programme

Authors:

Abualbishr Alshreef¹, Michelle Jenks², William Green², Simon Dixon¹

Authors affiliations:

1 Health Economics and Decision Science, School of Health and Related Research, University of Sheffield, Sheffield, Regent court, 30 Regent Street, Sheffield S1 4DA, UK

2 York Health Economics Consortium, University of York, Enterprise House, Innovation Way, York YO10 5NQ, UK

Correspondence to:

Abualbishr Alshreef, Health Economics and Decision Science, School of Health and Related Research, University of Sheffield, Regent Court, 30 Regent Street, Sheffield S1 4DA, United Kingdom
E-mail: a.o.alshreef@sheffield.ac.uk; Tel: +44 (0)114 222 0673 Fax: +44 (0) 114 272 4095

Abstract

The economic evaluation of medical devices is increasingly used to inform decision making on adopting new or novel technologies; however, challenges are inevitable due to the unique characteristics of devices. Cost-consequence analyses are recommended and employed by the English National Institute for Health and Care Excellence (NICE) Medical Technologies Evaluation Programme (MTEP) to help address these challenges. The aim of this work was to review the critiques raised for previous MTEP submissions and explore if there were common problems across submissions. We reviewed a sample of 12 economic submissions to MTEP representing 50 % of 24 sets of guidance issued to July 2015. For each submission, we reviewed the External Assessment Centre's (EAC) report and the guidance document produced by NICE. We identified the main problems raised by the EAC's assessments and the committee's considerations for each submission, and explored strategies for improvement. We found that the identification and measurement of costs and consequences are the main shortcomings within economic submissions to MTEP. Together, these shortcomings accounted for 42 % of criticisms by the EACs among the reviewed submissions. In certain circumstances problems with these shortcomings may be unavoidable, for example, if there is a limited evidence base for the device being appraised. Nevertheless, strategies can often be adopted to improve submissions, including the use of more appropriate time horizons, whilst cost and resource use information should be taken, where possible, from nationally representative sources.

Key points for decision makers

- The identification of costs and consequences, together with their measurement are the main shortcomings within economic submissions to MTEP.
- The main strategies to reduce these include using national references for unit costs and ensuring that the time horizon for the analysis is long enough to capture all relevant costs and health effects.
- Shortcomings with evidence identification and interpretation of the decision problem are also prevalent. Sponsors should be encouraged to use well-structured search strategies and follow the scope specified by NICE. Presentation and interpretation of results were identified less often to be a problem within MTEP submissions.

1. Introduction

The economic evaluation of medical devices is increasingly used to inform decision making on adopting new or novel technologies; however, challenges are inevitable due to the unique characteristics of devices [1-3]. The economic impact of medical technologies constitutes a substantial proportion of health spending, with an estimated 7.5 % of the total European health expenditure and 4.5 % in the UK [1]. In 2009, the English National Institute for Health and Care Excellence (NICE) introduced the Medical Technologies Evaluation Programme (MTEP) to evaluate devices whilst recognising the unique challenges this presents [1, 4].

The methods adopted by NICE for health technology assessments (HTAs) differ depending on the type of technology being appraised. In particular, the decision-making context differs when comparing medical devices to pharmaceuticals and this reflects the complexities of evaluating technologies with distinct properties. For instance, the NICE technology appraisal programme adopts cost-utility analysis as a primary method of economic evaluation of pharmaceuticals, which produces values in terms of incremental cost per quality-adjusted life years (QALYs) gained. However, cost-consequence analysis has been recommended and adopted as an appropriate method for evaluating medical devices within MTEP [5, 4]. During cost-consequence analysis the costs and benefits of a technology are compared to suitable alternatives, with benefits kept as a natural unit and not defined as a single measure, such as QALYs for cost-utility analysis [6].

