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Health Economics and Decision Science (HEDS)

Discussion Paper

The identification and review of cost effectiveness model parameters: a qualitative study

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DP 13/08

HEDS Discussion Paper

No. 13.08

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Abstract

Objectives: Health economic models are developed as part of the health technology assessment process in order to determine whether health interventions represent good value for money. These models are often used to directly inform health care decision-making and policy. The information needs for the model require the use of other types of information beyond clinical effectiveness evidence in order to populate the model parameters. The purpose of this research study was to explore issues concerned with the identification and use of information for the development of such models.

Methods: Three focus groups were held in February 2011 at the University of Sheffield with 13 UK HTA experts. Attendees included health economic modellers, information specialists and systematic reviewers. Qualitative framework analysis was used to analyse the focus group data.

Results: Six key themes, with related sub themes, were identified. The themes were model development, searching issues, reviewing issues, communication, knowledge and experience and reporting issues. There was considerable overlap between themes.

Conclusions: Key issues raised by the respondents included the need for effective communication and teamwork throughout the model development process, the importance of using clinical experts as well as the need for transparent reporting of methods and decisions.

Keywords: qualitative-research, model-parameters; cost-effectiveness-modelling; health-technology-assessment; evidence-based-decision-making

Acknowledgements/conflicts of interest

This project was funded by the Decision Support Unit of the National Institute for Health and Clinical Excellence (NICE). The funder had no involvement in the conduct of the study. The authors would like to thank the focus group participants for taking part in this study. The authors have no conflicts of interest to declare.

Introduction

The development of a health economic model typically forms part of the health technology assessment (HTA) process together with the development of a systematic review of the clinical effectiveness of the intervention being assessed. Health economic models require information in addition to clinical efficacy data and this includes evidence relating to relevant comparators, health utilities, resource use and costs, among others. Sources of evidence may include: randomised controlled trials (RCTs), observational evidence and other clinical studies, disease registers, elicitation of expert clinical judgement, existing cost-effectiveness models, routine data sources and health valuation studies. The way in which these information needs are identified and used can have a fundamental impact on the results of the model (1) and therefore on health care decisions and resulting policies. There is often a lack of transparency associated with how information needs are met in the development of cost effectiveness models. Drummond et al (2) found that much of the relevant data for estimating quality adjusted life years (QALYs) were not contained in the systematic review for the HTA, and that the chosen method for summarising the clinical data can inhibit the assessment of economic benefit.

Although some of the issues around the identification and reviewing of evidence for models have been discussed previously (1, 3-8) there remains very little formal guidance with respect to best practice in this area. This is an important consideration as it is not possible to review all evidence systematically to inform a health economic model and choices need to be made in terms of how evidence is synthesised and used. In their ISPOR-SMDM Modelling Good Research Practice Report (9), Briggs et al recommend that analysts should conform to the broad principles of evidence-based medicine and avoid “cherry picking” the best single source of evidence. While there is a need for transparent and reproducible methods there are also time and resource constraints which can influence how the model

development process operates. Chilcott et al (10) suggest that a potential source of errors in health technology assessment models is the separation of the information gathering, reviewing and modelling functions while Drummond et al (2) also suggest that some of the problems associated with model development could be reduced if evidence requirements were discussed at an early stage.

Kaltenthaler, Tappenden and Paisley (11, 12) have investigated issues relating to the conceptualisation of cost effectiveness models and the identification and review of evidence to inform models. Shared and explicit decision-making and transparent reporting of the choices and judgements that underpin model development were seen as being of key importance in the development of acceptable methods that take into account the specific requirements of the model development process. This research has gone some way forward in highlighting the key issues and offering suggestions for improving the model development process and the way in which it is reported. These are important issues that need to be considered by those involved in health technology assessments, including both researchers and decision makers.

The aim of this paper is to presents the findings from a series of focus groups held with UK HTA experts to explore some of the issues and concerns associated with the identification and review of evidence used in the development of cost effectiveness models. These findings are part of the evidence used to inform a recent NICE Technical Support Document (TSD) (13) and the issues specifically related to the selection and review of evidence are described in more detail elsewhere (12).

