Applicability Testing of WP5 toolkit - Round Two

Summary report, June 2008
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Acknowledgements

1. Abstract

This report details the responses to Round Two applicability testing of the WP5 Adaptation Toolkit (Version 3 November 2007).

The first version of the toolkit was developed based on the results of a questionnaire, in-house thinking on content and function, and a Delphi survey of 19 European HTA agencies.
From this a second version of the toolkit was developed (March 2007).

During Round 1 of applicability testing, evaluators from 16 European HTA agencies selected one or more HTA reports from a country other than theirs and tested the WP5 Adaptation Toolkit as an aid to adapting the report to meet the needs of their own health service, completing a specially designed qualitative evaluation sheet. Responses were submitted in May/June 2007 (and one in November 2007). Three of the evaluators took part in 1 hour face to face or telephone interviews to further explore their comments on the evaluation sheet.

From this feedback, refinements were made to the toolkit (version 3), and a different approach was adopted for the second round of applicability testing. Members of WP5 were invited to work in groups to examine the toolkit in respect of five topic areas, and to agree a joint response from each group. In addition, an opportunity was offered to members of WP4 and WP5 to use the Adaptation toolkit to adapt all or part of the WP4 Core HTA on Drug Eluting Stents. Finally, members of EUnetHTA outside WP5 or who had not worked on the development of the toolkit were invited to adapt a report of their choosing and comment using the evaluation form as in the first round of testing.

Responses were received in March-May 2008 from the five WP5 workgroups representing all 20 Associated Partners and six Collaborating Partners, and in addition from three independent evaluators, details of which are given in the Appendices. These responses form the basis of this report.

2. Introduction

The WP5 Adaptation Toolkit is one of the deliverables of WP5, designed to help HTA organisations/networks adapt HTA reports from another country for use within their own healthcare system. The toolkit has two objectives:

> (1) To enable the critical appraisal of HTA reports
> (2) To provide advice to aid adaptation

Version 2 of the toolkit was applicability tested by 16 European HTA agencies, who completed a semi-structured evaluation sheet for 17 HTA reports (one agency used the toolkit to adapt two reports). This outlined their views about the experience of applying the toolkit in the adaptation of an HTA report from another country for their local needs. Three of the evaluators took part in 1 hour face to face or telephone interviews to further explore their comments on the evaluation sheet.

Version 3 of the toolkit was applicability tested by all 20 Associated Partners and six Collaborating Partners in WP5, plus three independent evaluators who had not worked on the development of the toolkit. In total, 41 individual members took part in the multiple testing process.

3. Aims

The aim of Round 1 of the applicability testing was to allow HTA organisations to try out Version 2 of the Adaptation toolkit, by using it to adapt a single HTA report produced in another country to their own setting, and evaluating the toolkit for this purpose.

The aim of Round 2 of the applicability testing was to allow further examination of the toolkit in the context of identified topics and issues:

> Interactive version of the toolkit
> Diagnostic & Screening
> Organisational aspects
> Cost effectiveness modelling
> Transferability

In addition, members of EUnetHTA outside WP5, or who had not worked on the development of the toolkit, were invited to evaluate the toolkit by using it to adapt an HTA report, as in round 1, but completing a shorter version of the evaluation form.

4. Method

Round 2 of applicability testing was launched at the Venice face-to-face meeting of WP5 members (September 2007). Those present were invited to select one of five work groups and spent one session examining the toolkit in the context of one of the five topics and issues listed above. This formed the basis of the groups and group work which other members of WP5 were invited to join.

Participants
All 27 partner HTA agencies in WP5 were invited to take part in round two of the applicability testing. The response from the membership was excellent: a total of 38 individuals from 26 member agencies (all 20 Associated Partners plus 6 Collaborating Partners) joined in this activity, working in one of five collaborative groups as detailed in Appendix 3. A number of agencies provided two or even three individuals to work in one or more of the groups; two individuals participated in each of two work groups.

Each group was given a set of questions to address (see Appendix 4) although they were also welcome to develop their own areas of investigation. They worked collaboratively by email from November 2007 through to March 2008, producing a joint report from their group at the end of this period.

Group topics and questions
These are summarised below – the full topic sheets as given to each work group are attached at Appendix 4.

Group 1: Interactive toolkit

Group work problem
WP5 members have expressed the need to develop an interactive web-based version of our toolkit. How could this best be achieved?

Proposed solutions
- Need for guidance and help files (what to do next)
- Need for a validation test

Group 2: Diagnostic testing and screening

Group work problem
"Our toolkit is not very helpful in adapting HTAs on diagnostic testing or screening programmes".

Should we place a health warning on our toolkit, i.e. 'we do not recommend the use of this tool in adapting diagnostic test or screening HTAs'?

Or can you propose changes and/or additions to our toolkit that would enable better adaptation of such HTAs?

Proposed solutions
- Certain domains need further work (effectiveness domain most important)
- Specific relevance and reliability questions needed

Group 3: Organisational aspects

Group work problem
"The organisational aspects domain of our toolkit is confusing and not very helpful in the adaptation of data and information on organisational aspects".

Should we have an organisational aspects domain within our toolkit? If so, what changes and additions do you propose to make it clearer and more helpful for the user?

Proposed solutions
- Yes, this domain should be included in the toolkit
- Take 'level' out of the matrix – it is unhelpful, questions are better
- Feedback to the user is an important developmental factor (link to i-toolkit)

Group 4: Cost-effectiveness modelling

Group work problem

"It would be really helpful if the toolkit provided advice and information on how to adapt cost-effectiveness models".

Is this possible? And if so, how could it be achieved?

Proposed solutions

- Economic Evaluation group to work through the modelling issues
- Devise a question for **each** issue - c**ritical** questions

Group 5: Transferability

Group work problem

"Our toolkit doesn't provide enough advice on how to transfer information and data to another setting".

What do you think is required and how could this best be achieved?

Proposed solutions

- Need to make clear consequences of Yes/No questions
- Need better structure to questions, more explanations
- Set up a sub-group on transferability to link with WP4

Group organisation

Each group was invited to organise itself as it wished and to nominate a group leader (or facilitator) who would be responsible for co-ordinating the work of the group and feeding back on their experience in the form of a short written report. Members of each group were invited to participate in an eMeeting to assist in summarising their thoughts, but most felt this was not necessary and collated their response by email only.

Each group was also set a number of tasks, which are detailed on the group work sheets at Appendix 4.

Response rates

At the end of the work period (November 2007 – March 2008) the groups reported back on their findings (three groups reporting in March, one in April and one in May 2008). The five WP5 workgroups included representatives of all 20 Associated Partners and six of the Collaborating Partners, details of which are given in Appendix 1. In total, 38 individual members took part in the group work part of the Round 2 Applicability testing process. Two of these individuals contributed to two different work groups. Five partner agencies contributed to two or three different workgroups.

5 Outputs from five work groups

Each work group was free to determine its own format and approach, and therefore these vary between groups. Each response is presented here as generated by the work groups themselves, with some minor textual or typographical amendments.

Output from work group 1 – Interactive Toolkit

An interactive version of the toolkit might help the user to determine whether a report can be adapted to the local context by determining:
- its relevance using the speedy sifting element
- its reliability and transferability using the main toolkit

Functions of an interactive toolkit
In building an interactive toolkit based on the adaptation toolkit document, five main functions can be identified:

1) to initiate interaction with the toolkit and to identify the authorised person
2) to assist with use of the adaptation tool
3) to gather data on reports previously adapted using the adaptation toolkit. Every piece of gathered data would receive a mark or tag (metadata)
4) to present selected information from reports held in the database
5) to analyse the information gathered on all reports adapted

Each function requires specific design and development, but all these functions can be achieved by a web based interactive database.

In point 1, the main question is to decide who can be a registered user.

In point 2, the features to be included depend mainly on the elements of the adaptation tool. Thought needs to be given to the design, mainly the sequence in which the elements are presented to the users and the 'help' material that should be offered through hypertext. There should be a facility to compute numerical data to obtain summarized indices.

In point 3, which is relatively straightforward, it should be possible to gather the identification data of the report to be adapted, the data of the person and agency using the toolkit and every element of every domain of the definitive adaptation tool. There would be collection of data in as many sections as are activated by the identified person, beginning with the speedy sifting.

In point 4, the key question is to decide whether to offer all the information gathered from every adaptation process or selected information only. In this case the question is: what information does a user interested in adapting one report need from previous users that have done or tried to do the same task? This would include every element of the speedy sifting and, at least, all sections where adaptation has been tried, which ones have been successfully adapted and which not. Depending on this decision, the search form will vary.

In point 5, the database software should be able to do complex computations or, at least, to export data.

Added value
The added value of an interactive version of the toolkit *versus* a paper document is:
- rapid determination on whether a report can be adaptable;
- access to speedy sifting and main toolkit responses already completed by another user for a previous adaptation of the same report.

To achieve this,
1) <u>web pages based on the speedy sifting and the questionnaires of the main toolkit</u> need to be developed.

⇒ The Figure 1 "Pathway of questions and responses in the speedy sifting part of the toolkit" is a succession of questions to determine if a report is relevant for adaptation. This succession of questions needs to be translated into a succession of web pages:

Webpage 1: Are the policy and research questions relevant to your questions?
　　　If no, go to web page 2: STOP
　　　If yes, go to web page 3.
　　　What is the language of this report? Is it possible to translate this report into your language?
　　　If no, go to web page 2: STOP
　　　If yes:
Webpage 4: Is there a description of the health technology that has been assessed?
Webpage 5: Is the scope of the assessment specified?
Webpage 6: Has the report been externally reviewed?
Webpage 7: Is there any conflict of interest?
Webpage 8: When was the work that underpins this report done?
　　　Does this make it out of date for your purposes?
Webpage 9: Have the methods of the assessment been described in the HTA report?

⇒ Main toolkit

The speedy sifting section and the main toolkit questions should have scores attributed to them. The added value of an interactive version might be to have a rapid overall view of the result of the two sections. Experience gained within WP7 is that it will be helpful for users to have a rapid global view of their responses for each question box.

2) There needs to be a database containing the information entered for specific reports for both the speedy sifting and main toolkit sections. This database must be compatible with the EUnetHTA clearinghouse information platform.

Output from work group 2 – Diagnostic and Screening

(This group made a series of comments and suggestions on Section 5 of the Toolkit. These have been summarised here, with the workgroup suggestions shown in bold.)

Section 5.1 Technology use domain

Comment: should this section be renamed 'Description and use of technology'?

Question box 5 –Technology use domain questions

c) To assess transferability:

Q6 Is there any consideration of when and how technical characteristics affect outcomes?