1.1 Why are Medical Devices Different?

Medical devices are different from pharmaceuticals in many aspects [1, 3]. A key difference is that product life span for medical devices are generally shorter. This has implications on research and development spending, which, in turn, has a negative effect on evidence production [1]. Evidence production can also be limited with medical devices because designing an appropriate trial to evaluate the efficacy of the technology can be challenging. These challenges occur because medical devices often have multiple applications and the outcomes with a particular device may largely be driven by the skill of the operator. Furthermore, blinding of investigators and patients can often be difficult, or altogether impossible, which increases the risk of bias [7]. The impact of these characteristics is exacerbated by the fact that devices manufacturers are overwhelmingly small or medium-sized enterprises (SMEs), with limited research and development budgets [1]. Issues relating to unpublished studies and reporting bias for medical devices were highlighted by a guideline recently published by the European network for HTA (EUnetHTA) [8]. Therefore, evaluating medical devices in a different way to pharmaceuticals is required in order to take these characteristics into account.

1.2 Economic Submissions to NICE Medical Technologies Evaluation Programme

The MTEP process involves three key activities: (i) identification and selection of technologies that would benefit from national evaluations; (ii) routing of technologies by the medical technologies advisory committee (MTAC) for evaluation within the programme at NICE deemed most relevant; (iii) appraisal of technologies [9]. Prior to this appraisal process MTEP must be made aware of a technology's suitability for assessment and primarily the manufacturer of the medical device (sponsor) will notify NICE. Medical devices that are likely to be cost saving or cost neutral will generally be routed to MTEP, whilst technologies with more complex value propositions, such as those that generate additional health benefits (e.g. QALYs) but at a greater cost, may be

routed to alternative NICE programmes. These include the Technology Appraisal Programme and the Diagnostic Appraisal Programme [5]. Those devices that are routed through MTEP are evaluated based on the sponsor's clinical and economic evidence submission. The economic submission by the sponsor of a new medical device is a key element required by MTEP to assess the value of the technology to the National Health Service (NHS). The submitted evidence is critically assessed by an External Assessment Centre (EAC), an independent group commissioned by NICE, and their assessment report is considered by the committee, together with other information, to make recommendations. As part of their work the EAC may also undertake additional economic modelling, which should further inform the recommendations made by the committee. Recommendations on individual medical devices within MTEP are generally made on the basis of its potential for producing cost savings to the NHS and other patient benefits. MTEP can provide a number of different recommendations on individual devices, including: full recommendation, recommendation for specific circumstances, recommended in research and not recommended [5]. For all technologies that are evaluated via MTEP, the process will be summarised via medical technical guidance (MTG) and its publication is the final step in the evaluation.

1.3 Why We Might Expect Problems Within Economic Evaluations of Medical Devices?

Although the MTEP methods and process guides were developed to take into account the unique challenges that exist when undertaking an economic assessment of medical devices, we might still expect problems with economic analyses in practice. A less onerous regulatory framework, together with the limitations of being relatively small companies, has discouraged investment in economic expertise within SMEs [1]. At the time this review was started (July 2015) MTEP had published 24 sets of guidance on individual medical technologies since its introduction. This provides a good source of evidence for assessing the application of economic analyses within MTEP.

1.4 Objectives of this Review

The aim of this review was to summarise the critiques of sponsor's submissions to MTEP. The specific objectives were to identify any problems with the application of methods, explore which particular problems were more common as raised by the EAC's and the committee's discussions, and identify strategies for improvement in submission quality. Therefore, this review focuses on the appraisal of technologies by MTEP and does not consider the process for the identification, selection and routing of technologies. We reviewed the EAC's critique and committee considerations of economic submissions to NICE MTEP.

2. Methods

We reviewed a sample of 12 economic submissions to MTEP representing 50 % of the 24 sets of full guidance issued up to the time the sample was selected for this review. We used proportionate stratified random sampling to ensure that each category of medical devices and committee recommendations were represented in the sampling process. First, we split the sampling frame of the 24 sets of technologies into different strata to ensure a mix of devices, diagnostics and systems, together with mix of committee recommendations. Then we used random sampling techniques and selected a proportionate sample of 12 technologies included in this review. Only 12 submissions were selected for assessment due to time and budgetary constraints; however, given the

sampling technique we followed, we deem that these are reasonably representative of all economic submission to MTEP.

