EUnetHTA

HTA ADAPTATION TOOLKIT

WORK PACKAGE 5

REVISED: OCTOBER 2011 (VERSION 5)

The EUnetHTA-project is supported by
a grant from the European Commission

This project was funded by the NIHR Health Technology Assessment programme (project number 05/52/01) The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS or the Department of Health

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA HTA Adaptation Toolkit & Glossary
was developed by

Work Package 5

Adapting existing HTAs from one country into other settings

Work Package 5 Lead Partner: NCCHTA, NIHR Coordinating Centre for HTA, UK (now NETSCC, NIHR Evaluation, Trials and Studies Coordinating Centre)

October 2011

This document is version 5 of the WP5 adaptation toolkit.
Version 3 was used in the WP5 Applicability Testing Round Two (December 2007 to March 2008)
Version 4 had minor changes to prepare it for the Paris conference
Version 5 incorporates the relevant suggestions and recommendations from the Applicability Testing Round Two

Table of contents

Section 1 – Introduction

The objective of Work Package 5 (WP5)[1] of the EUnetHTA project 2006-2008 is to ensure the better use of existing health technology assessment (HTA) reports by developing a toolkit to help HTA agencies to adapt HTA reports from other countries, regions or settings for their own use. The purpose of adaptation is to enable an HTA agency in one setting to make use of an HTA report produced elsewhere, thus saving time and money.

The WP5 adaptation toolkit has been developed as an aid to HTA agencies in the adaptation of HTA reports from one setting into another. It is composed of a series of checklists, questions and resources. Its purpose is to enable assessment of a report's relevance, reliability and transferability. By doing so, the user can determine whether a report, or parts of a report, written for another setting, can be adapted for their own report in the context of their own setting (to be known from here on as the 'target setting').

The toolkit has been amended as a result of the first round of applicability testing carried out between March and June 2007. It was developed further as a result of the second round of applicability testing early in 2008. The current version incorporates all of the relevant suggestions from the second round of applicability testing. It is intended that the toolkit will also be developed into a user-friendly web-based toolkit.

Section 1.1 - Contents of the toolkit

This document is the final version of the toolkit (version 5). It contains the checklists and resources currently available to aid in the adaptation of HTA reports. These are displayed in numbered boxes within the text. Appendix 1 and Appendix 2 detail the role of the toolkit and its place within the stages of adaptation and describe the methods used to develop this toolkit. Appendix 3 is an accompanying brief glossary of HTA adaptation terms. Relevant terms highlighted within the text (in blue) link to their respective definitions and descriptions within this glossary. The full glossary is available on the EUnetHTA website[2].

Section 1.2 – Format of toolkit

Links to glossary terms and sections within this document appear in blue. Links to websites appear in red.

[1] WP5 was a partnership of 28 HTA agencies and networks across Europe who worked together to accomplish this objective. A list of WP5 partners can be found in appendix 2 of this document and on the EUnetHTA website: http://www.eunethta.eu/Public/Work_Packages/EUnetHTA-Project-2006-08/WP_5/

[2] The full Glossary of HTA Adaptation Terms can be found on the EUnetHTA website: http://eunetone.dimdi.de/_glossary/?q=node/19

Section 2 - What sorts of HTA reports can be adapted using the toolkit?

Health Technology Assessment (HTA) is defined as the systematic evaluation of properties, effects, and/or impacts of health care technology[3]. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policy making in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods[4].

Types of HTA report vary both between and within countries. In some places, HTA reports consist of systematic reviews and economic evaluations. Other organisations undertake more broad-spectrum assessments. Reports can be comprehensive assessments developed over months or even years, others are 'rapid reviews' and 'mini-HTAs' produced in days or weeks to provide a brief and timely HTA summary.

Currently, the WP5 adaptation toolkit will aid in the adaptation of HTA reports that are a synthesis of evidence. This is research that does not generate primary data but involves the qualitative or quantitative synthesis of information from multiple primary studies. Examples are literature reviews, systematic reviews, meta-analyses, decision analyses and consensus statements[2]. Adaptation of HTA reports that are primary research is not addressed in this toolkit.

Clearly, the more information, data and explanation provided in the HTA report for adaptation, the easier and more comprehensive the adaptation process. Thus, the toolkit would be best used as an aid to adapting more comprehensive HTA reports. However, it can also be used to adapt information and data from 'rapid reviews'and 'mini-HTAs' but the user will need to be aware of the purpose, and potential limitations, of the original report.

Key Message

This toolkit will aid in the adaptation of HTA reports that are a synthesis of evidence

[3] For details of what a 'health care technology' encompasses, see background section of Health Technology Assessment Monograph 2009; Vol 13: No. 59 http://www.hta.ac.uk/project/1511.asp

[4] Definition from the INAHTA HTA Glossary, 1st edition, July 2006.

Section 3 - The role of the toolkit

This toolkit will help HTA agencies adapt HTA reports by questioning and helping to assess:

(1) The relevance of the report i.e. is the policy and/or research question posed sufficiently similar to warrant adaptation of this report?
(2) Reliability i.e. an assessment of the quality of the report and
(3) Transferability i.e. guidance on issues for consideration when applying information/data to the target setting.

The toolkit has two sections:

- **Speedy sifting -** A screening tool which enables rapid screening of existing HTA reports to assess the relevance of the HTA report for adaptation. These questions are used first. The answers enable the user to judge whether to end the adaptation process or proceed to the main part of the toolkit

- **Main toolkit -** A more comprehensive tool with questions on reliability and issues regarding transferability.

To help users understand the role of the toolkit and what can be achieved by using this tool, one can draw an analogy with building houses! See **table 1**.

Table 1: How to build a new house using parts of an original one – or how to adapt information/data from one HTA report into material for another HTA report!

Step	House 	HTA report 
1	Brick bungalow. Four windows. Two doors.	HTA report from another setting. Has sections dealing with e.g. technology use, safety and effectiveness.
2	New property owner buys house, but wants a very different house on the same plot of land. Very keen to save money and time by using some parts of the original house in building a new one.	User from another HTA agency in a different setting (the target setting) wishes to use information and data from the original report to incorporate into their own new HTA report.
3	New property owner carefully demolishes original house. He assesses each part, to determine whether: (a) he wants these parts in his new house, (b) if they are of sufficient quality and (c) if they will fit within his new house design	Using the toolkit, the user can assess the original report, and its component parts, for (a) relevance, (b) reliability and (c) transferability
4	Having decided which parts of the original house meet the new owner's needs, he builds his new house and incorporates these parts where he sees fit	Having used the toolkit to decide which parts of the report meet the user's needs, he now incorporates these data/information into his own HTA report framework for the target setting. He may need to update these data and incorporate further sections within the report and/or local context data as required.
5	New two storey brick house. Eight windows. Two doors. Conservatory and a porch!	New HTA report for the target setting. Various updated sections dealing with e.g. technology use, effectiveness and cost-effectiveness (as required)

For more information on what adaptation means, the stages of adaptation and the place of the toolkit within these stages please view Appendix 1.

The toolkit can be used to adapt a whole HTA report or parts of it. Thus, it may not be necessary for users to work through the whole of the main part of toolkit. More guidance is provided in Section 5 of this document. However, all users should undertake 'speedy sifting' before using the more comprehensive tool.

Section 4 - Speedy sifting

The 'speedy sifting' section of the toolkit assesses the relevance of a report (or reports) for adaptation i.e. is the policy and/or research question posed in each report sufficiently similar to warrant adaptation of this/these report/s?

Users can assess the relevance of multiple reports on the same health technology and determine which reports are relevant. The aim is that users could make a decision on each HTA report within 2 hours[5].