Comment: WP4 has Use of technology and technical characteristics of the technology as separate domains

Question box 6 – Safety domain questions

b) To assess reliability

Comment: Several questions are in fact multiple, making an answer difficult to articulate in some cases.

Q10 Was the validity of all studies referred to in the text assessed using appropriate criteria (either when selecting studies for inclusion or in analysing the cited studies)?

Comment: Q10 should be re-written as:
a) Were the inclusion criteria used for the primary studies appropriate to the study question posed by the HTA report?

b) Were the criteria used to assess the validity of the primary study appropriate?

As you can see the answer to a) could be yes, to b) no, or vice versa, as well as being yes or no to both, in which case the question as currently phrased would be fine.

Q11 Which harms have been reported, how were they measured, and how were these data collected??
Comment: Equally, Q11 is really 3 questions which should be separated.

There are several more multiple questions in the rest of the domains.

5.2.1 Resources for the safety domain
Box 7 Resources to aid in the adaptation of safety data and information
Reliability

The work group suggest adding here:

An extension of the CONSORT Statement (Consolidated Standards for Reporting Trials) is made for better reporting of harms in randomised trials. Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, et al. Better reporting of harms in randomized trials: an extension of the CONSORT statement. Ann.Intern.Med. 2004 Nov 16;141(10):781-788.

A brief summary of the strengths and weaknesses of different study designs that may be included in a systematic review of harms is given by Jefferson and Jefferson T, Demicheli V. Balancing benefits and harms in health care: observational data on harm are already included in systematic reviews. BMJ 2003 Sep 27;327(7417):750.

Newcastle Ottawa scale is a tool to assess observational studies, available at http://www.ohri.ca/programs/clinical_epidemiology/oxford.htm .

STROBE-Statement provides a checklist of items that should be addressed in reports of observational studies. von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet 2007 Oct 20;370(9596):1453-1457.

Section 5.3 – Effectiveness (including efficacy) domain

Question box 8 – Effectiveness questions
b) To assess <u>*reliability*</u>

Q9 Was the validity of all studies referred to in the text assessed using appropriate criteria (either in selecting studies for inclusion or in analysing the studies that are cited)?

Additional question:
If there is no direct trial evidence, but separate studies test accuracy and treatment effectiveness, are the studies transferable enough to yield linked evidence of the effects of the diagnostic or screening test on patient outcomes?

c) To assess <u>*transferability*</u>

Q14. Would you expect the baseline risk of patients within your own setting to be the same as the baseline risk of those patients considered within the HTA report for adaptation?

Comment: Diagnostic accuracy is likely to be different in different settings.

5.3.1 Resources for the effectiveness domain
Box 9

Reliability

The work group have added the following resources:

QUADAS: a tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews	http://www.biomedcentral.com/1471-2288/3/25
Standards for the Reporting of Diagnostic Accuracy studies (STARD)	http://www.stard-statement.org/website%20stard/
Sampson M, McGowanJ, Lefebvre C, Moher D, Grimshaw J. PRESS: Peer review of electronic search strategies. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008.	http://cadth.ca/media/pdf/477_PRESS-Peer-Review-Electronic-Search-Strategies_tr_e.pdf
Jaeschke R, Guyatt G, Sackett DL. Users' guides to the medical literature. III. How to use an article about a diagnostic test. A. Are the results of the study valid? Evidence-Based Medicine Working Group. JAMA 1994 Feb 2;271(5):389-391. Jaeschke R, Guyatt GH, Sackett DL. Users' guides to the medical literature. III. How to use an article about a diagnostic test. B. What are the results and will they help me in caring for my patients? The Evidence-Based Medicine Working Group. JAMA 1994 Mar 2;271(9):703-707.	

Output from work group 3 – Organisational aspects

(This output is presented as a series of response to the tasks set for the work group. In this case, the tasks are in bold and the work group responses follow).

1) Read through the WP4 core model incorporate and the relevant information, data and links within the organisational aspects domain of the WP5 toolkit.

The terminology in the Toolkit should try to be consistent with the terminology used in the Core Model. For example, in the Core Model section "Assessment elements" (p.103), what are called "assessment elements or topics" in the Core Model are named in the matrix as "organisational aspects dimensions".

Re the glossary: there is no definition of "organisation" present - we could add the one provided in the Core Model (p. 97).

2) Re-develop the 'matrix' to make it easier to understand and use.

General comments on the matrix:
-        Definition and examples of what is meant for each <u>aspect</u> should be provided in the text (it may be that any of those aspects can change its empirical reference depending on the organisational level considered).

-        Definition and examples of what is meant for each <u>"organisational level"</u> should be provided (a synonym would be "target setting"?).

-        It is not clear what <u>"inter organisational and intra organisational"</u> means exactly and empirically refers to (an example of "inter organisational level" would be the regional/ provincial level in a federalist system? The "healthcare system level" is the national level?). We would propose the use of "organisational levels" intended as "levels of health care" as defined in the Core Model itself (p. 103, same section), that is local/ regional/ national level.

-        The body of the first version matrix is a generic list of "Types of <u>data</u> and <u>methods of analysis</u>. It would be more useful for each organisational level and aspect to highlight (or make reference to), the <u>questions</u> outlined in the Core Model (p. 110-115) which one would have to deal with if wants to collect <u>data and information</u> about the aspect at stake and the <u>methodology</u> that can be used for collecting those data/information

See below, a proposal for **redevelopment of the matrix** in the light of the Core Model, using an example about "utilisation".

3) Provide further explanations and clarity to the questions posed in this domain.

Box 12 Organisational aspects domain - additional questions

We would propose listing the questions according to what they are intended to assess. For example: questions 1, 3 and 4 help to assess relevance and transferability of data and information found in a report, while question 2 is related to the reliability of the methods used to collect data and information.

A proposal for redevelopment of the matrix

		"ORGANISATIONAL LEVEL"	
		NATIONAL/REGIONAL [1]	**LOCAL** [2]
ORGANISATIONAL ASPECTS	Utilisation a)		**Questions related to this element, see Core Model (eg. Q1 "**How is the tech. accepted by this level?", p. 110) **Target population and Type of data/information to be collected to answer the question/s:** Health professionals and operators views. **Methodology:** - Literature systematic review or/and - In depth interviews, focus groups etc. (qualitative social research methods) - Survey by questionnaires (quantitative methods) **Link to quality assessment tools** for kind of research (Box 13 in the Toolkit, p. 24)
	Work processes (b)		
	Centr/Decentr.(c)		
	Staff (d)		
	Job satisfaction (e)		
	Communication (f)		
	Finances (g)		
	Stakeholder (h)		

(1) Overall health services framework or macro level (national or regional/provincial).
(2) Single organisation (hospital, health trust etc.)
(a) Utilisation is one of the eight assessment elements listed within the organisational domain
by the Core model .

4) Test the usefulness of this domain by adapting data on organisational aspects from a chosen HTA report – collectively or individually on one report or on several different reports.

The agency ASSR Italy was commissioned in 2007 by the Italian National Ministry of Health to prepare a Video Capsule Endoscopy (VCE) HTA report for the Italian context (national level). The objectives were to identify and summarise available evidence about the diagnostic accuracy and safety of VCE for OGIB, and collect data on its costs, appropriateness of use and patient acceptability.

We decided to identify the most recent HTA report and "update" it. We realised that "updating" is fine for a systematic review or HTA report about diagnostic efficacy and safety, but not for all the parts of an HTA report (in this case we used "Endoscopie par capsule, KCE reports vol, 25 B, Belgium"). Some parts of this report which were related to the Belgian context (reimbursement status, sales of capsule etc.) were not used, although they gave us some broad indications and ideas.

Quality of information was high, and so was relevance, but the point is that you need to collect primary data and information from your own context and it is really difficult to transfer "primary" data about organisational aspects from a report for one country to a report for another country (with regard to this we are now undertaking a national survey to collect context specific data on diffusion of VCE, appropriateness of its use, direct and indirect costs and patient acceptability).

This does not apply to systematic review for dimensions like organisational aspects or patients' views: it could be transferable (after an assessment of the quality of the review and of the included study), but few or no HTA reports include a systematic review on those dimensions. Moreover, it is difficult to find qualitative or quantitative studies on those aspects on standard databases (Pubmed etc.), which makes it more and more difficult to perform any systematic review.

A broad concern: this experience has shown to us that for organisational aspects each country/organisation should feed its report with primary data collected via quantitative or qualitative methods etc.

Output from work group 4 - Cost-effectiveness modelling

A health-care evaluation model can be seen as an analytic methodology that accounts for events over time and across populations, that is based on data drawn from primary and/or secondary sources, and whose purpose is to estimate the effects of an intervention on valued health outcomes (**out:** consequences) and costs.[1]

Cost-effectiveness models usually aid decision making by revealing the relation between assumptions and outcomes. These assumptions include structural assumptions about causal linkages between variables: quantitative parameters such as disease incidence and prevalence, treatment efficacy and effectiveness, survival rates, health-state utilities, utilization rates, and unit costs; and value judgments such as the nature of the consequences that are valued by decision makers. A good study based on a model makes all of these assumptions explicit and transparent, and states its conclusions conditionally upon them.

Because decision modelling is a very technical field that not all health professionals are familiar with, we recommend including a short list of key introductory questions for decision modelling in the tool kit. Some critical questions could be posed as follows:

1 Specifying the decision problem: identifying the question to be addressed.

- Are the population and subpopulations defined?

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[1] Cft www.ispor.org

- Is information about location and setting included?
- Are the specific options that are being evaluated detailed?
- Which Institution makes the relevant decision?

2 Set of model boundaries

- Is it defined which of the possible (**out:** consequences) health outcomes of the options under evaluation will be formally modelled?

3 Structuring the decision model

- Is there good evidence of the clinical process (natural history of the disease) driving the model?

4 Populating the model: identifying and synthesizing evidence

- In case of absence of RCT, is it stated the kind of indirect or mixed treatment comparisons used?
- Do the authors explain how the probabilities of the clinical events under study are obtained?
- Where trials report various effectiveness measures, is it stated how effectiveness is estimated in terms of common endpoint?

5 Uncertainty and heterogeneity

- Is sensitivity analysis undertaken to identify which model´s conclusions are sensitive to the uncertainty of parameters?