Materials and methods

Three focus groups were held as part of a workshop with 13 HTA experts from UK universities in February 2011. The participants were a purposive sample, chosen to represent a variety of specialisms and included seven modellers, one health economist, one statistician, two information specialists and two systematic reviewers. Ethical approval for the focus groups was obtained from the University of Sheffield Research Ethics Committee. The focus groups were facilitator led (EK) and were recorded using digital media with the recordings transcribed verbatim. Standard qualitative research methods were used to conduct the focus groups and analyse the data (14). Framework analysis (14) was used to develop a thematic framework and the qualitative data were classified and organised into key themes and subthemes. The initial step was familiarisation with the transcribed data. Data were then coded and the conceptual framework was developed. Coding was checked by a second reviewer. Some of the themes were pre-identified and some were emergent. The topic guide for the focus groups is shown in Table 1. The discussions were open and participants were invited to discuss other points they felt were relevant but had not been included in the guide.

Table 1. Focus group topic guide

Session topic	Aim of the session and related questions
Model development	To identify key steps in model development and implementation (How does your "final" model structure arise? How do you know which parameters are relevant? How iterative is the process?).
Time constraints	To identify ways we might deal with the issue of time constraints in reviewing for model parameters (What compromises are acceptable to make?).
Sufficient evidence	To explore how we determine when there is sufficient evidence for model parameters and model development. (What is your interpretation of sufficient evidence?).
Communication and team work	To identify what constitutes good practice with regard to team work and communication. (What defines good communication and team work in this context?).
Problem structuring	To recommend good practice with regard to problem structuring (How do you decide what should be included in a model and what should be excluded?).
Identification of evidence	To provide guidance on key issues of evidence identification (non-standard information, rapid searching, comprehensiveness and sensitivity (Do we need to provide guidance on how to access non-standard information? How do we handle issues related to comprehensiveness and sensitivity? What advice can we offer with respect to rapid searching?).
Reviewing methods	To identify practical guidance for reviewing model parameters (How do we appraise for both quality and relevance? How does the process of inclusion/exclusion differ in the context of modelling? With rapid review methods what compromises are we willing to make?).
Recommendations for reporting	To provide practical recommendations on reporting of methods and decisions in reviewing for model parameters (How do we report decision making and judgements? What needs to be reported to allow judgement of the credibility of the model?).

Results

From the focus group transcripts the following six themes were identified: model development; searching issues; reviewing issues; communication; knowledge and experience and reporting issues. There was overlap between the themes as many of the issues raised were interrelated. The themes and related subthemes are shown in Table 2.

Table 2. Focus group themes and related subthemes

Theme	Related subthemes
Model development	• decision making • planning • use of existing models • conceptual models
Searching issues	• multiple information needs • sources of evidence
Reviewing issues	• selection and prioritisation of data • reviewing methods • minimising bias • hierarchies of evidence • study selection • assessment of evidence • evidence synthesis
Communication	• whole team communication • use of clinical experts • communication with information specialists
Knowledge and experience	• expertise • previous experience
Reporting issues	• transparency • language • accuracy vs. credibility

Theme 1 Model development

It was highlighted during the focus groups that a large number of decisions and judgements are made by modellers during the process of model development especially on aspects of relevance and appropriateness to the decision problem.

> "*So if you set up five criteria and then you end up judging what you choose on the basis of six criteria, only two of which were of the five you started out with, then I think it tells you something about how much judgement is required in the process..*"

However, the participants expressed concerns regarding the difference in judgements made by different modellers to represent the same part of reality. Hence the participants would feel more comfortable if the judgement to a particular decision problem did not rest solely with the individual developing the model but rather as a joint task between modellers, decision-makers, health professionals and other stakeholders who impact upon or are impacted upon by the decision problem under consideration. Failure to reflect conflicting views between alternative stakeholders may lead to the development of models which represent a contextually naïve and uninformed basis for decision-making.

> *"There is also an issue of whose judgement it is - is it down to the modeller to make that judgement or should it be in conjunction with other people in the team or a clinical expert? I don't feel comfortable about the modeller making all these judgements."*

Planning was regarded as a key element for model development. This could be in the form of a protocol or project plans that clearly state the project timelines, methodology for the model, information needs and key roles and responsibilities for all team members. Having the evidence requirements set prior to model implementation may allow the whole team to identify potentially useful information and may also help to keep track of changes made during the process.