The questions to be addressed when assessing the relevance of an HTA report (or parts of that report) for adaptation are shown in box 1:

Box 1: Speedy sifting questions

Speedy sifting questions: Assessment of relevance	Answer
1. Are the policy and research questions being addressed relevant to your questions?	Yes/No
2. What is the language of this HTA report? Is it possible to translate this report into your language?	Yes/No
3. Is there a description of the health technology being assessed?	Judgement needed
4. Is the scope of the assessment specified?	Judgement needed
5. Has the report been externally reviewed?	Judgement needed
6. Is there any conflict of interest?	Judgement needed
7. When was the work that underpins this report done? Does this make it out of date for your purposes?	Judgement needed
8. Have the methods of the assessment been described in the HTA report?	Judgement needed

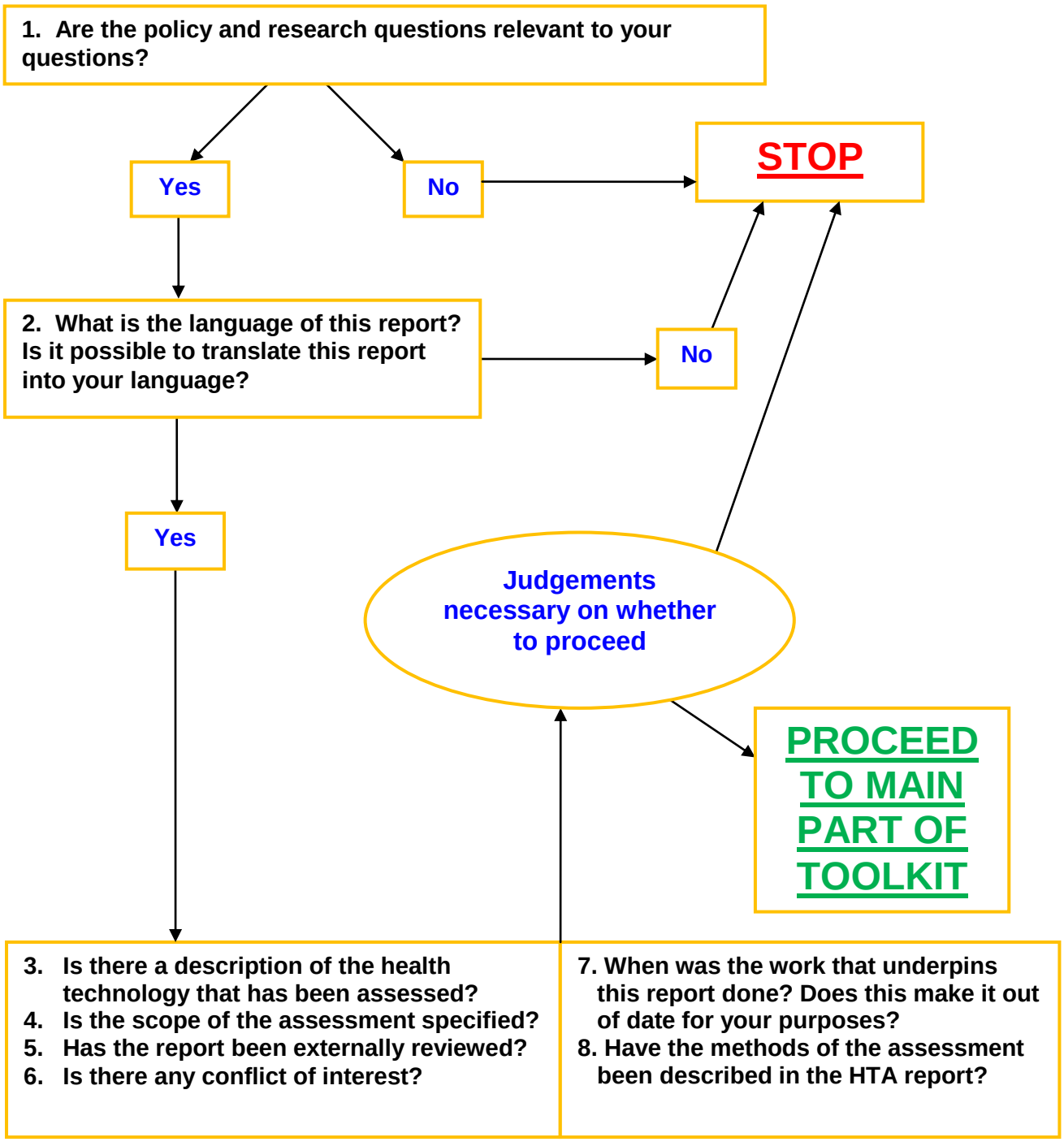
The first two questions posed in the speedy sifting section can result in either proceeding to the following question (with a 'yes' response) or ending the process (with a 'no' response). The following six questions (questions 3 to 8) require judgements to be made by the user. Collectively, as a result of responses to these questions, the user must decide whether to end the adaptation process or proceed to the main part of the toolkit (with/without concerns regarding adaptability). The user is questioning whether this report is suitable for their use.

When deciding whether a report is out of date, consider details such as: the date of literature searches, when data for clinical or economic evaluation was gathered, and whether the technology has changed significantly.

Figure 1 below shows the above eight questions that are posed in this part of the toolkit and how the user uses the information as a result of their answers.

[5] indication of time not a suggested time limit

Figure 1: Pathway of questions and responses in the speedy sifting part of the toolkit



A useful resource for further relevance questions is the INAHTA checklist. This checklist was developed both as an aid to writing new HTA reports and also for adapting reports. INAHTA checklist questions specifically relating to adaptation have been incorporated into the speedy sifting section of the toolkit. However, users may wish to consult the entire INAHTA checklist for further guidance (see box 2).

Box 2: Resource for Speedy Sifting section

Link to the INAHTA checklist in English, French and Spanish:
http://www.inahta.org/HTA/Checklist

Key Message

The speedy sifting questions assess the relevance of the report for adaptation. They help the user decide whether the report (or parts of it) might be suitable for their use.

Section 5 - Main part of the toolkit

The main part of the toolkit contains questions on reliability, specific relevance questions and issues regarding transferability of HTA report domains (or sections of an HTA report). It also contains links to resources that can provide further information to aid in adaptation (should the user choose to access further information). It is proposed that using this tool will take less than 5 days[1].

Currently, there are five domains within the WP5 adaptation toolkit. These domains are shown in box 3.

Box 3: Adaptation toolkit domains

- *5.1 The technology's use*: Current state of the health technology and alternative technologies and the technology's background
- *5.2 Safety*
- *5.3 Effectiveness* (including efficacy)
- *5.4 Economic evaluation*: costs, cost-effectiveness, cost-utility and cost benefit analysis
- *5.5 Organisational elements*: of health service generally and within settings

The main part of the toolkit can only be used to adapt information and/or data contained within an HTA report that includes one or more of these five domains. Currently, this toolkit would not enable the user to adapt information and/or data on legal, social or ethical elements. Please view box 4 for the justification behind the choice of these domains.

[1] indication of time not a suggested time limit

Box 4: Justification for choice of the five toolkit domains

Choice of domains for inclusion within the toolkit was addressed through a three stage process to ensure that the views of all 28 WP5 members were considered. The stages were as follows: (1) a preliminary questionnaire, (2) discussion at a face to face meeting and (3) Delphi[7] round 1 questionnaire.

Preliminary questionnaire
Members were surveyed to ask their opinion on which elements of the EUR-ASSESS framework (described as domains in this document) WP5 should focus on. The majority of members (over 50%) chose the five domains listed in box 3. Other domains received less support (39% of members or less). The main reason for this choice was that information and data in other domains (ethical, legal and social elements) would be less amenable to adaptation; specific information from the target setting would be required in the relevant section of the adapted HTA report.

Face to face meeting
Members were informed of the results from the preliminary questionnaire and the intention to include just these five domains. There was general agreement that these domains should be included in the toolkit.

Delphi round 1
A Delphi survey of members was undertaken. In the first round of this survey, members were asked again for their comments on the further developed toolkit content. There was general agreement that no further domains should be included in the toolkit at this stage. However, some members were keen that we review the inclusion of further domains when quality assessing the toolkit.

The main part of the toolkit can be used in its entirety i.e. as an aid to adapt information/data in all five domains or can be used to adapt information/data in one or more domains. Repetition of questions and themes across some domains is deliberate. Thus, the user can use just the parts of the toolkit that are relevant to their needs.

The 'development of the toolkit', questions and issues posed within the toolkit have been developed through WP5 members' commentary work. Questions originating from the literature are referenced in the footnotes. Questions arising from ideas or in-house experience have not been referenced. Appendix 2 provides more information on the development of the toolkit.

The output of the toolkit is adapted material from an HTA report that can be incorporated into a report for the target setting. Further work by the user, to identify local information and data, may be required before the HTA report within the target setting is completed.

Key Message

There are currently five domains within the main part of the toolkit. Users can utilise one or more of these domains to aid in adaptation, depending on their needs.