However, the group first assignment was to assess whether the model could be adapted. The answer was positive, even if with some conditions. The discussion about this issue raised the following concerns about the process of adapting a model:

- It requires time (5-6 months)
- It requires calculations
- Those who have developed the model must be willing to share it
- Some form of cooperation has to be established to be sure the model is fully comprehended
- Pharmaeconomic models from industry are often more difficult to obtain
- It is difficult to rebuild some models based only on paper documentation
- Univariate sensitivity analysis from the original model can be useful to identify factors that have a major influence on the results and thus should be specifically taken into account in the adaptation process (e.g. price of the technology under evaluation)
- Every adapted model should be validated for the country of interest before using it to predict future outcomes (this can be very time consuming!)
- Since country specific secondary data will hardly be available for all parameters of interest and there won't usually be enough time to collect primary data for missing data, some parameters will have to be left 'unadapted'. Thus, sensitivity analyses are very important for adapted models to test for uncertainty
- The whole adaptation process is to be seen as iterative rather than linear step by step.

Hence, when we speak of economic models, we are dealing with a complex issue. When we think about adapting models to specific settings, we must take into account that we are dealing with many parameters, and we must consider the differences in population, epidemiology, costs of one country with respect to others.

So, the group suggests that a definition of cost-effectiveness modelling could be incorporated in the glossary. Additionally, some explicit questions on CE modelling could be added in the toolkit.

According to ISPOR, criteria for assessing the quality of models falls into three areas: model structure, data used as inputs to models, and model validation. From this start point, the group defined some questions in order to assess the validity of the model, the quality of data retrieval and the validation of the adaptation the model.

Possible additional questions:

- Has the model been developed to answer the same research question/the same outcomes of interest?
  (if no, major adaptations may be required which take time)
- Which programme/software is the model based on?
  for example: a model on Excel basis can easily be used because it is standard software; other software (like TreeAge) requires a licence (which may be too expensive) and some training to understand the programme. Even if the model is in Excel it can be quite difficult to understand all its complexity for someone who hasn't been involved in developing the model from scratch.
- Is the quality of the model acceptable?
  (to check the quality, the checklist by Philips et al.[2], which has been mentioned already in our previous discussions is helpful)

Other issues that have to be taken into account when considering the quality and the transparency of the model include:

- Basic demography and epidemiology of the disease (e.g. overall life expectancy, age specific incidence and prevalence, etc.)
- Factors that influence epidemiology (e.g. differences in sexual activity or migration influence HPV prevalence)
- Resource use patterns and unit prices
- Population values (they can for example influence QALYs although QALYs are generally viewed to be transferable without adaptation)
- Country specific guidelines for economic evaluation (e.g. different discount rates, perspective)

All this information has to be clear in the model to be adapted and available for the country for which the report is to be adapted.

In conclusion, to answer the main question: "Is it possible to provide advice and information on how to adapt cost effectiveness models?", we can say that some conditions have to be fulfilled before proceeding to any kind of adaptation. Some questions posed in the toolkit can certainly be helpful but we must take into account that the process of adapting a model into another setting can require lot of time itself.

Finally, no preference was expressed on whether to include a specific section on CE modelling in the toolkit, but it could be useful to set out the conclusions we came to in the document in order to explain the introduction of the possible new questions.

References:
Briggs A, Claxton K, Sculpher M.: Key aspects of decision modelling for economic evaluation, in Decision modelling in Economic Evaluation: Oxford University Press, 2006.

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Philips Z, Ginnelly L, Sculpher M, Claxton K, Golder S, Riemsma R, Woolacoot N, Glanville J. Review of guidelines for good practice in decision-analytic modelling in health technology assessment 2004 Sep.8 (36):iii-iv, ix-xi, 1-158.

Milton C. Weinstein PhD (Chair), Bernie O'Brien PhD, John Hornberger MD, MS, Joseph Jackson PhD, Magnus Johannesson PhD, Chris McCabe MSc, Bryan R. Luce PhD, Principles Of Good Practice For Decision Analytic Modelling In Health Care Evaluation: Report of the ISPOR Task Force on Good Research Practices – Modelling Studies

Output of work group 5 - Transferability

This group considered Transferability in relation to the various headings of Toolkit section 5. The approach used was for individual group members to respond to the tasks in relation to a specific section and for other members to then comment on this. Tasks are shown in bold and the group's responses to these follow.

On 5.1 Technology use domain and Core Model chapters HealthProblems and current use and Technical characterictics (assessment elements A and B).

Task 1.
Consider the WP5 glossary definition for transferability. Is it clear, is it correct? Are we using this term in the same way within the toolkit? If not, propose a more appropriate 'toolkit' meaning for transferability for the glossary.

In general, it seems that the concept of transferability is used in the same sense. However I think we could introduce a differentiation between „results transferability" and „approach transferability". In many cases, a report will have results that are not applicable in the local context, however the approach followed to assess the aspect and reach the results can be replicated in the local context with few modifications. For example, if a systematic review of epidemiological surveys has been done to assess the prevalence of a disease among the population of Country A, researchers in Country B may use the same approach (e.g. search strategy, selection and quality assessment criteria), swapping the focus from Country A to Country B literature. In such a case, the benefit of using another country's reports depends on the transfer of a methodological approach to gather data from the local context.

General Comment: Use the same wording as in Core Model for „parts" of a report, change „Section" into „Domain".

General comment on Section 5.1
The section is introduced with the words: „Below is a list of seven questions to ask when considering the adaptation of information and/or data on technology use and development (box 5). "

The information obtained in this domain through the toolkit application does not only allow assessment of the transferability of the Domain itself. In fact it determines the transferability of other parts of the assessment as well. If at this stage, relevant differences in the target group, the utilisation of the technology, etc. are identified, it is very questionable whether the other domains, and especially the conclusions and/or (policy) recommendations can be transferred.

Proposal: Add this aspect to the introductory paragraph.

I have the impression, that the separation between „Reliability" and „Transferability" does not work very well.

Task 2.
Read through the WP4 core model and identify any relevant questions and/or resources on transferability that should be incorporated within the WP5 toolkit.

The core model makes some indications on approaches to answer the different issues and discusses briefly some issues on the limitations and advantages of some of them. The toolkit could incorporate (or at least refer clearly to) this information from the Core Model, especially to give some indications to answer Questions 3, 4, 5 of Box 5 in the toolkit (questions on

whether an issues was appropriately assessed). This information can be put in the Table accompanying the Toolkit.

Example:
„Question 4. Are patterns of utilisation, diffusion, indications and time trends adequately described?"

The differences between the questions of the Core Model and those of the Toolkit are in my view due to the different goals of both documents. In my opinion the Core Model is to be understood as a proposal of content and methodological approaches to conduct an HTA. The toolkit asks in the first line whether very essential information is present in a report and whether it was gathered and presented in an adequate manner, and if both are answered with Yes, whether the information can be taken one to one to another report. Thus I do not see any need to acommodate the questions between the two models.

Task 3.
Identify those toolkit questions where consequences of yes/no answers are unclear and propose direction as a result of the answer.

Task 4.
Suggest a more appropriate structure for questions within the toolkit.

Proposals for modification of questions and indications on action to be taken depending on answer *(blue italics)* In [brackets] explanations on how to answer are given. This is a proposal (not completly elaborated) on how the toolkit could be further developed to guide an adaptation process. Further development is needed if this kind of toolkit is desired.

Question 1: What is*/ are* the research question*(s)* considered?
> → *if no questions have been reported go to „Reliability" (assessment of relevance will be done after considering the rest of questions of the toolkit)*
> Is */are* the research question*(s)* considered within this section of the report relevant to your question*(s)*?
> → *Yes: go on to Question 2*
> → *No: Stopp here, further transferability assessment or extraction of information not worthy*

Question 2: Were conditions, target group, relevant interventions or comparisons between interventions and relevant outcomes appropriately defined?
> → *Yes* → *Are these the same as the ones proposed in your context?*
> > → *Yes[minimum requirement for yes is to share the same „condition and target group" as well as „intervention"]: Transferability of information from this domain probably given, Transferability from effectiveness domain expected to be very high [since it can be expected that the systematic review on effectiveness would have been conducted in the same way you would do it and come to the same selection of evidence]*
> > → *No [aswer „No" if „condition and target group" / „intervention" are not the same, even if comparison intervention or relevant outcomes are the same]: Transferability of any domain very low to cero, consider stopping the adaptation process for the whole report here.*
> → *No* → *Reliability of this and rest of domains not given, transferability very questionable, extraction of data from report can be expected not to be easy/ straightforward* → *consider stopping the adaptation process for the whole report here*

Question 3: Is the information provided on technology use and development ~~complete and~~ comprehensive *enough for your purpose*?
> → *Yes [comprehensive enough when it covers all aspects prospectively idenfirfied by you]* → Are the methods and sources used when elaborating the background information well documented?

→ Yes[answer yes if at least sources of information have been cited and can be accessed] → Some of these characteristics (as explained in acompanying table) seem to be intrinsic to technology→ transfer of information without further adaptation possible. For others go to Question 7.
→ No → Transfer with care or do not transfer → Conduct your own summary
→ No → Are the methods and sources used when elaborating the background information well documented?
→ Yes: Consider transfer of available information and addition of missing pieces with own information gathering after retrieving cited sources or contacting manufacturers in your own context.
→ No: Do not transfer these issues. Collect information on these topic following the approaches recommended in CM Domain „Technical Characteristics"

Question 4: Are patterns of utilisation, diffusion, indications and time trends adequately described?
→ Yes [adequate if according to methods proposed in CM Domain „Health Problem and current use"] → Go to Question 7
→ No → The information on these aspects is not reliable, thus you shouldn't transfer it.

Question 5: Is an analysis of the regulatory status of the technology provided (market admission, status in other countries)?
→ Yes → Does it apply to your own context?
→ Yes [EMEA approval status would apply]: Transfer without further adaptation
→ No: Gather your own information on this topic following recommendations on sources from CM [e.g. Domain Legal Aspects] Consider however integrating this information in your report for comparative purposes, as input for discussions, or formulation of policy options which can be relevant for the target audience of your report
→ No → Gather your own information on this topic following recommendations on sources from CM [e.g. Domain Legal Aspects]

Question 6: Is there any consideration of when and how *(variable)* technical characteristics affect
outcomes? [This kind of information has not been provided in the model, consider adding as issue in domain Technical Description]
→ Yes: Integrate this information in you report. Consider this information when assessing effectiveness Domain
→ No: Retreive this information on your own.

Question 7: Are there / or do you expect any differences in the use of this technology within the target setting (compared to the uses described in the HTA report for adaptation)?

→ Yes [you expect differences if for example legal status of technology in your context differs from the one of report, if reimbursement arrangements clearly differ (e.g. you expect other diffusion partners if your system fosters use of technology), resources available, etc.]: Do not transfer information on use, etc. even if appropriately collected (Questions 3,4). Consider following the same method used in the report being assessed for transferability to approach these issues in your own context, after necessary modifications have been done.
Handle overall conclusions, policy options, recommendations of original report carefully (you may discuss them in a comparative exercise, but probably won't be able to transfer them.