For each submission, two key documents were reviewed; the EAC's assessment report and the guidance document produced by NICE. Each document was reviewed by a single reviewer (AA, WG or MJ) and checked by a second reviewer (SD, WG or MJ). To avoid bias, those sets of guidance for which the authors or their institutions had been involved in developing were reviewed by an independent person. We followed the six stages specified by Drummond et al within their checklist for assessing economic evaluations in health care [10]. These are: decision problem interpretation and evidence identification; cost and consequence identification; measurement and valuation; choice of model and analysis; and presentation and interpretation of results.

First, the assessment report produced by the EAC was reviewed according to 13 criteria, of which 12 items were taken from a list of 24 checklist items included within the CHEERS checklist [11], and 1 item (searching for economic studies) is driven by the six stages of economic evaluation [10] and the MTEP methods guide [5]. Searching for published evidence is a substantial component of submissions to MTEP; and therefore, it is reasonable to be included as part of our assessment criteria. Only those checklist items relevant to MTEP economic submissions were included. These comprised: searching for economic studies, target population and subgroups, setting and locations, perspective, comparator, choice of health outcomes, estimating resources and costs, choice of model, time horizon, measurement of effectiveness, parameters, characterising uncertainty and presentation and interpretation of results (used instead of reporting incremental costs and outcomes). Although the 'searching for published evidence' item overlaps with 'estimating resources and costs' in the CHEERS list, we decided to keep this item separate as it is an integral part of economic submissions to MTEP. The checklist items excluded (with reason in brackets) are: title, abstract, background and objectives, valuation of preference-based outcomes, discussion, source funding, conflict of interest (more relevant to publications); discount rate, currency/price date, assumptions, analytic methods, characterising heterogeneity (related to model assessment). Since we didn't review the published evidence used, submissions or the models directly, we decided to exclude these 12 items from our assessment criteria. All EAC critiques were extracted and briefly described under the thirteen headings considered.

Second, the main issues considered and discussed by the committee were summarised under the same thirteen headings listed previously. Third, the key problems raised by the EAC's assessments and committee's considerations were matched and presented into a tabular format to compare across reviewed submissions. Fourth, the key problems identified were then grouped into six categories representing the different stages of economic evaluation in health care [10]. The 13 criteria specified above were each placed under one of the six categories. Finally, strategies for improvement for each set of problems were then identified based upon the MTEP methods guide and critiques provided by both the EACs and committee [5].

3. Results

A sample of 12 submissions was included in this review including 8 (67 %) technologies that had received positive recommendations for use in either the whole patient population as specified by the scope or in a subgroup of patients. The mix of sampled technologies included seven medical devices (58 %), two diagnostics (17 %) and three systems (technologies with system in the name, expected to comprise multiple components) (25 %). The list of medical technologies included in this review is presented in Table 1.

The main problems picked up by the EAC's assessment and committee's considerations for each medical technology are presented in the following subsections. A detailed description of the highlighted problems is provided as supplementary information.

3.1 Parafricta Bootees and Undergarments to Reduce Skin Breakdown in People with or at Risk of Pressure Ulcers

Three main critiques were raised by the EAC's economic assessment for Parafricta bootees and undergarments. These were: a lack of evidence on the effectiveness of the device in the community setting, a number of assumptions and estimates used to inform the economic model were incorrect or implausible, and the model structure was not appropriate [12]. The committee discussed three key cost-related issues: choice of the model, model parameters and uncertainty of results [13]. It concluded that further research is necessary to assess the length of stay in hospital, severity of pressure ulcers and the cost associated with pressure ulcers. The committee's final decision on this device recommended further research to address uncertainties relating to the claimed patient and system benefits.