Section 5.1 - Technology's use domain

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).

Question Box 5: Technology's use domain questions

a) To assess relevance:

1. What is the research question considered? Is the research question considered within this section of the report relevant to your question?

b) To assess reliability:

2. Were conditions, target group, relevant interventions or comparisons between interventions and relevant outcomes appropriately defined?

3. Is the information provided on technology use and development complete and comprehensive? Are the methods and sources used when elaborating the background information well documented?

4. Are patterns of utilisation, diffusion, indications and time trends adequately described?

5. Is an analysis of the regulatory status of the technology provided (market admission, status in other countries)?

c) To assess transferability:

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

7. Are there any differences in the use of this technology within the target setting (compared to the uses described in the HTA report for adaptation)?

Answers to these questions should help the user extract information and/or data from this section of the HTA report. This 'adaptation material' on technology use and development can be incorporated within an HTA report in your own setting. There may be a need to update these data and supplement it with local context data.

Section 5.2 - Safety domain

Below is a list of questions to ask when considering the adaptation of information and/or data on safety (box 6). The first two questions consider relevance of this section of a report. There follows a list of reliability questions and lastly, a list of questions relating to transferability.

Question Box 6: Safety domain questions

a) To assess relevance

1. Were harms or safety assessed?

2. Is the scope of the safety assessment relevant to your question?

b) To assess reliability

The aspects that should be assessed concerning the sources of information are:

3. Was the search for studies reasonably comprehensive?

4. Were special sources consulted? : disease registers, routinely data collected (on utilisation, costs, adverse effects,..), consumer associations, etc..

The aspects that should be assessed concerning the sources of safety data are:

5. What are the sources of information/data? E.g. surveillance databases, declaration of incidents, safety report, RCT, case reports

Quality of the safety assessment (i.e. appraisal of evidence)

6. Were the criteria used for deciding which studies to include in the HTA report reported?

7. Was bias in the selection of studies avoided?

8. Did the selection of studies (in particular the choice of eligible study designs) minimise the possibility of including studies with a high propensity for bias?

9. Were the criteria used for assessing the validity of the included studies reported?

10. 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?

11. Which risks have been reported and how were they measured?

12. a) Were the study outcomes valid?

    b) Were the study outcomes pertinent?

13. Are the number of patients, their representativeness and the quality of the data high enough to exclude a modest but clinically relevant rate of serious complications? i.e. what is the potential for overlooking a possible serious adverse event?

14. Is there a possibility for a ‘class’ effect adverse reaction or safety problem?

c) To assess transferability

15. Does the population described for eligibility match the population to which it is targeted in the target setting?

16. Are there any reasons to expect differences in complication rates (e.g. epidemiology, genetic issues, healthcare system (quality of care, surveillance))?

17. Are the requirements for its use (special measures needed for use/implementation, maintenance etc.) available in the target setting?

18. Is the necessary expertise (knowledge and skills) available in the target setting?

19. a) Is safety particularly dependent on training?
    b) Are there types of teams to which the procedure should be limited for safety reasons?
    c) Is there a need for special training or certification to deliver the intervention properly.
    d) Would it be possible (affordable) to organise such training, if any?

Answers to these questions should help the user extract information and/or data from this section of the HTA report. This 'adaptation material' on safety can be incorporated within an HTA report in your own setting. There may be a need to update these data and supplement it with local context data.

5.2.1 Resources for the safety domain

Box 7 below provides links to useful resources. The first resource provides additional, more detailed, reliability questions. The following resources provide further guidance and information on safety issues. The user may wish to consult any or all of these resources to aid in the adaptation of safety data and information.

Box 7: Resources to aid in the adaptation of safety data and information

Report from a World Health Organisation (WHO) meeting to provide guidance and input towards the development of rapid assessment methodologies for estimating harm caused by the health care system	http://www.nap.edu/books/0309090776/html/ link last checked: 09/2011
Standards throughout this 'Joint Commission Standards in Support of Patient Safety and Medical/Health Care Error Reduction (JCAHOR) Manual' are designed to improve patient safety and reduce risk to patients.	http://www.dcha.org/JCAHORevision.htm link last checked: 09/2011
This Agency for Healthcare Research and Quality (AHRQ) project aimed to collect and critically review the existing evidence on practices relevant to improving patient safety.	http://archive.ahrq.gov/clinic/tp/ptsaftp.htm link last checked: 09/2011
ECRI's mission is to promote the highest standards of safety, quality, and cost-effectiveness in healthcare to benefit patient care through research, publishing, education and consulting.	http://www.ecri.org/ link last checked: 09/2011
Agency for Healthcare Research and Quality (AHRQ) Mission: To improve the quality, safety, efficiency, and effectiveness of health care for all Americans.	http://www.ahrq.gov/ link last checked: 09/2011
NICE (National Institute for Health and Clinical Excellence) is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health in the UK.	http://www.nice.org.uk/ link last checked: 09/11
In response to a request from the Department of Health and Human Services, the Institute of Medicine convened a committee to produce a detailed plan to facilitate the development of data standards applicable to the collection, coding, and classification of patient safety information.	http://www.nap.edu/books/0309090776/html/ link last checked: 09/2011
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.	http://www.ncbi.nlm.nih.gov/pubmed/15545678 link last checked: 09/2011
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.	http://www.ncbi.nlm.nih.gov/pubmed/14512492 link last checked: 09/2011
Newcastle Ottawa scale is a tool to assess observational studies	http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp link last checked: 09/2011
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.	http://www.ncbi.nlm.nih.gov/pubmed/18064739 link last checked: 09/2011

Section 5.3 - Effectiveness (including efficacy) domain

Below is a list of relevance, reliability and transferability questions to ask when considering the adaptation of information and/or data on effectiveness and efficacy (box 8).

Question Box 8: Effectiveness questions

a) To assess relevance

1. a) What is the research question considered?
   b) Is the research question considered within this section of the HTA report relevant to your HTA question?
2. Are the outcome measures relevant for your HTA question?
3. Were the search methods used to find studies relevant to the main question(s) stated?

b) To assess reliability[6]

4. Was the search for studies reasonably comprehensive?
5. Were the criteria used for deciding which studies to include in the HTA report reported?
6. Was bias in the selection of studies avoided?
7. Did the selection of studies (in particular the choice of eligible study designs) minimise the possibility of including studies with a high propensity for bias?
8. Were the criteria used for assessing the validity of the included studies reported?
9. 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)?
10. Were the methods used to combine the findings of the relevant studies (to reach a conclusion) reported?
11. Were the findings of the relevant studies combined appropriately with respect to the main question the HTA report addresses?
12. Were the conclusions made by the authors supported by the data and/or analysis reported in the HTA report?
13. How likely is it that the relevance of this HTA report has changed due to additional research that had started, completed or been published since this Health Technology Assessment report?

[6] *The majority of these reliability questions have been taken from the 'Overview Quality Assessment Questionnaire': Shea BJ, Boers M, Grimshaw JM, Hamel CD, Bouter LM. Does updating improve the methodological and reporting quality of systematic reviews? BMC Medical Research Methodology 2006; 6:27.*

c) To assess transferability

14. 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)

    We would expect the relative risk to be the same and baseline risk different. The user needs to consider the impact of local epidemiological and demographic data on the baseline risk.

Answers to these questions should help the user extract information and/or data from this section of the HTA report. This 'adaptation material' on effectiveness (including efficacy) can be incorporated within an HTA report in your own setting. There may be a need to update these data and supplement it with local context data.

5.3.1 Resources for the effectiveness domain

Box 9 below provides links to useful resources to help in assessing the reliability of effectiveness data and information and links to some specific papers that may be of interest. The user may wish to consult any or all of these resources to aid in the adaptation of effectiveness data and information.