→ No: Information on diffusion, use, etc, can be transferred without further adaptation. Conclusions, policy options, recommendations from original report may be fully applicable to your context.

On Toolkit section 5.2 Safety and Core Model chapter safety (assessment elements C)

No response / comment received

On Toolkit section 5.3 Effectiveness and Core Model chapter clinical effectiveness (assessment elements D)

Task 1

1) We agree with how transferability is used in each domain of the toolkit (Technology use, Safety, Effectiveness, Economic).

However, in the toolkit, we only use the term "transferability"; so, introducing the term "generalisability" in the Glossary (as a synonym of transferability) does not help to understand what transferability means. It can create confusion because, we add other concepts as "external validity" which is related to generalisability and it is not related to transferability, and it is not useful for our toolkit.

For the Glossary, we ***propose***:
- *to add "generalisability" and its definition, but we do not recommend to write it as a synonym. Then,*
- *to add a link in "generalisability" as …..see "transferability", and*
- *add a link in "transferability" as ……… see "generalisability".*

Then we ***recommend*** as a definition for **"Transferability":**

"For the WP5 toolkit, transferability is about the ability to apply information and/or data from one report into a report for the user's target setting. Transferability is dependent on context specificity.
Each domain of the WP5 toolkit includes transferability questions and links to relevant resources. The purpose being to help the user decide whether they can adopt, need to adapt or disregard specific information/data when applying these to their target setting".

Task 2

2) In section 5.3 Effectiveness (on page 17), when assessing "transferability", only the following question appears:

Q14. Would you expect the baseline risk of patients within your own setting to be the same as the baseline risk of those patients considered within the HTA report for adaptation? (assuming that patients receive the same treatment and same comparator)

So, if it is not redundant or iterative, we ***recommend*** adding the same questions that are in SAFETY, but applied to EFFECTIVENESS, as follows:

* Does the population described for eligibility match the population to which it is targeted in the target setting?
* Are the requirements for its use (special measures needed for use/implementation, maintenance etc.) available in the target setting?
*   Is the necessary expertise (knowledge and skills) available in the target setting?
* Is effectiveness particularly dependent on training? Is there a need for special training or certification to deliver the intervention properly? Would it be possible (affordable) to organise such training, if any?

Then, comparing WP4Core and toolkit 5.3 (on effectiveness questions), we found that:

a) there is a lack of questions related to HRQL (health related quality of Life) between the two settings

b) there is a lack of questions related to how patient satisfaction has been measured as an outcome for effectiveness.

So, we ***propose*** the possible questions could be:

*	*Would you expect differences on HRQL measures within your own setting to be the same as those considered within the HTA report for adaptation?*
*	*Would you expect differences on how patient satisfaction values are measured within your own setting to be the same as those considered within the HTA report for adaptation?*

Task 3 and 4

3) Proposals on direction as a result of the answer. In the toolkit (page 16):

a)
Q1 - this question is similar to the 1st question of the "speedy sifting", so the answer can only be YES. If it is NO, then you should stop the adaptation process.

Q2 - if the answer is YES, go on with the next question; if the answer is NO, then you can stop the process or you may give a negative point to the question and you can continue with the next question. All negative points should be considered when finishing questions of Box 8.

Q3 - follow the instructions as in question 2.

b)
Q4, 5, 6, 7, 10, 12 -follow the instructions as in question 2

Q8,9 - combine both questions into one; and if the answer is YES, go on with the next question; if the answer is NO, then stop the process of adaptation.

Q11- when the answer is YES, go on with the next question. If it is NO, then you should stop the adaptation process.

Q13 - if the answer can be PROBABLY YES, then you should give a negative point; but when the answer is PROBABLY NO, go on to the next question.

c)
Q14 - when answering YES, go on to next question; when NO, go on applying the statement that follows question 14.

Now, we can summarize the negative points marked (maximum 8 points) and decide if we should stop the process of adaptation or we should continue ….taking into account the low or medium quality of the original HTA report and the possibility of overcoming those problems.

On section 5.4 Economic evaluation and Core Model chapter Costs and economic evaluation (assessment elements E)

Task 1.
Consider our WP5 glossary definition for transferability. Is it clear, is it correct? Are we using this term in the same way within the toolkit? If not, propose a more appropriate 'toolkit' meaning for transferability for glossary.

In my opinion the definition is clear.

Task 2.
Read through the WP4 core model and identify any relevant questions and/or resources on transferability that should be incorporated within the WP5 toolkit.

An important statement of the Core Model is that costs arenot transferable from one country to another.
The Core Model identifies 5 topics: resource utilisation, unit costs, indirect cost, outcomes/consequences and incremental cost effectiveness. These topics need to be mentioned in the Toolkit.

In the outcomes topic, the Toolkit needs to have a question on outcome measures other than QALYs.
The Toolkit consists of a much larger list of references, however two most cited in Core Model (Kristensen 2001 and Guidelines for the Economic Evaluation of Health Technologies, 2006) are not included. These should be included.

Task 3.
Identify those toolkit questions where consequences of yes/no answers are unclear and propose direction as a result of the answer.

I do not have any comments here.
Maybe it might be useful for countries without formal HTA that it is not obligatory to answer all the questions. And to start with those questions that are easily transmitted into one's country.

Task 4.
Suggest a more appropriate structure for questions within the toolkit.

I do not have a problem with the structure as it is, however if the structure were adjusted according to the 5 topics in the Core Model, it might have been clearer.

On section 5.5. Organisational aspects domain and Core model chapters
Organisational aspects

Similarities:
- Both WP's stress that organizational aspects have been studied and documented less extensively in HTA reports until now.
- Both WP's stipulate that findings in the Organizational aspects domain are expected to be more context-dependent and less transferable than other domains of an HTA.
- Both WP's mention the appropriateness of qualitative research for this domain and provide references.
- Both WP's make use of more or less the same topics within the organizational domain.

Comment:
The Core Model provides much more background information about the study of organizational aspects and makes an explicit choice for the translation model (instead of the diffusion model) about how organizational aspects of technologies can be conceptualized. Also, the methodology chapter refers to the model of Leavitt (1965) on organizational change. However, this model is not the one that is used to define the topics within the organizational domain. The step between the choice for the translation model and the selection of topics within the organizational domain is missing. I suppose that the categories are so general and at such a level of abstraction that these might be used within the translation model, but **it would be advisable to make this explicit.** Also, I can see that work has been done to phrase the issue-questions in line with the translation-model and from a non-deterministic point of view.

Proposal for the Core Model:
0. Make explicit how the domains follow from or fit into the translation model.

Task 2

Differences in Questions between Core Model and Toolkit

The Core Model (July 2007) has 8 topics in the organizational aspects domain: Utilisation, Work processes, (De)centralization, Staff, Cooperation and Communication, Finances, Management and Controlling, and Stakeholders. In the Toolkit the dimensions are similar, but Cooperation and communication is called Communication and the topic Management and Controlling is lacking. It is advisable to align the terminology.

Proposals:
1. to use in the Toolkit the term organisational aspects *topics* in stead of organisational aspects *dimensions.*
2. to propose to WP 4 to change *Cooperation and Communication* to the simple and adequate *Communication.*
3. To add the topic Management and Control to the Toolkit Figure 2 Organisational aspects matrix.
4. To follow the eventual updates of the Core Model as far as the number and names of organizational aspects topics is concerned.

Differences in Resources between Core Model and Toolkit

The resources used in the Organisational Aspects domain of the Core Model is an extensive list of references. Judged on the titles, most of these seem to be theoretical background documents on a) organization theory and b) on how to conceptualize the relationship between technology and organization of health care and c) general articles on HTA. Two articles seem particularly interesting specifically for the organizational aspects of HTA:

- on general documents dealing with organisational aspects:
Fulop N Allen P, Clarke A Black N. From HTA to research on the organization and delivery of health services: addressing the balance. Health Policy 63 (2003) 155-165.
- and on assessment of qualitative research:
Leyes M. Health technology assessment : the contribution of qualitative research. IJTAHC 19: 2 (2003) 317-329.

Proposals:
5. To add these two articles to the Toolkit
6. To skip or translate the document in Danish on Assessment of qualitative articles.
7. To present the references in both the Core Model and the Toolkit in the same way, e.g. both the bibliometric reference and an electronic link if available.

Task 3
Consequences of Yes/No questions

This is not an issue for the organisational aspects domain. It quite correctly says "a judgment will be necessary here" for most questions, and I don't think that more can or should be said.

(This concludes the outputs from Work group 5 and from all five work groups)

Conclusions to responses from Work groups

A number of specific practical proposals are made by the various work groups in order to improve and refine the Toolkit (and in some case recommendations have also been made in relation to the Core Model).

Where appropriate, these suggestions could be incorporated into a revised version of the Toolkit. This would then be reviewed as a whole document by all members of WP5 to arrive at a Final version of the Toolkit arising from Work Package 5.

6. Wider testing

In addition to the five groups working within the WP5 membership, members outside WP5 or who had not worked on the development of the toolkit, were invited to use the toolkit to adapt an HTA report of their choosing and provide feedback on their experience through an evaluation questionnaire (Appendix 6). Three individual members from three different HTA agencies took part in this exercise (see spreadsheet of Participants at Appendix 1).

These were DACEHTA/DSI in Denmark, OSTEBA in Spain, and the Directorate of Health in Iceland. Although these agencies were part of WP5, the individuals involved had not worked on the development of the Toolkit and were using it in the same way as any external user.

These individuals were not asked to send in their adapted report, although some sent a link to where it was available, in their own language. They were asked rather to complete a much simplified evaluation questionnaire, with, in addition to detail of the respondent and the HTA report they were adapting, the following 3 questions:

1 What did you like about the toolkit?
2 What did you not like about the toolkit?
3 Any other comments?

The full responses to these questions are given at Appendix 7, and are summarised at the end of the Results section.

Results – Responses

The reports chosen for adaptation were all English language reports, two from Canada and one from US. The reports dated from 2004, 2006 and 2007, and covered the topics of Telemedicine (telecardiology), Testing for BNP and NT-proBNP in the diagnosis and prognosis of heart failure, and Comparative clinical effectiveness and cost-effectiveness of treatment of acute migraine with triptans (and other relevant drugs).

Two of the respondents used the Toolkit actively to adapt a report and commented on all sections of the toolkit – the Speedy sifting section and all five domains. The DACEHTA/DSI report used the toolkit retrospectively to assess its usefulness in a specific context and focussed on the Economic Evaluation domain.