3.2 The Geko Device for Reducing the Risk of Venous Thromboembolism

The EAC's assessment report included a minor criticism of the unit costs utilised within the economic model and a more serious criticism around the clinical assumption underpinning the model [14]. The committee's discussions were focused around the plausibility of the assumption made by the sponsor relating to the clinical effectiveness of the device [15]. They recommended the geko device for people who have high risk of venous thromboembolism and for whom other mechanical and pharmacological methods of prophylaxis are impractical or contraindicated.

3.3 The MAGEC System for Spinal Lengthening in Children with Scoliosis

The EAC raised six issues associated with the sponsor's economic submission. The main problems were a poor search strategy for evidence, an inappropriate costing approach and the use of a model structure that had not been validated [16]. The EAC carried out additional work, which included: the adaptation of the sponsor's model (making it fully executable), updating some inputs to the model with more appropriate estimates and conducting sensitivity analyses to address uncertainty. The committee's discussion was focused around the use of the device among a subgroup of children with less than 35 months growth potential, the time horizon of the analysis and the additional cost savings which could be generated from not using spinal cord monitoring with the MAGEC system [17]. This technology was recommended for use in children with scoliosis aged 2 years and

over who require surgery to correct their spinal curvature when conservative methods such as bracing or casting have failed.

3.4 The E-Vita Open Plus for Treating Complex Aneurysms And Dissections of The Thoracic Aorta

The EAC highlighted five issues within the economic section of their assessment pertaining to the literature search, the economic model structure and time horizon as well as the presentation of the results of the analysis [18]. The committee's discussion was focused around the time horizon of the analysis and impact of the potential need for re-intervention on the effectiveness of the device [19]. The committee recommended adopting E-vita open plus to treat complex aneurysms and dissect the thoracic aorta in the patients who would otherwise need a two-stage repair procedure, but would not need an additional intervention in the descending aorta. This population was a subgroup of the original population evaluated as defined by the scope issued by NICE.

3.5 Ambu Ascope2 for Use in Unexpected Difficult Airways

Six issues were described by the EAC within the economic section of their assessment report relating to the literature search and the economic model's structure and inputs [20]. The committee had a number of serious considerations relating to the clinical setting modelled and the evaluation of uncertainty within the model [21]. Based on these considerations the committee requested additional cost modelling from the EAC in order to aid their decision making. The committee's final decision recommended the adoption of Ambu aScope2 as an acceptable alternative for emergency intubation in people with unexpected difficult airways where a multiple-use fibre optic endoscope is unavailable.

3.6 Watchbp Home A for Opportunistically Detecting Atrial Fibrillation During Diagnosis and Monitoring of Hypertension

The EAC's assessment identified a number of issues with the economic evidence submission. These included the estimation of costs from a societal perspective, the use of an inappropriate approach for estimating the target population expected to benefit from the device and use of a population in the economic analyses which differed from that specified in the scope [22]. The EAC undertook additional economic modelling work to resolve some of these issues. The main points discussed by the committee included the unknown cost impact of using this technology on younger populations due to lack of evidence and the uncertainty associated with the cost of stroke [23]. The committee's final decision recommended the use of WatchBP Home A device for people who are having their blood pressure checked in primary care (for example, at a GP surgery or clinic).

3.7 The Veriq System for Assessing Graft Flow During Coronary Artery Bypass Graft Surgery

Within the economic section of the EAC's assessment report, five problems were identified relating to the sponsor's search strategy, their economic model structure and the limited analyses of uncertainty within the model [24]. The committee's discussions were focused around the estimation of resource use and costs as well as the choice of other parameters within the analysis [25]. The committee recommended the adoption of the VeriQ system for assessing graft flow during coronary artery bypass graft (CABG) surgery.