Box 9: Resources for the adaptation of effectiveness data and information

A study to assess the validity of an index of the scientific quality of research overviews, the Overview Quality Assessment Questionnaire (OQAQ).	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&list_uids=1834807&dopt=abstract link last checked: 09/2011
How to use an overview, Centre for Health Evidence	http://www.cche.net/text/usersguides/overview.asp link last checked: 09/2011
How to use a systematic review about therapy	http://www.ebm.med.ualberta.ca/SystematicReview.html link last checked: 09/2011
Critical appraisal worksheet for therapy	http://www.cebm.net/index.aspx?o=1157 link last checked: 09/2011
Description of "critical appraisal" , Centre for Evidence Based Healthcare	http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/What_is_critical_appraisal.pdf link last checked: 09/2011
The *Cochrane Handbook for Systematic Reviews of Interventions* is the official document which describes in detail the process of creating Cochrane systematic reviews.	http://www.cochrane.org/resources/handbook/ link last checked: 09/2011
The aim of the PRISMA Statement is to help authors improve the reporting of systematic reviews and meta-analyses.	http://www.prisma-statement.org/ link last checked: 09/2011
The Agency for Healthcare Research and Quality (AHRQ) report into identifying methods to rate the strength of the scientific evidence underlying health care practice and recommendations in the research literature and technology assessments.	http://archive.ahrq.gov/clinic/epcsums/strenfact.htm link last checked: 09/2011
Descriptive method guidelines to help reviewers design, conduct, and report reviews of trials in the field of back and neck pain, Cochrane Collaboration Back Review Group	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12811274&dopt=Abstract link last checked: 09/2011
Paper: "The need for caution in interpreting high quality systematic reviews"	http://www.bmj.com/cgi/content/full/323/7314/681 link last checked: 09/2011

Section 5.4 - Economic evaluation domain

Below is a list of relevance, reliability and transferability questions to ask when considering the adaptation of information and/or data on economic evaluations (box 10).

Question Box 10: Economic evaluation questions

To assess relevance and reliability[7]

1. Was a well-defined economic question posed in an answerable form?

2. a) What is the question being asked in the report?
   b) Is the economic question relevant?
   c) What type of economic analysis is being performed to answer the question (i.e. cost-minimisation, cost consequences analysis, cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis)?

3. a) Has the viewpoint or perspective for the analysis been stated clearly, along with the reasons for this choice?
   b) Is it a societal perspective, third-party payer perspective, or patient perspective?
   c) Is the analysis presented in a disaggregated fashion showing these perspectives separately?

4. Was a comprehensive description of the competing alternatives given (i.e. can you tell who did what to whom, where and how often)?

5. Has the study included a comparison of alternative treatments for patients with the same clinical condition? Are those alternatives explicitly stated? Are the alternatives chosen valid and reasonable?

6. a) Has the evidence of the product's efficacy been established through randomised trials?
   b) Has the evidence of efficacy been supplemented by evidence of effectiveness applicable to the patient population or subgroups considered in the study?
   c) Has the latter evidence been derived from studies documenting routine use in clinical practice?
   d) Have all the relevant and significant variations in effectiveness for different subgroups been identified and reported?

7. Was the effectiveness of the programmes or services established?

8. a) Are the methods and analysis displayed in a clear and transparent manner?
   b) Are the components of the numerator (cost of each alternative) and denominator (clinical outcomes of each alternative) displayed?
   c) Are clinical outcomes expressed first in natural units and then translated into alternative units, such as benefits or utility?

9. Are all important and relevant costs and consequences (outcomes), including adverse effects for each alternative identified?

10. Were costs and consequences measured accurately in appropriate physical units (e.g. hours of nursing time, number of clinician visits, lost work-days, gained life-years)?

[7] *Questions taken from CCOHTA Guidelines for economic evaluation of pharmaceuticals, 2nd edition: Canada. Ottawa: Canadian Coordinating Office for Health Technology Assessment (CCOHTA); 1997 and Drummond MF, O'Brien BJ, Stoddart GL, and Torrance GW. Methods for the Economic Evaluation of Health Care Programmes. Oxford Medical Publications, UK, 1997; 2. edition.*

11. How is Health Related Quality Of Life (HRQOL) measured?

12. a) Is HRQOL an important component of an economic analysis for this question?
    b) Based on the sensitivity analysis how sensitive is the estimate of cost-utility to variations in HRQOL?

13. Were costs and consequences valued credibly?

14. Were costs and consequences adjusted for differential timing?

15. Are costs and consequences modelled (as a decision trees) with information derived from a variety of sources or estimated directly from specific patient population(s)?

16. a) Are capital costs and overhead costs included as well as operating costs?
    b) How are they measured?

17. How have indirect costs (i.e. productivity costs, cost of lost time) been identified and estimated?

18. a) For variables which are difficult to measure, what method is used to handle this difficulty?
    b) Does this method slant the analysis all in favour of one intervention in order to bias the analysis against the expected result?

19. Was an incremental analysis of costs and consequences of alternatives performed?

20. Was allowance made for uncertainty in the estimates of costs and consequences?

21. Were adequate sensitivity analyses undertaken i.e. when parameters with high uncertainty were analysed, did the direction of the results change?

22. If a stochastic sensitivity analysis was applied, are the underlying distribution functions justified?

23. What equity assumptions have been made in the analysis? For example, are QALYs gained by any individual considered equal?

24. a) Is the incremental cost-effectiveness ratio estimated for a specific clinical indication that represents the majority of all of its expected use by those covered under the programs operated by the decision-makers to whom the report is addressed?
    b) Are there other indications which have not been considered which involve a large amount of utilization for which the ratio may be very different?

25. a) Is there an estimate of the aggregate incremental expenditure required for the decision-makers to whom the study is addressed, to provide this product to patients covered by their programs?
    b) What is the estimate of aggregate incremental costs?
    c) Does this estimate cover all of the major indications for use of the product?

26. Did the presentation and discussion of study results include all issues of concern to users?

***To assess transferability*[8]**

27. How generalisable and relevant are the results, and validity of the data and model to the relevant jurisdictions and populations?

28. a) Are there any differences in the following parameters?
    I. Perspective
    II. Preferences
    III. Relative costs
    IV. Indirect costs
    V. Discount rate
    VI. Technological context
    VII. Personnel characteristics
    VIII. Epidemiological context (including genetic variants)
    IX. Factors which influence incidence and prevalence
    X. Demographic context
    XI. Life expectancy
    XII. Reproduction
    XIII. Pre- and post intervention care
    XIV. Integration of technology in health care system
    XV. Incentives

    b) If differences exist, how likely is it that each factor would impact the results? In which direction? Of what magnitude?
    c) Taken together, how would they impact the results and of what magnitude?
    d) Given these potential differences, how would the conclusions likely change in the target setting? Are you able to quantify this in any manner?

29. Does the economic evaluation violate your national/regional guidelines for health economic evaluation?

Answers to these questions should help the user extract information and/or data from this section of the HTA report. This 'adaptation material' on economic evaluation can be incorporated within an HTA report in your own setting. There may be a need to update these data and supplement it with local context data.

Jurisdiction is the authority given to a legal body, or to a political leader (Prime Minister, President, etc.) to deal with legal matters, and to pronounce or enforce legal matters. Jurisdictions are the territorial areas (eg. countries or regions) where particular laws or guidance (including policy decisions) apply.

[8] *List of factors taken from Welte, R. und Leidl, R., 1999, Übertragung der Ergebnisse ökonomischer Evaluationsstudien aus dem Ausland auf Deutschland: Probleme und Lösungsansätze, in: Leidl, R., Graf von der Schulenburg, J. M. und Wasem, J. (Hg.): Ansätze und Methoden der ökonomischen Evaluation. Eine internationale Perspektive, Baden-Baden: Nomos.*

5.4.1 Resources for the economic evaluation domain

Box 11 below provides links to useful resources to help in assessing the reliability, consideration of general issues, transferability and links to some specific papers that may be of interest. The user may wish to consult any or all of these resources to aid in the adaptation of economic evaluation data and information.