> *"I think that it would be useful for us to map out a list of things that you might consider … it may be useful to map out pathways in this particular way or problem*

structuring methods may have some role in identifying what should be included in a model and you could even suggest how that should be done."

"Knowing in advance the key pieces of information you're likely to need so that whoever is doing your title and abstract screening at the very beginning has enough codes for flagging things that may be of interest to the modellers."

The use of existing cost effectiveness models was discussed and the modellers' at the focus groups indicated that the main reason they used existing models to inform model development was to critique them from various angles so that they can avoid repeating the same mistakes and in turn produce a better model.

"I don't review models for their results, I don't review them to find things that I like – I review them to find things to avoid"

Whilst the use of existing models was considered to be potentially useful, it was suggested that they should be used with caution and should not be relied upon without considerable scrutiny, as the appropriateness or credibility of an existing model may be questionable or there may be a gap between the decision problem that the model was developed to address and the current decision problem under consideration.

"Well, you have to be a bit careful with that, don't you? Sometimes you trace it back and you find somebody just thought that number up about twenty years ago, and everyone's used it and they've all done that since."

Conceptual model development was an area where there was variability between participants concerning their approaches. Respondents discussed the use of several approaches including documenting proposed model structures, developing mock-up models in Microsoft Excel, developing sketches of potential structures, and producing written interpretations of the evidence. However the participants did all agree that having a draft model or conceptual model would help to develop a common understanding of the evidence

requirements amongst those involved in the model development. This would help to ensure that health professionals understood how the model would capture the impact of the interventions under consideration on costs and health outcomes, that the proposed model was clinically relevant and met the needs of the decision-maker, and provide an explicit platform for considering and debating alternative model structures and other model development decisions prior to implementation.

> *"You've got to sort of get a feel of what the model is doing, not just looking at a whole lot of numbers on the spread sheet. So that's why I'm a big believer in a back-of-an-envelope version of the model, which, .. forces you to really understand what's going on in the model."*
>
> *"start with a conceptual model … you can start with where you think the model should be, and then when you reach the point where you haven't got the data to put in the model and you have to simplify it."*

Furthermore, the interviewees expressed that where possible, alternative model development choices should be tested to assess their impact upon the model results.

> *"I guess my view of structural uncertainty is it's where you're equivocal about whether one set of assumptions is superior to another and it could be an entire characterisation of a disease process, which could have a flag which switches on and off, but you'd have to have built that model as well. And I think it's quite closely related to how formal the conceptual modelling is in identifying what those alternatives could be. I wouldn't expect someone to build 10 different models, but I'd expect them to consider what else they could have done and I'd like to know what else they could have done."*

Theme 2 Searching issues

One common concern raised amongst the interviewees in the focus groups was the need for appropriate searching methods to ensure the retrieval of relevant evidence for the model.

As cost effectiveness models have multiple information needs which require different types of evidence drawn from a variety of information sources, it was considered difficult to capture the information needs in a single search query. Therefore, exhaustive search methods such as those used in systematic reviews may not be feasible.

> *"…it's relatively easy to find cost studies, it's relatively easy to find RCTs, it's not so easy to find adverse events because they're hidden, they're not described in the records, so I think maybe hints about how difficult it is to search for something like this in Medline ..might be helpful."*

During the interviews, respondents discussed the difficulties in finding evidence and the different approaches used for seeking information, including formal Medline and other database searching, contacting experts in the field, searching registries and administrative or routine data sources, snowballing references, following leads, semantic technology, text databases and focused searching. However, the majority of the information retrieval processes are not explicit.