Those who used the Speedy Sifting section found it useful for rapid assessment of relevance and adaptability. There were no suggestions for improvement of this section.

OSTEBA gave detailed comments on the usefulness of all five domains of the main section of the toolkit, whilst DH Iceland made more general positive comments. DACEHTA/DSI found the questions within the Economic domain relevant and useful for economic evaluations. OSTEBA commented that their chosen report did not contain enough economic information to assess this section fully, and they used an additional study to supply this data.

Users found the links to further information and explanation useful, but accessing them tended to slow the adaptation process.

In terms of ways to improve the toolkit, the most detailed and constructive suggestions came form OSTEBA, who proposed the inclusion of an objective scale of relevance. They gave detailed suggestions for clarification of specific questions in each of the domains, sometimes in relation to wording, sometimes requiring additional explanation or information

Both OSTEBA and DH Iceland suggested the merging of certain pairs of related questions.

DACEHTA/DSI commented that the stated aim of the toolkit is to adapt reports that are a synthesis of evidence, whereas the questions in the economic evaluation section are focussed on the assessment of individual primary research/ economic evaluations. The implication here is that the stated aim is inaccurate and that the toolkit is better suited to the

assessment of primary economic evaluations than to guide a synthesis of primary economic studies.

A summary table of these individual responses follows. The original evaluation forms are at Appendix 7.

Conclusions to wider testing call

Although only three 'cold' adaptations were carried out using the toolkit in this part of the applicability testing, the responses provide a range of useful suggestions for further refinement of the toolkit. In contract to the five working groups, each concentrating on a specific topic and use of the toolkit, with which they are already familiar, these responses give a global overview from new users not previously involved in the toolkit development

This report was produced by the EUnetHTA team at NCCHTA Southampton UK, with contributions from all WP5 Partner Agencies (See Appendix 1).

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June 2008

Summary of responses to the wider call for testing by those not involved in development of the toolkit

HTA Agency	Country	HTA Topic	Date of publication	Language of report	Country of origin of report	Domain focus of adaptation
Basque Office for HTA (OSTEBA)	Spain	Telemedicine (telecardiology)	2004	English	Canada	All
N/A Directorate of Health	Iceland	Testing for BNP and NT-proBNP in the Diagnosis and Prognosis of Heart Failure	September 2006	English	USA	All
DACEHTA subcontracted to DSI Danish Institute of Health Services Research	Denmark	Comparative clinical effectiveness and cost-effectiveness of treatment of acute migraine with triptans (and other relevant drugs)	March 2007	English	Canada	Economic evaluation domain

Experience of using the Adaptation toolkit

1. What did you like about the Toolkit?	
<u>Speedy sifting</u>: We found this section of the toolkit very useful for a rapid assessment of the relevance of a given report for adaptation. The speedy sifting may aid a quick screening of the HTA reports that can be used for adaptation into our own report. <u>Main part of the toolkit</u>: The different sections that constitute the main part of the toolkit provide valuable information to help and guide the assessment of the studies included in the systematic review / HTA report. The main part of the adaptation toolkit points out several very relevant aspects regarding the usability of other HTA reports. 1) *Technology use domain:* the questions included in this domain are very useful to define the aspects related to the studied technology and to analyse if any of them differ from one concrete setting to another, especially with the aid of the further explanation link. As a general comment, the technology use domain has been a helpful tool to help determine the different purposes of the chosen telecardiology report. 2) *Safety domain:* the specific questions of this domain allow a thorough analysis of the safety issues related to the technology. However, it should be pointed out that the safety aspects were not the main focus of the chosen report in telecardiology.	OSTEBA

3) *Effectiveness domain*: the proposed questions for this domain are appropriate for the assessment of the relevance, reliability and transferability of HTA reports. The further explanation link at the end of box 8 is especially useful because several questions require further clarification of the key aspects that need to be looked at in the original HTA report. 4) *Economic evaluation domain:* given the nature of the chosen HTA report, it was impossible to carry out the assessment of the questions corresponding to the economic evaluation domain since there were not enough data regarding the economic evaluation within the selected report. Therefore, we selected a good quality study (which scored highly for the specified criteria in the field of economic analysis) included in the HTA report to carry out this task. We, therefore, evaluated the economic domain of the toolkit based on the study entitled "Reducing the cost of frequent hospital admissions for Congestive Herat Failure. A randomized trial of a home telecare intervention" (Jerant *et al.*, 2001). It should be pointed out that in the selected study the authors carry out a cost analysis of the selected alternatives, without any mention to the effectiveness of such treatments. We consider that the questions proposed for the economic evaluation domain are adequate for the intended purposes, i.e. to evaluate the relevance and reliability of a study in which a complete economic evaluation is carried out. The questions related to transferability aided the evaluation of the specific context of the different settings in which the economic analysis was conducted. 5) *Organisational aspects domain:* the key questions and aspects pinpointed in this domain are particularly useful for the specific case of telemedicine. We found the link with further information at the bottom of the Question box 12 very useful for the assessment of the organisational issues that may be relevant when adapting the HTA report.	
The speedy sifting questions cover all the main issues that I need to make a preliminary assessment. Good separation of the 5 domains that cover the main issues. Very good and comprehensive additional resources for all domains and general issues.	DH Iceland
The set of questions are relevant and useful for the assessment of primary economic evaluations.	DACEHTA /DSI
2. What did you not like about the Toolkit?	
As a general comment, it would be useful to include guidance to advise how the information obtained through the toolkit can be applied in deciding whether an HTA report or parts of it are relevant for adaptation. It could be useful to include some kind of straight forward scale to decide objectively whether the report is useful or not. 1) *Technology use domain:* Regarding Question 6 to assess transferability, it would be useful to explain the main considerations to take into account for each type of technology (avoiding the generalisation given in the further explanation). In question 7, there is a need to explain what are the different uses to be considered (Protocol? Patients? Indications?) 2) *Safety domain:* in Question 1, there was a need to follow up the link for further explanation. In Question 7, the aim is not very well understood (maybe there is a need for information about how bias in the selection of studies can be avoided).	OSTEBA

3) *Effectiveness domain*: Question 14 (transferability assessment) is formulated in a way that is not easy to understand unless the link for further explanation is followed. The question could be rephrased or slightly altered in order to make it clearer. The rest of the questions from box 8 are clear and easy to understand. However, on some occasions it was necessary to consult the link for further explanation, making the process slightly slower. A few questions of the domain may not be applicable to the specific topic of the report under evaluation, *i.e.*: telecardiology. 4) *Economic evaluation domain:* From our point of view, Questions 6 and 7 (related to effectiveness) in box 10 could be put together into a single question. The same applies to Questions 11 and 12 (related to health – quality of life) and Questions 21 and 22 (related to the sensitivity of the analysis). This could help to make this specific domain of the toolkit a bit lighter. Regarding Question 28 within the transferability section, parts c) and l) require further clarification. In part c) instead of using "relative costs", it would be better to use "direct costs" and in part l) we could not understand what "reproduction" refers to. 5) *Organisational aspects domain:* With regard to the "Organisational aspects matrix", more information should be provided to aid the completion of the matrix. It is not clear how to fill out the matrix and how can it help to determine whether the information regarding the organisational aspects of the HTA report is relevant or not.	
Long but necessarily so. In the main toolkit, perhaps some less important questions might be separated from others (hierarchy of importance??) (5.1. no.4, 5.2. nos. 18+19). Repeated similar questions (i.e. 5.2. no 15 vs 5.3. no. 14) and validity questions that might be combined or marked accordingly (5.2. no 9 and 10 = 5.3. no 8 and 9). These are all minor suggestions without me seeing any practical solution or at least none that could make this very good work better.	DH Iceland
The stated aim of the toolkit is to aid in the adaptation of HTA reports that are a synthesis of evidence. The adaptation of HTA reports that are primary research is not addressed in the report (section 2, p. 4). My perception of the questions in the economic evaluation domain is that they are focused on the assessment of individual primary research / individual economic evaluations, and less focused on assessment of secondary synthesis of primary economic studies. Indeed, the two main sources of the questions (CCOHTA/CADTH guidelines and Drummond et. al) are both developed with the assessment of a primary economic evaluation in mind. Contrary to the stated aim of the toolkit, this part of it is best suited to the assessment of individual, primary economic evaluations, and not really	DACEHTA /DSI

very well suited to guide a synthesis of primary economic studies. As a tool for adaptation of a secondary analysis of economic evaluations, like the one we encountered in the Canadian report, most of the questions in the effectiveness section of the tool appear to be useful also for the economic part of an HTA. Questions 1,2,3,5 and perhaps 6 in the economic evaluation section can be used to describe inclusion and exclusion criteria in a secondary research project. They can be seen as a sub-specification of question 5 in the effectiveness section. Most of the other questions in the economic section address quality characteristics or other characteristics of the individual primary economic evaluation. A useful secondary analysis should extract data on as many as possible of these characteristics. In my opinion, these issues are relevant for a secondary analysis, but in this specific context, they should be rephrased to reflect the focus on adaptation of secondary research.	
3. Other comments	
Section 5.5 – Organisational aspects domain. As a general comment to section 5.5,we would like to point out that, although we fully agree that the organisational aspects should be included in HTA reports, there is an inherent difficulty in doing so since it requires an in-depth knowledge of the health services organisation in both settings – our particular setting, and the setting of the study/report. It would be useful to add some links with general information to provide an overview of the different health systems from other countries.	OSTEBA
Works better for Interventions than Diagnosis understandably Congratulations – great work.	DH Iceland
The speedy sifting part of the toolkit was not directly relevant for our task as a subcontractor. The selection of the topic and the report to review/comment on was done by DACEHTA. The "adaptation" in this particular case consists of writing a "commented foreign health technology assessment". The purpose of our report was to summarize methods and results of the original report and critically assess if and how the results of the original report can be used when deciding on how to treat acute migraine in Denmark. The adaptation toolkit wasn't actually used when we produced our report. Our comments are based on a retrospective assessment of the usefulness of the adaptation toolkit in this particular context, and focus on the usefulness of the economic evaluation domain of the toolkit.	DACEHTA /DSI