Box 11: Resources for the adaptation of economic evaluation data and information

The objective of these guidelines is to assist the "doers" of economic evaluations to produce credible and standardized economic information that is relevant and useful to decision makers in Canada's publicly funded health care system, CADTH	http://www.rees-france.com/IMG/pdf/2006_CCOHTA_EconomicGuidelines_e.pdf link last checked: 09/2011
Guidelines for Economic Evaluation of Pharmaceuticals: Canadian Coordinating Office for Health Technology Assessment	http://www.cadth.ca/media/pdf/peg_e.pdf link last checked: 09/2011
Paper: "Development and Validation of a Grading System for the Quality of Cost-Effectiveness Studies"	http://www.lww-medicalcare.com/pt/re/medcare/abstract.00005650-200301000-00007.htm;jsessionid=FvHWsGYx1HVV6bvMrpJ4MTyvrTLZknpmbGhdv5ctppVFQjLlfNjV!-1480123504!-949856144!8091!-1 link last checked: 09/2011
Paper: "Economic Evaluations in International Health Technology Assessments – A Study of Methodologies"	http://www.sst.dk/publ/Publ2004/Sundhedsoekonomiske_evalueringer_MTV.pdf link last checked: 09/2011
Paper: "Review of guidelines for good practice in decision-analytic modelling in health technology assessment"	http://www.ncbi.nlm.nih.gov/pubmed/15361314 link last checked: 09/2011
Paper: "A critical review of health-related economic evaluations in Australia: implications for health policy."	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10141252&dopt=Abstract link last checked: 09/2011
Paper: "The cost-benefit approach"	http://bmb.oxfordjournals.org/cgi/reprint/30/3/252.pdf link last checked: 09/2011
Paper: "Estimating costs in the economic evaluation of medical technologies"	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=2113891&dopt=Abstract link last checked: 09/2011
General issues	
Policy brief: Health Technology Assessment: An introduction to objectives, role of evidence, and structure in Europe, European Observatory on Health Systems and Policies	http://www.euro.who.int/__data/assets/pdf_file/0018/90432/E87866.pdf link last checked: 09/2011
Guidelines for the Economic Evaluation of Health Technologies, CADTH	http://www.ispor.org/peguidelines/source/HTAGuidelinesfortheEconomicEvaluationofHealthTechnologies-Canada.pdf link last checked: 09/2011
Paper: "Standardizing methodologies for economic evaluation in health care. Practice, problems, and potential."	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8423113&dopt=Abstract link last checked: 09/2011
Paper: "Guidelines for authors and peer reviewers of economic submissions to the BMJ"	http://www.bmj.com/cgi/content/full/313/7052/275 link last checked: 09/2011
Paper: "Review of guidelines for good practice in decision-analytic modelling in health technology assessment."	http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=15361314&dopt=Citation link last checked: 09/2011

Transferability issues	
Paper: "Generalisability in economic evaluation studies in healthcare: a review and case studies"	http://www.ncbi.nlm.nih.gov/pubmed/15544708 link last checked: 09/2011
Paper: "Analyzing differences in the costs of treatment across centers within economic evaluations"	http://eprints.whiterose.ac.uk/612/ link last checked: 09/2011
Paper: "Extrapolation of cost-effectiveness information to local settings."	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10180659&dopt=Citation link last checked: 09/2011
Specific topics	
Paper: "Economic evaluations in the critical care literature: do they help us improve the efficiency of our unit?"	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8797635&dopt=Abstract link last checked: 09/2011

Section 5.5 - Organisational elements domain

Before utilising this section of the toolkit, it is important to recognise:

(1) Information and data on organisational elements is absent from most European HTA reports.

(2) There are no instruments/checklists that have been specifically designed to appraise the reliability of methods and the validity of results of organisational elements assessments. This is probably related to the fact that there is no single way to assess these elements.

(3) Organisational approaches differ greatly between health care settings or countries; this section of the toolkit is the least likely to produce transferable elements, and it would be advisable to supplement with local data.

However, there is increasing interest in including such information in future HTA reports. Therefore, general information regarding organisational elements is included within the toolkit. The organisational elements toolkit domain will simply serve to provide a classification of the elements, and some key questions, that should be considered when adapting this part of an HTA report.

'Organisational elements' refers to the ways in which health care is organised within a particular health care system, between organisations or within a health care organisation. For example, which elements of a care pathway are carried out by which organisations (inter-organisational level), which professions are responsible for which elements of care and whether the right skills exist to exploit the technology (intra-organisational level), which technologies would be supported in terms of policy or funding (healthcare system level).

When adapting information and data from organisational elements sections of an HTA report, you should consider the organisational elements matrix shown below (Figure 2).

5.5.1 Organisational elements matrix

The purpose of the organisational elements matrix is to help the user understand what information/data are in the HTA report, thereby helping to determine the relevance of this information for the user's own report.

The matrix will help the user clarify which organisational level/s (and which elements within those levels) have been considered within the report, and the type of data and method of analysis that has been undertaken to assess organisational elements. A list of the dimensions of organisational elements that can potentially be affected by the technology, and can affect the implementation of the technology, has been proposed by the EUnetHTA 2006-2008 Work Package 4 (the rows of the matrix in Figure 2 below).

5.5.2 How to use the matrix

It is intended that the user fills out the matrix by inserting ticks within it to show (1) the information/data available for a certain level and dimension and (2) what the user requires information/data on i.e. which levels and dimensions?

Figure 2: Organisational elements matrix

		"ORGANISATIONAL LEVEL" ("target setting")		
		NATIONAL	**REGIONAL**	**LOCAL**
ORGANISATIONAL ASPECTS	Utilisation	**Type of data and methods of analysis** Data from research (quantitative and qualitative) Literature reviews Routine data Informal knowledge and anecdotes Judgements Models		
	Work processes			
	(De)centralisation			
	Staff			
	Job satisfaction			
	Cooperation and Communication			
	Finances			
	Stakeholder			

Guidance Notes

Type of data/information to be collected to answer the question/s:
-Literature systematic review or/and
- In depth interviews, focus groups etc. (qualitative social research methods)
- Survey by questionnaires (quantitative methods)
- Routine data and informal anecdotes

Resources for quality assessment tools research are in Box 13 in the Toolkit, p. 29

5.5.3 After using the matrix

On completion of this exercise, adaptation questions to ask are (Box 12):

Question Box 12: Organisational elements domain additional questions

a) To assess relevance:

1. Are the dimensions assessed relevant for my own research questions?

If no, adaptation of organisational elements data from this report unnecessary

2. Is the analysis transferable (statistically or analytically)? (this will be dependent on the structure of the health care system and similarities of units of analysis)

A judgement will be necessary here.

3. Are the results applicable to my context?

A judgement will be necessary here.

b) To assess reliability:

4. Are the theories and methods used relevant and reliable ones?

A judgement will be necessary here.

Answers to these questions should help the user extract information and/or data from this section of the HTA report. This 'adaptation material' on organisational elements can be incorporated within an HTA report in your own setting. There may be a need to update these data and supplement it with local context data.

5.5.4 Resources for the organisational elements domain

Box 13 below provides links to useful resources to help in addressing organisational elements issues and assessment of qualitative research. The user may wish to consult any or all of these resources to aid in the adaptation of organisational elements data and information.

Box 13: Resources for the adaptation of organisational elements information

General documents dealing with organisational elements	
This Danish Centre for Health Technology Assessment (DACEHTA) handbook provides an introduction to the scientific methods and instruments in HTA. In particular to the four main elements of an HTA analysis – the technology, the patient, the organisation, and the economy.	http://www.sst.dk/publ/Publ2008/MTV/Metode/HTA_Handbook_net_final.pdf link last checked: 09/2011
Mini-HTA is a management and decision support tool based on the reasoning involved in HTAs. The tool may be used, for example, when a hospital is contemplating the introduction of a new health technology. It is a checklist with a number of questions concerning the prerequisites for and consequences of using new health technologies (produced by DACEHTA)	http://www.sst.dk/publ/Publ2005/CEMTV/Mini_MTV/Introduction_mini_HTA.pdf link last checked: 12/11/07
Assessment of qualitative research	
This paper outlines two views of how qualitative methods might be judged and argues that qualitative research can be assessed according to two broad criteria: validity and relevance.	http://www.bmj.com/cgi/content/full/320/7226/50 link last checked: 12/11/07
This is a brief review which indicates how observational methods can be used to "reach the parts that other methods cannot".	http://www.bmj.com/cgi/content/full/311/6998/182 link last checked: 12/11/07
This article argues that three interrelated criteria can be identified as the foundation of good qualitative health research: interpretation of subjective meaning, description of social context, and attention to lay knowledge	http://qhr.sagepub.com/cgi/content/abstract/8/3/341 link last checked: 12/11/07

Section 6 - General resources

Box 14 below lists general toolkit resources and hyperlinks to those resources. These resources provide information on adaptation issues, transferability questions and previous related EU funded projects. These resources can be consulted if further information and guidance is required in these areas.