3.8 Inditherm Patient Warming Mattress for The Prevention of Inadvertent Hypothermia

The EAC's assessment report raised six issues relating to the economic submission of this technology. These included limitations in the literature searching strategy, not undertaking subgroup analysis specified by the scope, the estimation of costs, the economic model structure, plausibility of parameters used, and that sensitivity analyses were poorly conducted [26]. The committee's discussion focused on two points: the cost associated with purchasing additional Inditherm components and the credibility of estimated cost savings [27]. The committee's final decision recommended the use of the Inditherm Patient Warming System for patients undergoing operations that carry a risk of inadvertent hypothermia.

3.9 Ambulight PDT for the Treatment of Non-Melanoma Skin Cancer

Three main issues were identified by the EAC in the economic section of their assessment report which related to the estimation of resource use, the literature searches and lack of sensitivity analyses to explore uncertainty within the economic model [28]. The committee discussed issues relating to the health-care setting that was modelled as well as the poor presentation of the model's results [29]. The committee reported that the case for adopting Ambulight PDT was not supported by the evidence. This was due to a limited amount of clinical evidence and high levels of uncertainty relating to the cost implications of the device.

3.10 The MIST Therapy System for the Promotion of Wound Healing

The EAC critiqued the economic evidence submission and raised four main issues. These were the estimation of resources and costs, the choice of health outcomes, measurement of effectiveness and the limited time horizon of the model [30]. Three main issues were considered by the committee: estimating resource use and costs, measurement of effectiveness, and characterising uncertainty [31]. The committee's final decision recommended further research to address the uncertainty associated with the relative clinical effectiveness of the MIST Therapy system.

3.11 BRAHMS Copeptin Assay to Rule Out Myocardial Infarction in Patients with Acute Chest Pain

The EAC identified a large number of issues associated with the economic evidence submission with the key issues being the estimation of resources and costs, the time horizon of the model and the measurement of effectiveness [32]. The main issues discussed by the committee were the sources and estimation of resource use and costs utilised within the economic model [33]. The committee recommended further research within a UK clinical setting to compare the BRAHMS copeptin assay in combination with cardiac troponin testing against sequential cardiac troponin testing for ruling out myocardial infarction.

3.12 Sequent Please Balloon Catheter for In-Stent Coronary Restenosis

The main issues raised by the EAC following critique of the economic evidence submission were that not all patient subgroups were included as specified by the scope, the evidence was taken from a German setting, the economic model structure had not been validated, and there was a lack of probabilistic sensitivity analyses [34]. The committee's discussion was focused around four issues: the comparator treatment within the model, the time horizon of the analysis, model input parameters and uncertainty in results [35]. The committee recommended the use of SeQuent Please balloon catheter for use in patients with in-stent restenosis in bare metal coronary artery stents.

Summarising MTEP Economic Submission Critiques

The types of problems raised by either the EAC or the committee varied between submissions with some common issues, as shown in Table 2. The proportions of submissions with problems in each category based on the EAC assessments are shown in Table 2. The most prevalent shortcomings according to the EAC assessments were cost and consequence identification and measurement, as well as decision problem definition and evidence identification (Fig. 1). Twenty-one percent of the issues identified fell into each of these categories. Other issues, including problems with the presentation and interpretation of results, were far less frequent (6 %). Figure 1 presents the proportions of problems within economic submissions to MTEP as identified by the EAC for all categories based on the different stages of economic evaluation in health care.

4. Discussion

Through an analysis of a sample of previous submissions to MTEP, cost and consequence identification and measurement were found to be the most prevalent shortcomings within economic submissions to MTEP. These consist of estimating resource use and costs, choice of health outcomes and choice of parameter estimates used to inform the economic model. To avoid these problems, cost and resource use information should be taken from national estimates or nationally representative sources where possible. Data from national databases should be supplemented with systematic searches of the published literature, where required. Where less applicable evidence is available or assumptions need to be made, validation by clinical experts should be sought.