> *"In terms of parameters, we frequently have parameters that are only ever reported incidentally and are not included in any keywords, any titles or anything, things like unusual or irregular adverse events, for example, that turn up in a table, over a wide range of trials and non-trial (evidence), - how do you find them? I don't know any systematic way that could do that. It's pot luck really, you suddenly come across one and then a few more, and they may be different indications even and it's difficult to find a realistic range."*
>
> *"… I'm sure that some of the things I've had to resort to to obtain particular estimates much more resemble investigative journalism than having anything to do with what I'm trained to do"*
>
> *"…picking up the phone to lots of people to find out (what) is there .. an individual patient dataset for this class of people? .. it's not all about reviewing, it's not all about bibliographic searches."*

The need for guidance and advice was expressed regarding factors that impact on the way evidence is identified e.g. what search techniques might be used to maximise the rate of return of potentially relevant evidence and to ensure appropriate steps have been taken to make the process systematic, reproducible and transparent.

> *"It's any information whatsoever, and the identification of evidence is any information seeking process, which includes searching on Medline formally or phoning people up or having a group of clinicians who advise your project, you draw information from all of them and you use that information as evidence to support or justify or make decisions about the model to give it credibility. And as soon as you start to say, well yes there is a difference and we just need guidance on searching, it suddenly excludes a lot of information seeking processes that are absolutely knitted in to the model development process and.... includes clinicians, they have a role in modelling .. it's that idea of credibility I think, that they give such a lot to"*

Theme 3 Reviewing issues

Reviewing issues identified by the participants included: selection and prioritisation of data, methods for reviewing, the importance of minimising bias, the use of hierarchies of evidence, issues around study selection, assessment of evidence and evidence synthesis. These are covered in considerably more detail elsewhere (12).

The processes of selecting and prioritising evidence used to inform parameter estimates were considered to be important. It was suggested that additional attention should be given to the reporting of parameters which are deemed to be more important to the model or to instances in which the preferred decision regarding the choice of evidence is equivocal. The participants felt that it was important to prioritise parameters and focus reviewing resources on those most likely to impact on model outputs, bearing in mind that the importance of parameters is subject to change during the course of the modelling process.

Due to the time and resource constraints within the HTA process it was felt that rapid review methods might be necessary to identify and select evidence. As the use of rapid review methods risk missing relevant information it was considered essential that methods were reported transparently, including the potential limitations of the chosen methods.

A variety of potential biases may be introduced through the process of rapidly reviewing evidence to inform model parameters estimates. Bias may also be introduced through the purposive selection of evidence to create more or less favourable results. One suggested option to reduce such bias was to ensure and to demonstrate that more than one member of the team was involved with making decisions where choices about parameter values and distributions need to be made.

> *"…when somebody is making a decision it isn't just one person it's a team, because … most of the methods within systematic reviewing are double checking what everybody has done. So maybe … for the modellers to use the systematic reviewers and a range of clinical advisors to make sure that no one person makes the decision about these without consulting."*

There is a wide range of types of evidence used to populate models and hierarchies of evidence sources, as suggested by Coyle et al (15), were felt to be useful as a means of judging the quality of individual parameter estimates and aid the study selection process. In order to incorporate the quality of individual studies into the selection process, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) (16) system was suggested as potentially providing a framework for rating the quality of evidence from all potential sources of all data components that may be used to populate model parameter.

"…using the GRADE system… fairly early as soon as you had your conceptual model you might take that to your decision-makers and say which are the critical and important clinical outcomes which can extend to all the different parameters as well."

With regard to study selection and assessment of evidence, it was suggested that relevance or applicability could be assessed first in order to speed up the evidence selection process.

"Normally you go through a full gamut of analysing threats to internal validity first but actually if you look at applicability or relevance first, in a time constrained scenario, often that fatally rules out a huge bunch of stuff that you don't need to look at."

The participants felt that after appraising studies for relevance, quality, should be assessed preferably using standardised quality assessment tools. In this context, quality assessment may be difficult due to the absence of standardised methods for all types of information used to populate the model. Also, some studies may be poorly reported. Establishing quality assessment criteria *a priori* was a recommended option.

In many situations, the issue of synthesis was not considered relevant due to study heterogeneity and the case that often only one or two values are appropriate for use in populating a model parameter. However, where there are more than one or two potentially relevant studies the participants stressed the importance of appropriate synthesis methods.