Appendix 1

**Participation in WP5 Applicability Testing Round 2,
October 2007- March 2008**

Agency			Activity
Associated Partner (AP)			
AETSA	Sevilla	Spain	Groups 1 & 4
ASR	Bologna	Italy	Group 3
ASSR	Rome	Italy	Groups 3 & 4
Cochrane Collaboration	Oxford	UK	Group 2
DACEHTA	Copenhagen	Denmark	Group 3 & Wider call
DIMDI	Cologne	Germany	Group 1
DSI		Denmark	Group 4 & Wider call
FinOHTA	Helsinki	Finland	Groups 2,3 & 4
HAS	Paris	France	Group 1
IPH		Slovenia	Group 5
KCE		Belgium	Group 3
LBI (ITA)	Vienna	Austria	Group 4
NOKC		Norway	Group 2
OSTEBA	San Sebastian	Spain	Group 5 & Wider call
Regione Veneto	Venice	Italy	Groups 3 & 4
SEP	Canary Is	Spain	Group 1
TU Berlin	Berlin	Germany	Group 5
UCSC	Rome	Italy	Groups 2 & 3
University Tartu	Tartu	Estonia	Group 4
ZonMW		Netherlands	Group 5
Collaborating Partners (CP)			
Directorate of Health		Iceland	Group 2 & Wider call
PHGEN	Bielefeld	Germany	Group 1
HTA agency		Poland	Groups 1, 4 & 5
Hauptverband ………	Vienna	Austria	Group 2
IMM		Portugal	Group 1
OEBIG		Austria	
SNHTA	Lausanne	Switzerland	Group 5

Participation in WP5 Applicability Testing Round 2 October 2007-March 2008

Agency			Group 1 Interactive Toolkit	Group 2 Diagnostic & Screening	Group 3 Organisational aspects	Group 4 Cost-effectiveness modelling	Group 5 Transferability	Wider call
Associated Partner (AP)								
AETSA	Sevilla	Spain	Victor Sarmiento-Gonzales			Victor Sarmiento-Gonzales Belén Corbacho Martín		
ASR	Bologna	Italy			Elena Berti Roberto Grilli			
ASSR	Rome	Italy			Alessandra Lo Scalzo	Maria Rosaria Perrini		
Cochrane Collaboration	Oxford	UK		Mike Clarke				
DACEHTA	Copenhagen	Denmark			Camilla Palmhøj Nielsen			(Henrik Hauschildt Juhl)
DIMDI	Cologne	Germany	Hans-Peter Dauben					
DSI		Denmark				Jakob Kjelberg		Henrik Hauschildt Juhl
FinOHTA	Helsinki	Finland		Iris Pasternack Kristian Lampe	Ulla Saalasti-Koskinen	Pirjo Räsänen	Kristian Lampe	
HAS	Paris	France	Fabienne Quentin					
IPH		Slovenia					Eva Turk	
KCE		Belgium			Mark Leys			
LBI (ITA)	Vienna	Austria				Philipp Radlberger Ingrid Zechmeister		
NOKC		Norway		Katrine Bjørnebek Frønsdal				
OSTEBA	San Sebastian	Spain					Nieves Sobradillo Rosa Rico	Estibalitz Orruño
Regione Veneto	Venice	Italy			Giampietro Rupolo	Teresa Gasparetto		
SEP	Canary Is	Spain	Julio Lopez Bastida					
TU Berlin	Berlin	Germany					Marcial Velasco	
UCSC	Rome	Italy		Thomas Jefferson	Marina Cerbo			
University Tartu	Tartu	Estonia				Kersti Meiesaar		
ZonMW		Netherlands					Jessika van Kammen	

| Agency | | | Group 1 | Group 2 | Group 3 | Group 4 | Group 5 | Wider call |
			Interactive Toolkit	**Diagnostic & Screening**	**Organisational aspects**	**Cost-effectiveness modelling**	**Transferability**	
Collaborating Partners (CP)								
Directorate of Health		Iceland		Prof Sigurdur Thorlacius				Sigurður Helgason
PHGEN	Bielefeld	Germany	Tobias Schulte in den Baumen					
HTA agency		Poland	Jadwiga Czeczot			Łukasz Tanajewski	Zbigniew Krol	
Hauptverband ………	Vienna	Austria		Irmgard Schiller-Fruewirth				
IMM		Portugal	Cristina Sampaio					
OEBIG		Austria						
SNHTA	Lausanne	Switzerland					Bernard Burnand	

Appendix 2

Thank you again to all WP5 Members who attended the WP5 Members' Meeting in Venice 27-28 September 2007. It was an extremely productive meeting, with active participation by all those who attended. A note of the meeting is attached here and can also be found on the EUnetHTA website, together with presentation slides.

Part of the programme involved active group work on the WP5 Glossary, and a note by Claire Rosten of the feedback from that session is also attached.

Plans for the final stage of the WP5 work package were outlined in Venice, and work was commenced on the second round of Applicability Testing for the Adaptation Toolkit. This will focus on ways of working with the Toolkit, and members each selected one of **five topic areas** to work on:

> Interactive Toolkit
> Diagnostic & Screening
> Organisational Aspects
> Cost-effectiveness Modelling
> Transferability

A note of the issues generated by these groups in Venice, plus a list of the members of each work group is attached here – we have added *in italics* the names of those who, though not present, were suggested by colleagues, or whom we think will be interested in this topic area. The work will proceed by email and teleconference, culminating in an eMeeting and report in March 2008.

Please look at the list – if your name has been added to a group and you would prefer to work on a different topic area, please let us know. Similarly, if you wish to volunteer yourself or a colleague for a particular work group, please let us know.

We would like to finalise these groups before the end of November – please **confirm** your participation by **Friday 23 November 2007**. If we hear nothing, we will assume you are happy with your group. More detailed instructions will be sent out to each group individually.

NB Every WP5 Associated Partner organisation **must** participate in at least **one** Work Group – if different colleagues from an organisation wish to participate in more than one group, that is fine. We hope that as many Collaborating Partners as possible will also participate.

WP5 Lead Partner NCCHTA, Southampton UK, is also working on a more comprehensive Toolkit version 3 which will be offered in December to EUnetHTA members outside WP5 who have not been involved with the Toolkit development, in order to test its use among a wider user group. Further information on this will be sent out via the Members' Updates.

If you have any questions on the above, please do not hesitate to contact me, by email or by telephone.

With best wishes

Eleanor Bell
Project Manager EUnetHTA project
National Coordinating Centre for HTA (NCCHTA)
University of Southampton
Southampton SO16 7PX

Tel: +(44) 23 80 595623
email: e.bell@soton.ac.uk
www.hta.ac.uk/eunethta

Appendix 3

WP5 Applicability Testing Round 2 – Work group membership

Work Group 1 – Interactive Toolkit

Fabienne Quentin, HAS, France (AP)

Victor Sarmiento Gonzalez, AETSA, Spain (A*P)*

Hans-Peter Dauben, DAHTA @ DIMDI, Germany (AP)

Julio Lopez Bastida, Canary Is., Spain (AP)

Jadwiga Czeczot, HTA Agency, Poland (CP)

Tobias Schulte in den Bäumen, PHGEN, Germany (CP)

Cristina Sampaio, IMM, Portugal (CP)

Work Group 2 – Diagnostic & Screening

Iris Pasternack, FinOHTA, Finland (AP)

Katrine Bjørnebek Frønsdal, NOKC, Norway (AP)

Kristian Lampe, FinOHTA, Finland (AP)

Mike Clarke, Cochrane Collaboration, UK (AP)

Thomas Jefferson, UCSC Rome, Italy (AP)

Irmgard Schiller-Fruewirth, Hauptverband…, Austria (CP)

Prof Sigurdur Thorlacius, Iceland (CP)

Work Group 3 – Organisational Aspects

Alessandra Lo Scalzo, ASSR Roma, Italy

Marina Cerbo, UCSC, Roma, Italy (AP)

Camilla Palmhøj Nielsen, DACEHTA, Denmark (AP)

Giampietro Rupolo, Regione Veneto, Italy (AP)

Elena Berti, ASR Bologna, Italy (AP)

Roberto Grilli, ASR Bologna, Italy (AP)

Ulla Saalasti-Koskinen, FinOHTA, Finland (AP)

Mark Leys, KCE, Belgium (AP)

Work Group 4 – Cost-effectiveness modelling

Teresa Gasparetto, Regione Veneto, Italy (AP)

Victor Sarmiento-Gonzalez, AETSA, Spain (AP)

Belén Corbacho Martín, AETSA, Spain (AP)

Kersti Meiesaar, University Tartu, Estonia (AP)

Maria Rosaria Perrini, ASSR Roma, Italy (AP)

Philipp Radlberger, LBI (ITA), Austria (AP)

Ingrid Zechmeister, LBI (ITA), Austria (AP)

Pirjo Räsänen, FinOHTA, Finland (AP)

Jakob Kjelberg, DSI, Denmark (AP)

Łukasz Tanajewski, HTA Agency, Poland (CP)

Work Group 5 – Transferability

Jessika van Kammen, ZonMW, Netherlands (AP)

Kristian Lampe, FinOHTA, Finland (AP)

Eva Turk, IPH, Slovenia (AP)

Marcial Velasco, TU Berlin, Germany (AP)

Nieves Sobradillo, OSTEBA, Spain (AP)

Rosa Rico, OSTEBA, Spain (AP)

Zbigniew Krol, HTA Agency, Poland (CP)

Bernard Burnand, SNHTA Lausanne, Switzerland (CP)

Appendix 4

Group 1: Interactive toolkit

Group work problem

WP5 members have expressed the need to develop an interactive web-based version of our toolkit. How could this best be achieved?

Proposed solutions

- Need for guidance and help files (what to do next)
- Need for a validation test

Group organisation

It is up to the group how they wish to organise themselves. For simplicity, we have suggested a group leader, but you are free to nominate someone else if you wish. The group leader (or facilitator) will be responsible for co-ordinating the work of the group and feeding back on the experience in the form of **a short written report.**
Proposed leader: Hans-Peter Dauben

Timescale:

Group has until early March 2008 to undertake this task. An **e-Meeting** will be scheduled as soon as you are ready for you to report your findings and discuss progress.
Please complete the short written report **no later than 14 March 2008.**

Tasks:

1. Group members to test the usefulness of the current i-toolkit prototype as developed by H-P Dauben. Group members should each identify a report to adapt, and adapt it unaided using the interactive version of the toolkit. Members should feedback comments on the usefulness of the i-toolkit prototype to the facilitator, suggesting improvements as necessary.
2. Group members should further develop the i-toolkit as a result of the above testing, e.g. incorporating a logical flow of questions into i-toolkit.
3. A developed prototype i-toolkit should be presented to the group eMeeting before 14 March 2008.

The intention subsequently would be to offer the i-toolkit prototype for testing within the whole WP5 membership.