Another prevalent shortcoming is the evidence identification and interpretation of the decision problem by the sponsor, which includes searching for economic studies, target population and subgroups, setting and location, perspective and comparator(s). Similar to our findings, the EUnetHTA guide has identified obtaining full information about the existing evidence and publication bias as issues requiring specific attention since data on high-risk medical devices remain unpublished [8]. The guidance suggested broadening literature searches to include the best available evidence since the approval process of medical devices within Europe does not require randomised controlled trial evidence on efficacy and effectiveness. However, SMEs have previously noted that undertaking literature searches and obtaining relevant academic papers is a timely and expensive process that prohibits the completion of submissions [36]. Furthermore, in many cases it is not possible to identify relevant evidence to use in the submission, as medical devices are often associated with limited evidence bases for the reasons discussed in Sect. 1.1. Nevertheless, submissions could still be improved if manufacturers are able to undertake more structured search strategies of the databases recommended by MTEP and by matching the economic model to the decision problem specified by NICE within their scope.

Other shortcomings identified by our review related to the time horizon of the model, choice of the model structure and presentation of results. The time horizon for cost and consequences valuation should be long enough to capture any cost differences between the device in question and its comparator(s). The choice of the model and the analysis conducted led to issues including a lack of exploration of uncertainty and the exclusion of relevant device related adverse events within the analysis. Uncertainty within models can be explored through the use of sensitivity analysis, whilst all relevant adverse events should be included within the model. The incorrect use of perspective was only identified in one submission, that of “Watch BP Home A”, where modelling was undertaken from societal perspective. This should be undertaken from the NHS and personal

social services perspective in line with the MTEP methods guide [5]. Finally, issues around the presentation and interpretation of results can be mitigated by highlighting the most realistic scenario and presenting the results from other, supplementary, scenarios within the submission.

More generally, there was little evidence in the vast majority of the submissions of a clear conceptual basis for the structure of the model in terms of which events and outcomes were captured, how they should be measured and over what time frames. ‘Conceptual modelling’ is an important part of model development and its use can help guard against contextually inadequate models [37]. Whilst there is no direct evidence relating to the extent of any conceptual modelling that supported the economic submissions, our overall conclusions are consistent with the view that such modelling was generally inadequate.

A previous review of MTEP suggested that the programme has some way to go to meet its principal aims [1]. These aims were: simplifying access to evaluation, speeding up the assessment and appraisal process and increasing the evaluative capacity within NICE. Our findings from this review provide an insight into the practical application of MTEP methods over the past five years. Limitations of evidence and knowledge about economic evaluations within device companies are evident. Guidance for early assessment of medical devices is available in the literature [38-40]; however, they do not appear to be cited or applied within the economic submissions to MTEP across the board. This review also highlights deficiencies in the economic models submitted by sponsors. In many cases these deficiencies are inevitable, particularly given the issues with evidence production that have been discussed previously. Furthermore, sponsors may lack the relevant training and resources to develop economic models that meet the requirements of MTEP. One potential solution would be to request that the EAC assists the sponsor with their economic submission, or perhaps completes the submission themselves. Given the EAC already commonly undertakes additional modelling as part of their contribution, this is unlikely to result in extra work and in fact may allow more robust models to be developed in an efficient manner. If the EAC were to complete the initial submission the sponsor could provide input at designated time points to ensure the EAC is fully informed in regards to the device in question. This proposal would have similarities with the process followed by the Diagnostic Assessment Programme at NICE [41]. If the burden on the sponsor were to be reduced, this may also encourage more SMEs to notify NICE of their technology, increasing the pool of innovative technologies that NICE has the opportunity to appraise. If there is a significant increase in notifications, the MTEP routing process may have to be adjusted to ensure the most relevant technologies are prioritised for appraisal.