Box 14: General toolkit resources

General adaptation issues	
WHO review of the literature on applicability, transferability, and adaptation of guidelines.	http://www.health-policy-systems.com/content/4/1/25 link last checked: 09/2011
Paper describing the structures and working methods of guideline programs.	http://intqhc.oxfordjournals.org/cgi/content/full/15/1/31 link last checked: 09/2011
AGREE (Appraisal of Guidelines, Research and Evaluation in Europe) project paper on the development and validation of an international instrument for assessing the quality of the process and reporting of clinical practice guideline development.	http://qshc.bmj.com/cgi/content/full/12/1/18 link last checked: 09/2011
Report from the Conference on Guideline Standardization to define a standard for guideline reporting.	http://www.annals.org/cgi/reprint/139/6/493.pdf link last checked: 09/2011
Paper describing a framework for evaluating and adapting existing practice guidelines for local use by health care organizations and groups. The framework presents the major issues related to guideline adaptation and breaks them down into manageable steps.	http://www.blackwell-synergy.com/doi/abs/10.1111/j.1552-6909.2002.tb00086.x link last checked: 09/2011
Paper reviewing the literature on adaptation of guidelines and to propose a systematic approach for adaptation of guidelines.	http://intqhc.oxfordjournals.org/cgi/content/abstract/18/3/167 link last checked: 09/2011
A series of reviews of methods that are used in the development of guidelines.	http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=17116254 link last checked: 09/2011
Questions relating to how generalisability can be tackled in systematic reviews	http://www.scielosp.org/scielo.php?script=sci_arttext&pid=S0042-96862005000600020&lng=en&nrm=iso&tlng=en link last checked: 09/2011
Clinical guidelines are only as good as the evidence and judgments they are based on. The GRADE (Grades of Recommendation Assessment, Development and Evaluation) approach aims to make it easier for users to assess the judgments behind recommendations.	http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=15205295 link last checked: 09/2011
Previous EU funded projects	
ECHTA/ECAHI Report – "European collaboration for health technology assessment: developing an assessment network" and HTA Europe Report –	http://www.eunethta.eu/Public/About_EUnetHTA/HTA/EU-supported-HTA-projects/

"Health Technology Assessment in the European Union"	link last checked: 09/2011
EUR-ASSESS Project Subgroup report on Methodology. Methodological guidance for the conduct of health technology assessment	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9194352&dopt=Citation link last checked: 09/2011
Working Group 4 Report to develop and disseminate best practice in undertaking and reporting assessments, and to identify needs for methodological development.	http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=106849 link last checked: 09/2011
Transferability issues	
Checklist for identifying guidelines requiring adaptation. It contains questions around factors which influence the applicability or transferability of guidelines across different settings. Questions relevant for the safety, effectiveness and cost-effectiveness domains of the toolkit.	http://www.health-policy-systems.com/content/4/1/25/table/T1 link last checked: 09/2011
General HTA resources	
NICHR (National Information Center on Health Services Research and Health Care Technology) HTA 101: Introduction to HTA	http://www.nlm.nih.gov/nichsr/hta101/ta101_c1.html link last checked: 12/11/07

Section 7 - End of the toolkit

This concludes the toolkit guidance. Output from using the toolkit will be adaptation material that is relevant, reliable and transferable to the target setting. This material can then be incorporated into your own local HTA report framework. You can supplement this material with further information/data in order to develop an updated HTA report specific for your target setting.

Debbie Chase
Ruairidh Milne
Nick Hicks
Hilary Bunce
Claire Rosten
Sheila Turner
Liz Payne

November 2007

Eleanor Guegan
Ruairidh Milne
Alexander Pordage

Revised October 2011

Appendix 1: Background

This appendix provides an overview of the adaptation process and the role and purpose of the toolkit.

What is adaptation?

The purpose of adaptation is to enable an HTA agency in one country (or region or setting) to make use of an HTA report produced elsewhere, thus saving time and money. This sounds simple but in reality, the adaptation process is complex.

Making use of all or part of an HTA report from elsewhere could be done in a wide range of ways (see items 1 to 4 below). There is a spectrum, with progressively more of the original report being used and so more possibility of saving time and money through reduced duplication. Items 1 to 3 require further work beyond the use of information from the report to develop your own report.

1. *Summarising*: translate the summary and use this for background information

2. *Updating searches*: using the original search strategy to identify any more recent evidence or adding to the search strategy and extending it.

3. *Adapting*: the systematic extraction of relevant HTA information from an existing report (from a whole report or from part of a report)

4. *Adopting*: making use of the report without making any changes at all (except perhaps translation into your own language)

The 'product' of the adaptation process is information that has been extracted from the report that is (a) relevant to your needs, (b) quality assessed (c) critically appraised and d) is ready to be incorporated into a new framework for an HTA report in your own setting or country. The process of adaptation therefore involves, to varying degrees, the following steps:

a) checking the relevance of the question(s) addressed in the original report to the question you are facing

b) identifying the information in the report which is relevant and most likely to be transferable to your setting

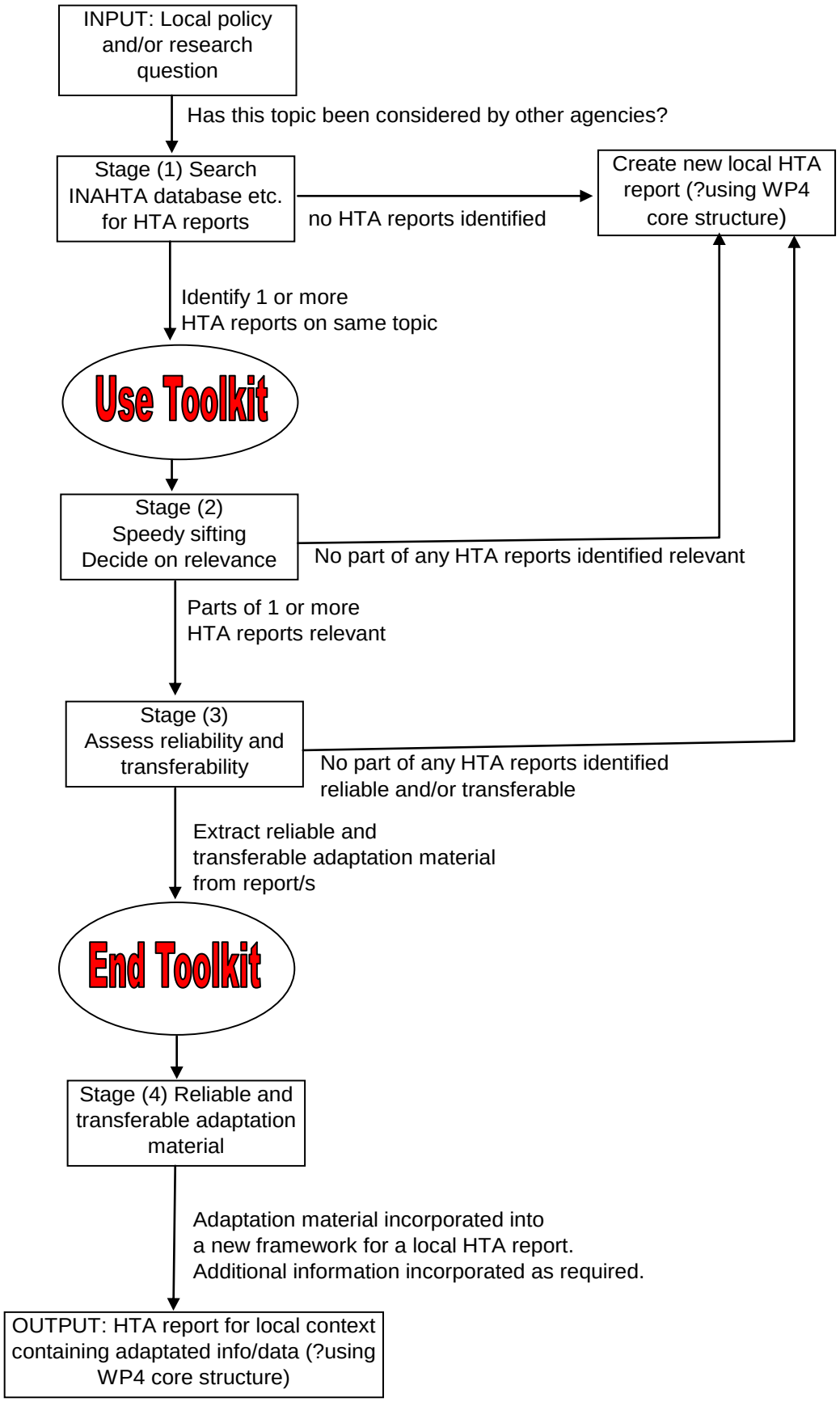
c) assessing the reliability of the information under various domains (benefits, harms, cost-effectiveness, organisational impact, social and legal issues, etc)

d) identifying and setting out the problems which may occur when the extracted, relevant, quality assessed information is transferred into a local HTA report; and deciding how to deal with them

What is the role of the toolkit in the different stages of adaptation?