Theme 4 Communication

Focus group participants agreed that in order to have a credible and robust model effective communication across the whole project team was crucial. This might include modellers, clinical experts, decision-makers, information specialists, systematic reviewers of effectiveness studies and other researchers. The group agreed that all parties involved should have a common understanding of the model development process which could be achieved by recruiting clinical experts quite early on in the process and involving them in the

development of the conceptual model, writing protocols, highlighting evidence needs, and having regular meetings with the whole team, presenting and discussing the model. These meetings should use non-technical language easily understood by clinical experts and other team members. Also considered important was the sharing of internal draft reports.

> *"…always having clinical experts, and not just one who is local and face-to-face, but a panel who are available for sort of correspondence by e-mail, very early. You recruit them early and involve them in the model development process, which again will also be a fairly whole-team endeavour initially, so that the people who are doing the systematic review of effectiveness studies will be party to most of those conversations about the conceptual modelling of what the model structure might eventually look like."*

Engaging with experts and other researchers can serve as a face validity check to ensure that important information has not been missed, that the most appropriate parameter estimates are used and the opportunity for errors is reduced.

> *"this is another reason why it's important to have, as well as clinical experts, .. other people who are researchers or have worked in the area, so at least after you've made some of these choices, then you can do .. reality checks and say, .. is there anything we've missed, are there any other recent or grey literature studies that might provide an alternative estimate …..?"*

An issue raised during the focus groups was the lack of communication and understanding between modellers and information specialists. This inadvertently led to the development of ineffective search strategies. It was felt important that modellers engage with the information specialist and keep them updated with the process of model development and information needs so that an effective and focused search strategy can be developed.

> *"the ..ability to go back to the information scientists and say this is more specifically what I'm looking for, but likewise also once the preliminary modelling results come*

back, that that should feedback as well to say we don't need to do this search anymore because the parameter that we thought it was going to inform is not going to affect the way this particular model works ..."

Theme 5 Knowledge and experience

Expert opinion was considered to be crucial in developing the model structure especially that of clinical experts, as this was felt to help to develop an understanding of the decision problem.

"When we are presented with a new disease area, often the first time …. You are missing things all the way down the line. If you had.....somebody else's expertise in the modelling field to draw on, you could make a much better job of it."

In addition, opinions of clinicians and a wider group of people who are involved in caring for patients are essential, as they can help provide parameter estimates or identify alternative sources of evidence (including unpublished literature). Hence, this information forms the cornerstone of a model's contextual relevance.

"….but also expert opinion. It just seemed to be one of the main adverse events of the use of cochlear implants in children that the clinical community had very high on going concerns about, so I think we had early feedback that the model could or should try to include it, even though our early pilot model had shown it was negative."

Furthermore clinical experts and other researchers can serve as a reality check to ensure that important information has not been missed and that the values used are appropriate.

"one of our … clinical experts... pointed out that viral resistance was not included in our model. And we'd reviewed every single model of prophylaxis – none of those included it, and we'd reviewed the clinical evidence base, and that wasn't there ..and it completely changed the results."

The modeller's previous knowledge and experience of the disease area was also considered to be extremely important, particularly in a time and resource constrained scenario.

> *"If you've been working in that field, and built up a network in it, then you are a long way ahead, and you have what you need."*
>
> *"…you've got some ideas about what's going to be potentially reliable information that could also inform the search and make the search results a bit briefer."*
>
> *"I think there's something else also about the historical, and, perhaps, the individual experience of what has tended to drive the results of models. So I think utility weights of key health states would be a key thing that past experience would have shown often ends up being one of the most important drivers of results"*

Theme 6 Reporting issues

Transparency was considered to be an important issue by the focus group participants. It was also felt that there often was not enough time to ensure that the methods used were reported adequately.

> *"I think transparency is one of the big things that is missing, isn't it? In the whole of modelling, anyway, there's the transparency issue."*
>
> *"...even if you have enough time to do that as an analyst you might not have enough time to write it up in a way that would make it more transparent."*

A comprehensive account of every evidence source used in the modelling process was considered to be very time consuming and potentially difficult to read. Suggested alternatives included the use of a brief summary table of the main inputs and sources of information in the main report with the possibility of more detailed information presented in appendices.