Optional extra: If one member completes Task 1 ahead of others, then if possible offer the   i-toolkit to a colleague who has not helped to develop it and ask them to test it unaided, then report back / learn the lessons from this experience.

eMeeting:

The purpose of this is sharing + validation. The outcome of the group work and eMeeting will be a document report to WP5 lead organisation, NCCHTA.

A date and time of the eMeeting will be scheduled by NCCHTA in consultation with group members.

Please ensure that you have the requisite CENTRA technology installed locally and have practised using it well before March 2008.

Debbie Chase
Eleanor Bell
NCCHTA, Southampton UK
November 2007

Group 2: Diagnostic testing and screening

Group work problem

"Our toolkit is not very helpful in adapting HTAs on diagnostic testing or screening programmes".

Should we place a health warning on our toolkit, i.e. 'we do not recommend the use of this tool in adapting diagnostic test or screening HTAs'?

Or can you propose changes and/or additions to our toolkit that would enable better adaptation of such HTAs?

Proposed solutions

- o Certain domains need further work (effectiveness domain most important)
- o Specific relevance and reliability questions needed
- o Minor changes needed – lends itself to an interactive version which pre-selects relevant questions for this domain.

Group organisation

It is up to the group how they wish to organise themselves. For simplicity, we have suggested a group leader, but you are free to nominate someone else if you wish. The group leader (or facilitator) will be responsible for co-ordinating the work of the group and feeding back on the experience in the form of **a short written report**.
Proposed leader: Lisa Lund Håheim

Timescale:

Group has until early March 2008 to undertake this task. An **e-Meeting** will be scheduled as soon as you are ready for you to report your findings and discuss progress.
Please complete the short written report **no later than 14 March 2008.**

Tasks:

1. The group felt that work should focus on the **effectiveness** domain of the toolkit. Members should propose questions on the effectiveness of diagnostic tests and screening programmes (and links to resources) for incorporation into the toolkit. Members should state where these questions fit within the current version of the toolkit and provide explanations for questions (where there might be misunderstanding)

2. If time, the group should consider whether there is a need for questions (and resources) on diagnostic tests and screening in the other toolkit domains (selected domains or all domains).

__eMeeting:__

The purpose of this is sharing + validation. The outcome of the group work and eMeeting will be a document report to WP5 lead organisation, NCCHTA.

A date and time of the eMeeting will be scheduled by NCCHTA in consultation with group members.

Please ensure that you have the requisite CENTRA technology installed locally and have practised using it well before March 2008.

Debbie Chase
Eleanor Bell
NCCHTA, Southampton UK
November 2007

Group 3: Organisational aspects

Group work problem

"The organisational aspects domain of our toolkit is confusing and not very helpful in the adaptation of data and information on organisational aspects".

Should we have an organisational aspects domain within our toolkit? If so, what changes and additions do you propose to make it clearer and more helpful for the user?

Proposed solutions

- o Yes, this domain should be included in the toolkit
- o Take 'level' out of the matrix – it is unhelpful, questions are better
- o Feedback to the user is an important developmental factor ($\rightarrow$ i-toolkit)
- o Co-ordinate this domain with WP4

Group organisation

It is up to the group how they wish to organise themselves. For simplicity, we have suggested a group leader, but you are free to nominate someone else if you wish. The group leader (or facilitator) will be responsible for co-ordinating the work of the group and feeding back on the experience in the form of a **short written report**. *Proposed leader:* Camilla Palmhøj Nielsen

Timescale:

Group has until early March 2008 to undertake this task. An **e-Meeting** will be scheduled as soon as you are ready for you to report your findings and discuss progress.

Please complete the short written report **no later than 14 March 2008.**

Tasks:

1. Read through the WP4 core model section on organisational aspects and incorporate the relevant information, data and links within the organisational aspects domain of the WP5 toolkit.
2. Re-develop the 'matrix' as discussed earlier to make it easier to understand and use.
3. Provide further explanations and clarity to the questions posed in this domain.

4. Test the usefulness of this domain by adapting data on organisational aspects from a chosen HTA report – you can do this collectively or individually on one report or on several different reports.

__eMeeting:__

The purpose of this is sharing + validation. The outcome of the group work and eMeeting will be a document report to WP5 lead organisation, NCCHTA.

A date and time of the eMeeting will be scheduled by NCCHTA in consultation with group members.

Please ensure that you have the requisite CENTRA technology installed locally and have practised using it well before March 2008.

__Debbie Chase__
__Eleanor Bell__
NCCHTA, Southampton UK
November 2007

Group 4: Cost-effectiveness modelling

Group work problem

"It would be really helpful if the toolkit provided advice and information on how to adapt cost-effectiveness models".

Is this possible? And if so, how could it be achieved?

Proposed solutions

- o Economic Evaluation group to work through the modelling issues
- o Devise a question for **each** issue - c**ritical** questions
- o Other issues proposed by group

Group organisation

It is up to the group how they wish to organise themselves. For simplicity, we have suggested a group leader, but you are free to nominate someone else if you wish. The group leader (or facilitator) will be responsible for co-ordinating the work of the group and feeding back on the experience in the form of a short written report.
Proposed leader: Teresa Gasparetto

Timescale:

Group has until early March 2008 to undertake this task. An **e-Meeting** will be scheduled as soon as you are ready for you to report your findings and discuss progress.
Please complete the short written report **no later than 14 March 2008.**

Tasks:

1. Incorporate proposed questions (suggested during group work) into the current version of our toolkit. Check that the group are happy with these additions and if there are further questions to include on modelling (and any links to resources).

2. Provide some proposed text and explanation for this part of the cost-effectiveness domain.

3. Test this section of the toolkit, i.e. adapt a cost-effectiveness model using the questions and resources proposed by the group and feed back.

eMeeting:

The purpose of this is sharing + validation. The outcome of the group work and eMeeting will be a document report to WP5 lead organisation, NCCHTA.

A date and time of the eMeeting will be scheduled by NCCHTA in consultation with group members.

Please ensure that you have the requisite CENTRA technology installed locally and have practised using it well before March 2008.

Debbie Chase
Eleanor Bell
NCCHTA, Southampton UK
November 2007

Group 5: Transferability

Group work problem

"Our toolkit doesn't provide enough advice on how to transfer information and data to another setting".

What do you think is required and how could this best be achieved?

Proposed solutions

- Need to make clear consequences of Yes/No questions
- Need better structure to questions, more explanations
- Set up a sub-group on transferability to link with WP4
- Need a clear definition of transferability

Group organisation

It is up to the group how they wish to organise themselves. For simplicity, we have suggested a group leader, but you are free to nominate someone else if you wish. The group leader (or facilitator) will be responsible for co-ordinating the work of the group and feeding back on the experience in the form of **a short written report.** **_Proposed leader:_** Jessika van Kammen

Timescale:

Group has until early March 2008 to undertake this task. An **e-Meeting** will be scheduled as soon as you are ready for you to report your findings and discuss progress.

Please complete the short written report **no later than 14 March 2008.**

Tasks:

1. Consider our WP5 glossary definition for transferability. Is it clear, is it correct? Are we using this term in the same way within the toolkit?
   If not, propose a more appropriate 'toolkit' meaning for transferability for glossary.

2. Read through the WP4 core model and identify any relevant questions and/or resources on transferability that should be incorporated within the WP5 toolkit.

3. Identify those toolkit questions where consequences of yes/no answers are unclear and propose direction as a result of the answer.

4. Suggest a more appropriate structure for questions within the toolkit.

eMeeting:

The purpose of this is sharing + validation. The outcome of the group work and eMeeting will be a document report to WP5 lead organisation, NCCHTA.

A date and time of the eMeeting will be scheduled by NCCHTA in consultation with group members.

Please ensure that you have the requisite CENTRA technology installed locally and have practised using it well before March 2008.

Debbie Chase

Eleanor Bell

NCCHTA, Southampton UK

November 2007

Appendix 5

<u>**Call to all EUnetHTA members**</u>

<u>**HTA Adaptation Toolkit – Applicability Testing Round 2**</u>

Over the past 18 months, Work Package 5 members have worked together to develop a EUnetHTA HTA adaptation toolkit. This toolkit is composed of a series of checklists and resources which address the relevance, reliability and transferability of data and information from existing reports.

The toolkit was launched at the HTAi Barcelona conference in June 2007. Since that time, we have asked our WP5 members to test the toolkit for quality assurance purposes (applicability testing round 1). Members were asked to adapt an HTA report, of their choosing, using the toolkit, into a report for their own setting. We have made some further refinements to the toolkit as a result of this first testing round.

We would now like to ask the entire EUnetHTA membership (outside of WP5) to test the toolkit for applicability testing round 2. Please undertake this task (on one or more HTA report/s) and provide us with feedback by 14th March 2008.

The latest version of our Toolkit (version 3) can be found on WP5 pages of the EUnetHTA website.
www.eunethta.net/Members_only/Workpackages/Workpackage_5/Applicability_testing/

Please:

(1) Use the toolkit and associated tables to help you adapt an HTA report, of your choosing, into a report for your local setting

(2) Complete the brief evaluation form (one per HTA report adapted) and forward it to eunethta@soton.ac.uk by 14th March 2008

Your contribution will help us further quality assure our EUnetHTA adaptation toolkit. This toolkit will be promoted to HTA agencies worldwide. We want to get it right!

Many thanks in anticipation and kind regards,

EUnetHTA team,
NCCHTA
Southampton UK

5 December 2007

Appendix 6

eunethta

Dear EUnetHTA members,

Welcome to the second round of applicability testing the EUnetHTA HTA adaptation toolkit!

Your task is to adapt one or more HTA reports using our toolkit. Please choose which HTA report/s you would like to adapt. Use the toolkit to help you adapt your chosen report/s and then complete this evaluation form for each individual HTA report you choose to adapt, e.g. if you adapt information from two different reports dealing with the same topic please complete a form for each report, i.e. two forms. Please e-mail eunethta@soton.ac.uk with your completed evaluation form by **14th March 2008**. There is no need to submit your adapted report/s to us – only the evaluations.

We look forward to receiving your completed evaluation forms.

If you have any questions or concerns regarding this task, please do not hesitate to contact us.

Kind regards,

NCCHTA EUnetHTA team
Southampton UK

Ruairidh Milne
Nick Hicks
Debbie Chase
Eleanor Bell
Claire Rosten
Liz Payne

5 December 2007

Section A: Information about you			
HTA Agency		Country	
Name of respondent		Email	

Section B: Information about the report you wish to adapt	
HTA topic	
Report title	
Authors	
Date of publication	
Language of report	
Country of origin	
URL link to report *(if possible)*	

Section C: Information about your experience of using our adaptation toolkit
1. What did you like about the toolkit?

