

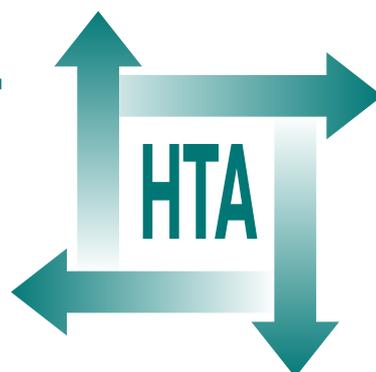
Development of a toolkit and glossary to aid in the adaptation of health technology assessment (HTA) reports for use in different contexts

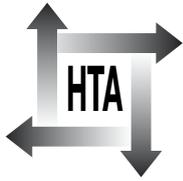
D Chase, C Rosten, S Turner, N Hicks
and R Milne



November 2009
DOI: 10.3310/hta13590

Health Technology Assessment
NIHR HTA programme
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Development of a toolkit and glossary to aid in the adaptation of health technology assessment (HTA) reports for use in different contexts

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Declared competing interests of authors: none

Published November 2009

DOI: 10.3310/hta13590

This report should be referenced as follows:

Chase D, Rosten C, Turner S, Hicks N, Milne R. Development of a toolkit and glossary to aid in the adaptation of health technology assessment (HTA) reports for use in different contexts. *Health Technol Assess* 2009; **13**(59).

Health Technology Assessment is indexed and abstracted in *Index Medicus/MEDLINE*, *Excerpta Medica/EMBASE*, *Science Citation Index Expanded (SciSearch®)* and *Current Contents®/Clinical Medicine*.

NIHR Health Technology Assessment programme

The Health Technology Assessment (HTA) programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The research findings from the HTA programme directly influence decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC). HTA findings also help to improve the quality of clinical practice in the NHS indirectly in that they form a key component of the 'National Knowledge Service'.

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First is the commissioned route. Suggestions for research are actively sought from people working in the NHS, from the public and consumer groups and from professional bodies such as royal colleges and NHS trusts. These suggestions are carefully prioritised by panels of independent experts (including NHS service users). The HTA programme then commissions the research by competitive tender.

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Third, through its Technology Assessment Report (TAR) call-off contract, the HTA programme commissions bespoke reports, principally for NICE, but also for other policy-makers. TARs bring together evidence on the value of specific technologies.

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 05/52/01. The contractual start date was in January 2006. The draft report began editorial review in August 2008 and was accepted for publication in April 2009. The project was jointly funded by the HTA programme and the European Commission. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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ISSN 1366-5278

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Published by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk), on behalf of NETSCC, HTA.

Printed on acid-free paper in the UK by Henry Ling Ltd, The Dorset Press, Dorchester.



Abstract

Development of a toolkit and glossary to aid in the adaptation of health technology assessment (HTA) reports for use in different contexts

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Objectives: To develop a health technology assessment (HTA) adaptation toolkit and glossary of adaptation terms for use by HTA agencies within EU member states to support them in adapting HTA reports written for other contexts.

Methods: The toolkit and glossary were developed by a partnership of 28 HTA agencies and networks across Europe (EUnetHTA work package 5), led by the UK National Coordinating Centre for Health Technology Assessment (NCCHTA). Methods employed for the two resources were literature searching, a survey of adaptation experience, two rounds of a Delphi survey, meetings of the partnership and drawing on the expertise and experience of the partnership, two rounds of review, and two rounds of quality assurance testing. All partners were requested to provide input into each stage of development.

Results: The resulting toolkit is a collection of resources, in the form of checklists of questions on relevance, reliability and transferability of data and information, and links to useful websites, that help the user assess whether data and information in

existing HTA reports can be adapted for a different setting. The toolkit is designed for the adaptation of evidence synthesis rather than primary research. The accompanying glossary provides descriptions of meanings for HTA adaptation terms from HTA agencies across Europe. It seeks to highlight differences in the use and understanding of each word by HTA agencies. The toolkit and glossary are available for use by all HTA agencies and can be accessed via www.eunethta.net/.

Conclusions: These resources have been developed to help HTA agencies make better use of HTA reports produced elsewhere. They can be used by policy-makers and clinicians to aid in understanding HTA reports written for other contexts. The main implication of this work is that there is the potential for the adaptation of HTA reports and, if utilised, this should release resources to enable the development of further HTA reports. Recommendations for the further development of the toolkit include the potential to develop an interactive web-based version and to extend the toolkit to facilitate the adaptation of HTA reports on diagnostic testing and screening.



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Glossary and list of abbreviations

Glossary

Commentary work Development of toolkit content. This involved drawing on experience of adaptation, expertise and the literature.

Context The place where results from a health technology assessment (HTA) report need to be applicable (this could be at the level of the country, society and/or specific health-care provider).

Domain A part of the toolkit. There are five domains within the toolkit, namely technology use and development, safety, efficacy and effectiveness, economic evaluation and organisational aspects.

e-meeting A meeting undertaken via an internet link.

EUR-ASSESS The EUR-Assess Project began in 1994, and is aimed at co-ordinating health-care technology assessment activities in Europe, with the goal of improving the quality and value for

money of technology assessments undertaken in European countries, and improving decision-making concerning adoption and use of health-care technology.

Partners/partnership HTA agencies, organisations and individuals involved in developing the toolkit and glossary

Speedy sifting The first section of the toolkit whereby the user can assess the relevance of an HTA report for adaptation. It is known as 'speedy sifting' because the user can quickly decide which reports to consider further and which reports are irrelevant.

Adaptation toolkit A collection of resources to help with the adaptation of HTA reports.