The two main strengths of this work are, first, that it is the first known critical appraisal of economic submissions to MTEP and, second, by looking at both the EAC and committee documents, those problems that were of particular concern to decision makers were identified. However, there are also several limitations. First, we did not review each of the submissions directly, but relied on the critiques of the EACs and the committee. There are four different EACs that work with NICE for MTEP currently and additional centres have been involved previously. Each EAC may apply distinct methodologies for their critique process. Second, it is based on a small sample size of 12 technologies. Third, no differentiation or weighting was given to the size of each problem identified. And finally, the committee’s final decision does not only rely on the sponsor’s submission and EAC’s report, but may consider other evidence such as consultations from clinical experts and patient groups, as well as the sponsor’s submission, which were not considered here.

Overall, this review generates a good, initial, understanding of the application of methods for economic analyses employed by the MTEP for evaluating medical devices. The results suggest that there are common problems with the economic evidence submitted by medical device companies within one national guidance process. This is despite the fact that the required methods are simpler than those seen for pharmaceutical products. If decision makers want device manufacturers to produce better quality evidence, then methods by which this can be achieved need to be explored. Without this, the guidance process will continue to spend resources on amending flawed analyses or potentially rejecting technologies due to inadequacies in the submissions. These consequences have the effect of limiting the opportunities for manufacturers who are faced with short product lifespans.

5. Conclusions

Although previous reviews about the role of MTEP have highlighted some challenges, to the best of our knowledge, this is the first review of individual submissions to MTEP. Shortcomings within the economic submissions were identified based on the EACs assessment and matched with MTAC's considerations. These shortcomings might have implications for the aims of MTEP, which include speeding-up evaluation and encouraging early uptake of novel medical technologies in the NHS. Cost and consequence identification and measurement are the main limitations of economic submissions to MTEP; using national reference costs and systematic searching of the literature can be followed as strategies to reduce these problems.

Author Contributions

The manuscript was prepared by AA, MJ, WG and SD and the review of the EAC reports and guidance documents was undertaken by AA, MJ and WG with advice from SD. AA, MJ and SD were involved in conceptualisation and design of the work.

Compliance with Ethical Standards

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Potential conflict of interest

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Table 1 List of medical devices included in this review – this includes a categorisation of the type of device and the date on which the final guidance was published

Medical technologies guidance	Category	Final guidance publish date
Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers (MTG20)	Device	November 2014
The Geko device for reducing the risk of venous thromboembolism (MTG19)	Device	June 2014
The MAGEC system for spinal lengthening in children with scoliosis (MTG18)	System	June 2014
The E-vita open plus for treating complex aneurysms and dissections of the thoracic aorta (MTG16)	Device	December 2013
Ambu aScope2 for use in unexpected difficult airways (MTG14)	Device	July 2013
WatchBP Home A for opportunistically detecting atrial fibrillation during diagnosis and monitoring of hypertension (MTG13)	Diagnostic	January 2013
The VeriQ system for assessing graft flow during coronary artery bypass graft surgery (MTG8)	System	November 2011
Inditherm patient warming mattress for the prevention of inadvertent hypothermia (MTG7)	Device	August 2011
Ambulight PDT for the treatment of non-melanoma skin cancer (MTG6)	Device	July 2011
The MIST Therapy system for the promotion of wound healing (MTG5)	System	July 2011
BRAHMS copeptin assay to rule out myocardial infarction in patients with acute chest pain (MTG4)	Diagnostic	June 2011
SeQuent Please balloon catheter for in-stent coronary restenosis (MTG1)	Device	December 2010

MTG=medical technology guidance, PDT=photodynamic therapy.