As highlighted in Theme 1, model development involves making a large number of decisions and judgements. The participants believed that it was important that these decisions are

clearly documented and reported to ensure the credibility of the model. Key aspects include the following: search strategies, selection and justification of studies and model parameters; structural assumptions, decisions relating to the prioritisation of key information needs, acknowledgment of limitations and potential biases and documentation of any deviations from the study protocol.

> *"you would want to explain your choice. You would want to, because that would support the credibility, wouldn't it?"*
>
> *"It's more like the thought process you went through to get there, and what did you, you decide not to do, and why did you not go that way, or why did you choose this way?"*
>
> *"As long as you make the choice explicit …, give an indication where the selection came from and what other possibilities there were, that would .. be uncertainty rather than bias that if we had chosen this one, this would have happened."*

Several participants believed that the language used in reporting model development and results should be clearly understood by health professionals and other individuals involved in the process. The model could be represented in both diagrammatic and textual forms using non-technical, non-mathematical language.

> *"Again the language to describe that sort of thing would have to be very careful because I think, the way I would write it, would almost always imply it's going to be a Markov model which may not be the best way of modelling something, so I think however it's expressed, it needs to be more in terms of principles and things to consider than anything too prescriptive."*

In terms of model credibility it was emphasised that the modeller needs to cater for the target audience and there is a tension between accuracy and credibility.

> *"..but you know that the clinical audience … will expect to see that factor, because the literature has been going on about it for years, like the risk of meningitis with*

cochlear implants, ….. It's important for people to see the Markov state for it, even if it's functionally going to be useless. So I think we are playing lots of tensions to do with meeting the right audience, trading off accuracy versus credibility."

Discussion

This research highlights some important issues in the identification and review of evidence for model parameters as identified by the focus group participants who are all experts in the field of health technology assessment. Six key themes were identified by the participants: model development, searching issues, reviewing issues, communication, knowledge and experience and reporting issues. The respondents thought that the model development process requires a large number of decisions and judgement and several approaches to conceptual modelling were suggested. The types of information needed and the sources of this information were issues felt by the respondents to warrant different approaches to searching than those found within the field of systematic reviewing. Reviewing efforts should be focused on those parameters deemed to be more important to the model and transparency in the reporting of review methods was considered essential. Effective communication with all members of the modelling team throughout the process was considered important. The use of clinical experts was deemed to be essential and the modeller's and other team members experience in a specific disease area were both thought to be useful for development of models. Transparency was considered crucial in the reporting of methods and results and documentation of decisions made throughout the process was thought to be important to ensure the model's credibility. There was considerable overlap between themes. For example, reviewing of previous models was suggested as useful for informing searching approaches.

The participants in these focus groups have several years of experience in the field of cost-effectiveness modelling of health technologies. The findings from these focus groups helped to inform the development of a NICE Technical Support Document providing guidance on the identification and review of evidence for cost effectiveness model (13). This goes some way forward in suggesting options for good practice in identifying and reviewing evidence for use in cost effectiveness models. These issues are of interest to all those working in health

technology assessment internationally, including researchers and policy makers as how evidence is identified and reviewed for used in cost effectiveness models can have a big impact on health technology assessments and subsequent health care policy decisions.

There were some limitations with this research. Only UK participants were included in the focus groups. Researchers from other countries may have different views. Only one method (focus groups) was used to collect data. There may have been different results if interviews, questionnaires or other qualitative research methods were used. Only academic researchers participated in the focus groups and it would therefore be useful to determine the views from industry, health outcomes and research agencies and policy making agencies such as NICE in subsequent research.

There are many unanswered questions with respect to how to identify, review and select evidence to inform model parameters, hence a number of areas warrant further research. There is a need for accepted standards for documentation of decisions and the use of sources of evidence such as expert clinical opinion. There is also a need for the development of appropriate search methods and rapid review methods for the identification and review of evidence used in cost effectiveness models.

Conclusions

The findings of this research highlight some of the important issues in the use of evidence in cost effectiveness models. Effective communication and team work throughout the model development process was considered important was transparent reporting of decisions made throughout the process. These issues are of importance to policy makers and those involved in making decisions regarding the use of health technologies. Consideration of these issues helps to make the model development process more transparent and easier to understand and thus facilitates health care decision making and health policy development.

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