The flow-diagram below (figure 3) shows the stages of adaptation, from research/policy question to final HTA report adapted for a local context and at which stages the toolkit will help with adaptation.

Figure 3: Stages of adaptation, from input to output and role of the toolkit



The following is an explanation of process undertaken at each of the stages shown in figure 2.

Input

A policy/research question is posed within a local context. To reduce time and cost, the agency searches for HTA reports that have been published in this topic area.

Stage 1 – identification of HTA reports

The INAHTA database *(?eventually Clearinghouse search engine*) is searched for HTA reports in this topic area. If none are found, a new HTA report is required. If one or more HTA reports are identified, these can be taken forward for 'speedy sifting'.

It is recommended that the full version/s of these HTA reports are made available for 'speedy sifting'[9].

Stage 2 – use of the toolkit for speedy sifting

This first section of the toolkit will help users to determine whether HTA report/s should be considered further for adaptation.

Based on answers to questions posed in the 'speedy sifting' section, users considering adaptation of a report would then make their own judgement on whether to: (1) proceed to the main section of the toolkit, (2) seek further information or (3) not take this report forward for adaptation.

Stage 3 – Main part of toolkit, assess reliability and transferability

This main section of the toolkit would help users assess the reliability and transferability of information/data from a report/s from another setting and decide how to use it.

Stage 4 - Output of the toolkit

Output of the toolkit will be adaptation material i.e. information and/or data that is relevant, reliable and transferable to the target setting.

Output

The toolkit output will be supplemented by further information and/or data by the user in order to develop an updated HTA report specific for the target setting. It is recommended that new reports are developed using the HTA core structure/framework.

[9] WP5 meeting attendees agreed that they would want to see the full HTA report/s when 'speedy sifting' not just summary/other.

Appendix 2: Development of the toolkit

This appendix lists the member organisations involved in undertaking WP5 work and describes the methods used to develop the toolkit. A number of methods were employed both to understand members' experience of adaptation and to consider the purpose and develop the content of the toolkit. These methods were as follows; literature searching, survey of adaptation experience, a two round Delphi survey for toolkit development, meetings and individual members' commentary work. A two stage review process was also undertaken. Applicability testing of the toolkit commenced in 2007.

WP5 members

19 Associated Partners

AETSA, Spain
ASR, Italy
Cochrane Collaboration, UK
DACEHTA, Denmark
DAHTA@DIMDI, Germany
DSI, Denmark
FinOHTA, Finland
HAS, France
LBI@HTA, Austria
Universita Cattolica del Sacro Cuore, Italy
KCE, Belgium
NOKC, Norway
Servicio Canario de la Salud, Canary Islands
OSTEBA, Spain
TU Berlin, Germany
IPHRS, Slovenia
Region Veneto, Italy
University of Tartu, Estonia
ZonMW, The Netherlands

7 Collaborating Partners

Institute of Molecular Medicine, Portugal
SNHTA, Switzerland
University of Iceland, Iceland
Austrian Health Institute, Austria
PHGEN, Germany
Hauptverband der Österreichischen Sozialversicherungsträger, **Austria**
AHTAPol, Poland

Previous Collaborating Partner: **HTA unit Aarhus University Hospital** Denmark

Literature searching

WP5 members were asked to identify key papers on the adaptation of HTA reports. A web based writeboard was set up for members to view and identify further papers. These papers were read by the lead partner and their findings considered in relation to the development of our toolkit.

Survey on experience of adaptation

A survey on members' experience of adaptation was undertaken in April 2006. A key question asked was about the HTA report headings (domains) WP5 should focus on, and therefore include in the toolkit.

Full details of the methods, content and results of the preliminary survey will be made available on WP5 extranet.

Delphi round 1 survey and WP5 face to face meeting

Based on these ideas and adaptation survey response, a possible toolkit structure was described in the first round Delphi survey questionnaire. This was sent to WP5 members in May 2006.

Full details of the methods, content and results of Delphi round 1 survey will be made available on the WP5 extranet.

WP5 members had the opportunity to comment on these ideas both in their response to the questionnaire and at the WP5 face to face meeting. The face to face meeting took place in London, England in June 2006. Twenty-four of the 28 WP5 agencies were represented at this meeting. Minutes of this meeting can be viewed from: http://www.eunethta.net/WP5_documents/WP5MeetingDocs/WP52006mtgmins.pdf

At the WP5 face to face meeting, participants were asked to undertake group work to consider the role and function of the toolkit and its place within the stages of adaptation.

Delphi round 2 survey

Toolkit structure and composition was developed further by the Lead Partner as a result of the Delphi round 1 response and discussions at the WP5 face to face meeting.

The structure and function of the toolkit and its place within the stages of adaptation was presented in the Delphi round 2 questionnaire. WP5 members were asked to comment on these proposals. They were also asked to consider the development of user friendly software.

Full details of the methods, content and results of Delphi round 2 survey will be made available on the WP5 extranet.

Members' commentary work

Having agreed which domains would be included within the draft toolkit, WP5 members were asked to produce commentaries on the content of these domains. All associated partners and those collaborating partners expressing an interest undertook commentary work during May to August 2006. Commentary work was allocated to members by their expressions of interest for working on specific domains (as stated in the initial experience of adaptation survey).

Members were asked to consider checklists, questions and issues within specific domains for inclusion within the toolkit. They were asked to identify publications, draw on their own experience and provide ideas where no existing checklists could be identified.

Between 3 and 6 members worked independently on each toolkit domain. Once received, commentaries were collated and e-meetings, for each toolkit domain, were scheduled to discuss which of the checklists, questions and issues should be incorporated within the toolkit.

As a result of e-meeting discussions, the lead partner collated the finalised checklists for each domain.

Review process

There were two stages to the review process:

(1) Review of domain checklists, speedy sifting questions and consideration of inclusion of recommendations and implications

(2) Review of draft toolkit

For stage 1, members who did not undertake commentary work on a specific domain were randomly allocated the finalised checklists for one of the other four domains. In addition, all members were asked to provide final agreement on the speedy sifting questions and to consider whether questions regarding recommendations and implications should be included within the toolkit. This was undertaken in October 2006.

Reviewed checklists, questions and issues for each domain were collated by the lead partner.

For stage 2, the toolkit was made available on the extranet for review by all WP5 members. This was undertaken in November 2006.

A toolkit guidance document was produced for the M12 (December 2006) deadline.

Future work

The WP5 toolkit has been tested in two rounds of applicability testing, and revisions made as necessary.

Appendix 3: Brief Glossary of HTA Adaptation Terms

November 2007

This glossary contains excerpts from the Glossary of HTA Adaptation Terms. It contains descriptions for the various adaptation terms used in the Toolkit obtained either from the INAHTA glossary or descriptions formulated by Work Package 5 of the EUnetHTA project.

Terms

A

Adaptation
Advice
Applicability

C

Conflict of Interest
Context Specific

D

Domain

E

Effectiveness
Efficacy
Evidence Synthesis

G

Generalisability
Guidance
Guideline

H

Health Technology
Health Technology Assessment

P

Policy
Policy Makers
Policy Questions

R

Relevance
Reliability

S

Secondary Research
Setting
Speedy Shifting

T

Toolkit
Transferability

Term	Description
Adaptation	EUnetHTA **Issue** The purpose of adaptation is to enable an HTA agency in one country (or region or setting) to make use of an HTA report produced elsewhere, thus saving time and money. This sounds simple but in reality, the adaptation process is complex. **Different types of HTA reports** Not all 'HTA reports' are the same. Some just contain information about technologies, some also contain recommendations about how they should be used (in the English context, these are respectively 'assessment' and 'appraisal'). Of those that contain information, some are reports of new studies and some are a synthesis of research i.e. systematic reviews. Some are produced very quickly, in a few days; some take a year or more to produce.