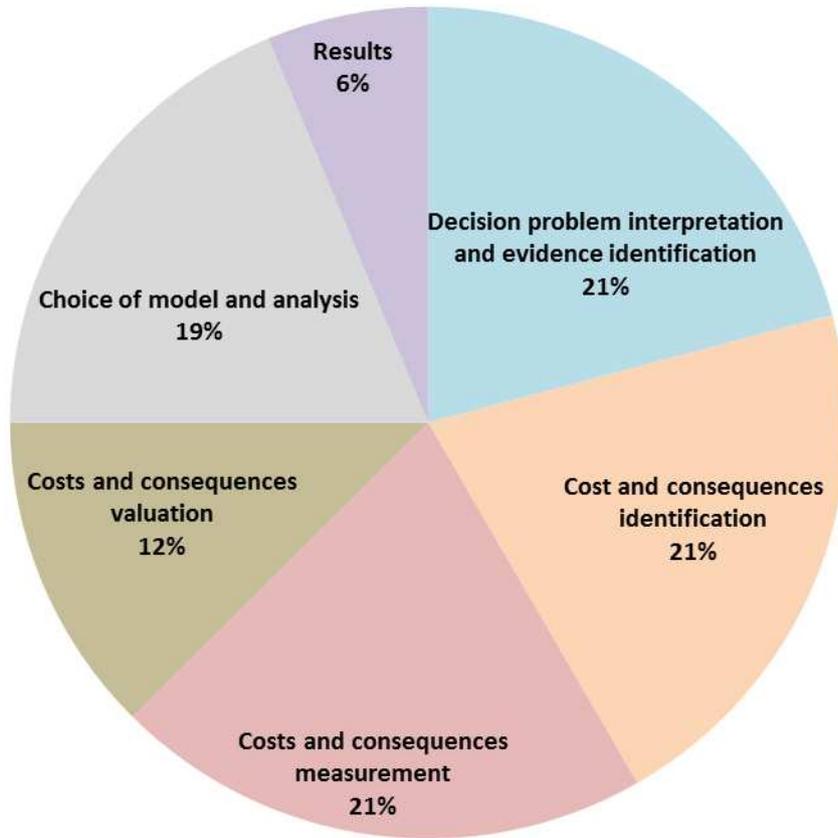
Table 2 Overview of the problems raised by the EACs and Committee's considerations across submissions. Problems were separated into six groups, and further categorised into thirteen issues. For each of the 12 submissions assessed, problems raised within the EAC assessment and those discussed by the committee, are indicated separately.

Category of problem raised			Medical technologies guidance												
Group	% of problems raised by the EACs	Issue	Parafricta	Geko	MAGEC System	E-vita	Ambu aScope	WatchB P Home A	VeriQ	Inditherm PWM	Ambulight	MIST Therapy System	BRAM HS	SeQuent	
Question/ decision problem interpretation and evidence identification	21%	Searching for economic studies	*		*	*	*	*+	*	*	*		*	*	
		Target population and subgroups			+			*+		*				*	
		Setting and location						*+	*+			+			*
		Perspective							*+						
		Comparator							*+					*	*+
Cost and consequences identification	21%	Estimating resources and costs	*	*	*+		*	*+	+	*+	*	*+	*+	*	
		Choice of health outcomes	*					*+	*			*+			
Costs and consequences measurement	21%	Measurement of effectiveness		*+		+	*					*+	*		
		Parameters	*+		*+	*		*+	*+	*			*	+	
Costs and consequences valuation	12%	Time horizon	*		*	*+						*+	*	*+	
Analysis	19%	Choice of model	*+		*+		*	*+	*	*+			*	*	
		Characterising uncertainty	*+		*		+	*+	*	*	*		*	*+	
Presentation and interpretation of results	6%	Presentation and interpretation of results				*	*				+		*		
NICE final decision			Further research	Recommended for population in Scope	Recommended for population in Scope	Recommended for a subgroup of the population in Scope	Recommended for a subgroup of the population in Scope	Recommended for population in Scope	Recommended for population in Scope	Recommended for a subgroup of the population in Scope	Not recommended	Further research	Further research	Recommended for population in Scope	

* Represents a problem with the methods used by the sponsor raised by the EAC's assessment

+ Represents a discussion by the committee around the methods used by the sponsor

Fig. 1 Common problems identified by the EACs assessment across economic submissions – Problems identified by the EAC were separated into six categories. The percentages reflect the proportion of all problems that fit into each category.



EAC external assessment centre