2. What did you not like about the toolkit?

3. Any other comments?

Please e-mail eunethta@soton.ac.uk with your completed evaluation form by **14th March 2008**. Thank you.

Appendix 7 – Evaluation responses to wider call

Section A: Information about you			
HTA Agency	Basque Office for HTA (OSTEBA)	Country	Spain
Name of respondent	Dr Estibalitz Orruño Dr Nora Ibargoyen Juan Carlos Bayon	Email	e-orruno@ej-gv.es n-ibargoyen@ej-gv.es jc-bayon@ej-gv.es

Section B: Information about the report you wish to adapt	
HTA topic	Telemedicine (telecardiology)
Report title	Evidence for the benefits of telecardiology applications: a systematic review
Authors	David Hailey, Arto Ohinmaa, Risto Roine
Date of publication	2004
Language of report	English
Country of origin	Canada
URL link to report *(if possible)*	http://www.ihe.ca/hta/hta_unit.html

Section C: Information about your experience of using our adaptation toolkit
4.   What did you like about the toolkit?
Speedy sifting: We found this section of the toolkit very useful for a rapid assessment of the relevance of a given report for adaptation. The speedy sifting may aid a quick screening of the HTA reports that can be used for adaptation into our own report. Main part of the toolkit: The different sections that constitute the main part of the toolkit provide valuable information to help and guide the assessment of the studies included in the systematic review / HTA report. The main part of the adaptation toolkit points out several very relevant aspects regarding the usability of other HTA reports. 1) *Technology use domain:* the questions included in this domain are very useful to define the aspects related to the studied technology and to analyse if any of them differ from one concrete setting to another, especially with the aid of the further explanation link. As a general comment, the technology use domain has been a helpful tool to help determine which are the different purposes of the chosen telecardiology report.

2) *Safety domain:* the specific questions of this domain allow a thorough analysis of the safety issues related to the technology. However, it should be pointed out that the safety aspects were not the main focus of the chosen report in telecardiology.

3) *Effectiveness domain*: the proposed questions for this domain are appropriate for the assessment of the relevance, reliability and transferability of HTA reports. The further explanation link at the end of box 8 is especially useful because several questions require further clarification of the key aspects that need to be looked at in the original HTA report.

4) *Economic evaluation domain:* given the nature of the chosen HTA report, it was impossible to carry out the assessment of the questions corresponding to the economic evaluation domain since there were not enough data regarding the economic evaluation within the selected report. Therefore, we selected a good quality study (which highly scored for the specified criteria in the field of economic analysis) included in the HTA report to carry out this task. We, therefore, evaluated the economic domain of the toolkit based on the study entitled "Reducing the cost of frequent hospital admissions for Congestive Herat Failure. A randomized trial of a home telecare intervention" (Jerant *et al.*, 2001). It should be pointed out that in the selected study the authors carry out a cost analysis of the selected alternatives, without any mention to the effectiveness of such treatments. We consider that the questions proposed for the economic evaluation domain are adequate for the intended purposes, i.e. to evaluate the relevance and reliability of a study in which a complete economic evaluation is carried out. The questions related to transferability aided the evaluation of the specific context of the different settings in which the economic analysis was conducted.

5) *Organisational aspects domain:* the key questions and aspects pinpointed in this domain are particularly useful for the specific case of telemedicine. We found the link with further information at the bottom of the Question box 12 very useful for the assessment of the organisational issues that may be relevant when adapting the HTA report.

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5. What did you not like about the toolkit?

As a general comment, it would be useful to include a sort of guidance to advice about how the information obtained through the toolkit can be applied in deciding whether an HTA report or parts of it are relevant for adaptation. It could be useful to include some kind of straight forward scale to decide objectively whether the report is useful or not.

1) *Technology use domain:* Regarding the Question 6 to assess transferability, it would be useful to explain the main considerations to take into account for each type of technology (avoiding the generalisation given in the further explanation). In question 7, there is a need to explain what are the different uses to be considered (protocol? Patients? Indications?)

2) *Safety domain:* in Question 1, there was a need to follow up the link for further explanation. In Question 7, the aim is not very well understood (maybe there is a need of information about how can bias in the selection of studies be avoided).

3) *Effectiveness domain*: Question 14 (transferability assessment) is formulated in a way that is not easy to understand unless the link for further explanation is followed. The question could

be rephrased or slightly altered in order to make it clearer.

The rest of the questions from box 8 are clear and easy to understand. However, in some occasions it was necessary to consult the link for further explanation, making the process slightly slower. A few questions of the domain may not be applicable to the specific topic of the report under evaluation, *i.e.*: telecardiology.

4) *Economic evaluation domain:* From our point of view, Questions 6 and 7 (related to the effectiveness) in box 10 could be put together into a single question. The same applies to Questions 11 and 12 (related to health – quality of life) and Questions 21 and 22 (related to the sensitivity of the analysis). We think that this could help making this specific domain of the toolkit a bit lighter.

Regarding the Question 28 within the transferability section, we think that parts c) and l) require further clarification. In part c) instead of using "relative costs", we think it would be best to use "direct costs" and in part l) we could not understand properly what "reproduction" refers to.

5) *Organisational aspects domain:* With regards to the "Organisational aspects matrix", we think that there should be more information provided to aid the completion of the matrix. It is not clear how to fill out the matrix and how can it help to determine whether the information regarding the organisational aspects of the HTA report is relevant or not.

6. Any other comments?

Section 5.5 – Organisational aspects domain.
As a general comment to section 5.5, we would like to point out that, although we fully agree that the organisational aspects should be included in HTA reports, there is an inherent difficulty in doing so since it requires an in-depth knowledge of the health services organisation in both, our particular setting, and the setting of the studies/report.

It would be useful to add some links with general information to provide an overview of the different health systems from other countries.

Please e-mail eunethta@soton.ac.uk with your completed evaluation form by **14th March 2008**. Thank you.

Section A: Information about you			
HTA Agency	NONE (Directorate of Health)	Country	Iceland
Name of respondent	Sigurður Helgason	Email	sh@centrum.is

Section B: Information about the report you wish to adapt	
HTA topic	Testing for BNP and NT-proBNP in the Diagnosis and Prognosis of Heart Failure
Report title	Testing for BNP and NT-proBNP in the Diagnosis and Prognosis of Heart Failure
Authors	Balion C, Santaguida P, Hill S, Worster A, McQueen M, Oremus M, McKelvie R, Booker L, Fagbemi J, Reichert S, Raina P.
Date of publication	September 2006
Language of report	english
Country of origin	USA
URL link to report *(if possible)*	http://www.ahrq.gov/clinic/tp/bnptp.htm

Section C: Information about your experience of using our adaptation toolkit
7. What did you like about the toolkit?
The speedy sifting questions cover all the main issues that I need to make a preliminary assessment. Good separation of the 5 domains that cover the main issues. Very good and comprehensive additional resources for all domains and general issues.

8. What did you not like about the toolkit?

Long but necessarily so.

In the main toolkit perhaps some less important questions might be separated from others (hierarchy of importance??) (5.1. no.4, 5.2. no 18+19).
Repeated similar questions (i.e. 5.2. no 15 vs 5.3. no. 14) and validity questions that might be combined or marked accordingly (5.2. no 9 and 10 = 5.3. no 8 and 9).

These are all minor suggestions without me seeing any practical solution or at least none that could make this very good work better.

9. Any other comments?

Works better for Interventions than Diagnosis understandably
Congratulations – great work.

Please e-mail eunethta@soton.ac.uk with your completed evaluation form by **14th March 2008**. Thank you.

Section A: Information about you			
HTA Agency	DSI Danish Institute for Health Services Research	Country	Denmark
Name of respondent	Henrik Hauschildt Juhl Deputy Director	Email	hhj@dsi.dk

Section B: Information about the report you wish to adapt	
HTA topic	Comparative clinical effectiveness and cost-effectiveness of treatment of acute migraine with triptans (and other relevant drugs)
Report title	Triptans for Acute Migraine: Comparative Clinical Effectiveness and Cost-effectiveness
Authors	Membe S. McGahan L. Cimon K. Gawel M. Giammarco R. Mierzwinski-Urban M
Date of publication	March 2007
Language of report	English
Country of origin	Canada
URL link to report *(if possible)*	http://cadth.ca/index.php/en/publication/690

The "adaption" in this particular case consists of writing a "Commentated foreign health technology assessment". The purpose of our report was to summarize methods and results of the original report and critically assess if and how the results of the original report can be used when deciding on how to treat acute migraine in Denmark.

DACEHTA subcontracted the work to DSI and an independent clinical expert. The topic (the foreign report) was chosen by DACEHTA.

The adaptation toolkit wasn't actually used when we produced our report. The following comments are based on a retrospective assessment of the usefulness of the adaptation toolkit in this particular context.

The following comments on the toolkit focus on the usefulness of the economic evaluation domain of the toolkit.

Section C: Information about your experience of using our adaptation toolkit

10. What did you like about the toolkit?

The set of questions are relevant and useful for the assessment of primary economic evaluations.

11. What did you not like about the toolkit?

The stated aim of the toolkit is to aid in the adaptation of HTA reports that are a synthesis of evidence. The adaptation of HTA reports that are primary research is not addressed in the report (section 2, p. 4).

My perception of the questions in the economic evaluation domain is that they are focused on the assessment of individual primary research / individual economic evaluations, and less focused on assessment of secondary synthesis of primary economic studies. Indeed, the two main sources of the questions (CCOHTA/CADTH guidelines and Drummond et. al) are both developed with the assessment of a primary economic evaluation in mind.

Contrary to the stated aim of the toolkit this part of it is best suited to the assessment of individual, primary economic evaluations, and not really very well suited to guide a synthesis of primary economic studies.

As a tool for adaptation of a secondary analysis of economic evaluations, like the one we encountered in the Canadian report, most of the questions in the effectiveness section of the tool appears to be useful also for the economic part of an HTA.

Question 1,2,3,5 and perhaps 6 in the economic evaluation section can be used to describe in- and exclusion criteria in a secondary research project. They can be seen as a sub-specification of question 5 in the effectiveness section.

Most of the other questions in the economics section address quality characteristics or other characteristics of the individual primary economic evaluation. A useful secondary analysis should extract data on as many as possible of these characteristics. In my opinion these issues are relevant for a secondary analysis, but in this specific context they should be rephrased to reflect the focus on adaptation of secondary research.

12. Any other comments?

The speedy sifting part of the toolkit was not directly relevant for our task as a subcontractor. The selection of the topic and the report to review/comment on was done by DACEHTA.

Please e-mail eunethta@soton.ac.uk with your completed evaluation form by **14th March 2008**. Thank you.