[Back to Top](#)	**Adaptation is a part of a spectrum** Making use of all or part of an HTA report from elsewhere could be done in a wide range of ways (see items 1 to 4 below). There is a spectrum, with progressively more of the original report being used and so more possibility of saving time and money through reduced duplication. Items 1 to 3 require further work beyond the use of information from the report to develop your own report. *Summarising*: translate the summary and use this for background information *Updating searches*: using the original search strategy to identify any more recent evidence or adding to the search strategy and extending it. *Adapting*: the systematic extraction of relevant HTA information from an existing report (from a whole report or from part of a report) *Adopting*: making use of the report without making any changes at all (except perhaps translation into your own language) **Adaptation is a process** The 'product' of the adaptation process is information that has been extracted from the report that is (a) relevant to your needs, (b) quality assessed (c) critically appraised and d) is ready to be incorporated into a new framework for an HTA report in your own setting or country. The process of adaptation therefore involves, to varying degrees, the following steps: a) checking the relevance of the question(s) addressed in the original report to the question you are facing, b) identifying the information in the report which is relevant and most likely to be transferable to your setting, c) assessing the reliability of the information under various domains (benefits, harms, cost-effectiveness, organisational domain assessment elements, social and legal issues, etc), d) identifying and setting out the problems which may occur when the extracted, relevant, quality assessed information is transferred into a local HTA report; and deciding how to deal with them.
Applicability [Back to Top](#)	[INAHTA Glossary](#) The degree to which the results of an observation, study or review hold true in other settings.
Clinical Question *See* **Policy**	
Conflict of Interest [Back to Top](#)	[INAHTA Glossary](#) A situation in which the private interests of someone involved in the assessment or evaluation process (e.g. interviewer, rater, scorer, evaluator) have an impact (either positive or negative) on the quality of the evaluation activities, the accuracy of the data, or the results of the evaluation.

Context Specific Setting [Back to Top](#)	EUnetHTA **Context** and **setting** both refer to the *place* and *time* from which the evidence for the HTA report has come and/or in which the HTA report will be used. Time and place are both important dimensions of context/setting, as are level (national, regional, local), the kind of decision being made. '**Setting**' in particular is commonly used in HTA to refer narrowly to an organizational dimension of health care, such as primary, secondary or tertiary care, or community care. We commonly say that legal issues around a technology's use are context-specific, but sometimes estimates of clinical efficacy and safety can also be context-specific. This is especially likely, for instance, with surgical procedures. If HTA evidence, or an HTA report, is '**context-specific'**, this may mean that something about them cannot or should not be applied to other settings without careful adaptation. Context-specific, therefore, implies 'not generalisable' and 'not transferable'.
Domain *See* **Toolkit**	
Effectiveness **Efficacy** [Back to Top](#)	INAHTA Glossary **Effectiveness:** The benefit (e.g. to health outcomes) of using a technology for a particular problem under general or routine conditions, for example, by a physician in a community hospital or by a patient at home. **Clinical Effectiveness:** The extent to which a specific intervention, procedure, regimen, or service does what it is intended to do under ordinary circumstances, rather than controlled conditions. Or more specifically, the evaluation of benefit to risk of an intervention, in a standard clinical setting, using outcomes measuring issues of importance to patients (e.g. ability to do daily activities, longer life, etc.). **Efficacy:** The benefit of using a technology for a particular problem under ideal conditions, for example, in a laboratory setting, within the protocol of a carefully managed randomized controlled trial, or at a "center of excellence."
Evidence Synthesis **Secondary Research** [Back to Top](#)	*Please note: "Evidence synthesis" and "Secondary Research" are treated here as meaning the same.* INAHTA Glossary Research that does not generate primary data but that involves the qualitative or quantitative synthesis of information from multiple primary studies. Examples are literature reviews, meta-analyses, decision analyses and consensus statements.
Generalisability	EUnetHTA **Generalisability** refers to whether the results of an HTA report can be extrapolated to other settings. This is sometimes referred to as 'external validity'. **Generalisable information/data** can be readily adopted. However, the

Back to Top	more context specific, the less likely that data/information in one report can be adopted into another i.e. transferred without making any changes or additions. 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.
Guideline *Back to Top*	INAHTA Glossary Clinical Practice Guideline: A systematically developed statement to assist practitioner and patient decisions about appropriate health care for one or more specific clinical circumstances. The development of clinical practice guidelines can be considered to be a particular type of HTA; or, it can be considered to be one of the types of policymaking that is informed or supported by HTA.
Health Technology *Back to Top*	INAHTA Glossary Any intervention that may be used to promote health, prevent, diagnose or treat disease, or for rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures and organisational systems used in health care.
Health Technology Assessment *Back to Top*	INAHTA Glossary Health technology assessment (HTA): the systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods.
Organisation	EUnetHTA “Organisation has been defined as a consciously coordinated social unity (Robbins 1987). An organisation has rather clear boundaries and its activities, which target certain goals, are continuous. An organisation is formed in order to assign and carry out special tasks and coordinate these tasks (Schein 1985)…”
Policy **Policy Makers** **Policy Questions** **Clinical Question**	EUnetHTA **Clinical question**. In the field of evidence based healthcare, the patient-intervention-comparison-outcome (PICO) formula is widely used to construct a clinical question. P - patient, population of patients, problem I - intervention (e.g. a therapy, test) C - comparator or control (e.g. another therapy, placebo) O - outcome This formula helps users to combine all elements of the clinical scenario in an orderly fashion. PICO works well for HTA effectiveness questions. PICO is also used to help formulate search strategies, when clinicians are looking for relevant evidence to help them answer a clinical question. An HTA research question is the question which the HTA report seeks to answer in a scientific way. Typically, it will include a number of different

Back to Top	PICO questions and other research questions. A **policy question** is a question posed by policy makers, those who in the context of HTA have to make decisions about the health care that groups of people will be offered. It may be very poorly differentiated (such as, "what are we going to do about drugs for Alzheimer's disease?") or more precise ("for which patients should donepozil be prescribable on the NHS?"). In summary, a policy question is about what to do; an HTA question is about what we know; and a clinical question is about the evidence relating to a particular patient or group of patients.
Relevance **Reliability** Back to Top	EUnetHTA In the context of adapting HTA reports, a reliable report is one that a potential user can trust and rely on: they can trust that what it says is true. If so, they may be adopted or considered for adaptation for another setting. One way of assessing **reliability** in a standardized way is through the use of quality checklists, such as those that are included in the EUnetHTA Toolkit. Note however that **reliability** is a tricky word and should be used with caution. Although reliability is widely used in HTA as above, in other situations, it refers to repeatability, which leads to the common observation that a repeatable test is not necessarily a valid one. However, in the case of HTA, reliability can also be used to mean "how far something can be relied on or trusted", which is very close to (internal) validity. The **relevance** of an HTA report is determined by how closely the policy and research question(s) in the report match the research questions that are of interest to the user. Relevance is therefore a relative or subjective matter: it is the relevance for the user and not a general 'standard' relevance. Relevance therefore depends on the setting, the knowledge of the adapting person and the policy question. A report might be very **relevant** even if it is not **reliable** – and vice versa.
Secondary Research *See* **Evidence Synthesis**	
Setting *See* **Context Specific Setting**	
Speedy Sifting *See* **Toolkit**	
Technology *See* **Health Technology**	
Toolkit **Speedy Sifting Domain**	EUnetHTA The EUnetHTA adaptation **toolkit** has been developed to aid HTA agencies in the adaptation of HTA reports that are a synthesis of evidence. It contains checklists of questions and resources to enable the

Back to Top	assessment of a report's relevance, reliability and transferability. Currently, the **toolkit** is in the form of a word document. It will be developed into something more interactive, in the context of the planned web-based clearing house. It consists of 6 of modules: one generic and 5 specific to certain parts (or domains) of HTA reports. The generic module ("**Speedy Sifting**") enables the rapid assessment of the relevance of the report. The five specific **domains** relate to technology use and development, safety, effectiveness, economic evaluation and organisational elements. The reliability and transferability of information and data within these 5 domains can be assessed using these parts of the toolkit. The toolkit output is adaptation material that can be incorporated into a new framework for an HTA report in a target setting.
Transferability	EUnetHTA For the WP5 toolkit, transferability is about the ability to apply information from one report into a user's target setting. 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 pieces of information when applying these to their target setting.