Wiki-glossary An electronic web-based version of the HTA adaptation glossary. This enables users to submit their own descriptions for HTA adaptation terms.

List of abbreviations

ECHTA/ ECAHI	European Collaboration for Health Technology Assessment/European Collaboration for Health Interventions Project	NCCHTA	National Coordinating Centre for Health Technology Assessment, now part of the National Institute for Health Research (NIHR) Evaluation, Trials and Studies Coordinating Centre (NETSCC)
EUnetHTA	European Network for Health Technology Assessment	WHO	World Health Organization
HTA	health technology assessment	WP	work package
INAHTA	International Network of Agencies for Health Technology Assessment		

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.



Executive summary

Health technology assessment (HTA) reports are frequently produced on the same health technologies in different countries at around the same time. Potential exists for resources to be saved and directed towards the production of additional reports on different health technologies if existing reports can be adapted for use in different settings. The European Network for Health Technology Assessment (EUnetHTA) project was set up in 2006 to link HTA agencies, research institutions and health ministries across Europe. The creation of this network has enabled the development of practical tools to support the HTA process. Two of these tools are described in this report: the HTA adaptation toolkit and its associated glossary of adaptation terms. These two resources were developed to support HTA agencies in adapting HTA reports written for other contexts.

The objectives of this work were to develop an HTA adaptation toolkit and glossary of adaptation terms for use by HTA agencies within EU member states. This report describes their development and quality assurance testing. The current versions (at the time of writing) of both documents can be found in this report.

Both the toolkit and the glossary were developed by a partnership of 28 HTA agencies and networks from across Europe (known as EUnetHTA work package 5). This partnership was led by the National Coordinating Centre for Health Technology Assessment (NCCHTA), now part of the National Institute for Health Research (NIHR) Evaluations, Trials and Studies Coordinating Centre (NETSCC), in Southampton, UK. The approach to development was pragmatic, utilising the skills of the partners. An iterative process was used to understand partners' experiences of adaptation, identify and explore their views of its purpose and develop the content of the toolkit and glossary. Methods employed for the two resources were literature searching, a survey of adaptation experience, two rounds of a Delphi survey, meetings of the partnership and drawing on the expertise and experience of the partnership, two rounds of review and two rounds of quality assurance testing. All partners were requested to provide input into each stage of development.

The resulting toolkit is a collection of resources that helps the user assess whether data and information in existing HTA reports should and could be adapted for their own setting. These resources are in the form of checklists of questions on relevance, reliability and transferability of data and information and links to useful websites. The dimensions covered by the toolkit are relevance, reliability and transferability of HTA reports. Legal, ethical and social aspects are beyond the scope of the toolkit. The toolkit is designed for the adaptation of evidence synthesis rather than primary research.

The accompanying glossary provides descriptions of meanings for HTA adaptation terms from HTA agencies across Europe. It is intentionally non-prescriptive, seeking to highlight differences in the use and understanding of each word by HTA agencies.

The toolkit has implications for practice:

- The preparation of HTA reports requires both time and financial resources. Adaptation of an existing HTA report may reduce the cost and time incurred during the production of new reports.
- This may lead to an increase in the potential for HTA organisations to have the resources available to report on a greater breadth of new health technologies.

The recommendations for the further development of the toolkit are as follows:

- The toolkit is currently in a PDF version and there is the potential to develop an interactive web-based version.
- There is scope to extend the toolkit to facilitate the adaptation of HTA reports on diagnostic testing and screening.
- There is scope for further testing, review and improvement both within the EUnetHTA partnership and beyond to external organisations.
- There is the potential to develop a wiki-version of the glossary.

- There is the potential for more work to be undertaken to incorporate closer integration with other EUnetHTA outputs.

The toolkit and glossary are available for use by all HTA agencies and can be accessed via www.eunethta.net/. These resources have been developed to help HTA agencies make better

use of HTA reports produced elsewhere. They can be used by policy-makers and clinicians to aid in understanding HTA reports written for other contexts. However, the main implication of this work is that there is the potential for the adaptation of HTA reports and, if utilised, this should release resources to enable the development of further HTA reports.

Chapter I

Background

Health technology assessment (HTA) agencies produce HTA reports for their respective health ministries to support local health-care policy-making.¹ Reports from many of these agencies can be readily accessed through internet search engines at any time.² In general, assessments on the same health technologies are required by different health ministries at around the same time.³ Creating numerous reports on the same health technology is not only more resource intensive but also reduces the opportunity to develop further reports on other health technologies. Given the accessibility and volume of such reports, it seems intuitive that existing reports should be adapted for other contexts.

The HTA movement began in the late 1970s. In its beginnings,⁴ efforts concentrated on methods of evidence synthesis. In the 1980s the focus shifted to strengthening links with policy-makers, particularly in Europe. Then, in the 1990s, efforts focused towards more effective dissemination and implementation.^{5,6} More recent emphasis has been directed towards enhancing links between HTA agencies across countries. These stronger links have provided opportunities to share evidence globally about the outcomes and effectiveness of health care.⁷ Alongside these developments there has been a movement from assessments on high-cost drugs and devices to assessments on 'softer' technologies, public health interventions and health-care needs.⁵

In general, HTA is viewed as the systematic evaluation of health-care technologies. There are subtle variations to this definition but the approach remains the same. It is a policy research approach, ideally providing an objective assessment that supports health-care decisions and policy-making.⁸⁻¹⁰ HTA can be managed by the state, by research institutions, through the health system or commercially. HTA agencies can serve the country or the region to provide specific services in relation to HTA.

The link between HTA and decision-making is similar to that between evidence-based health care and evidence-based policy-making.⁵ Evidence-based health care has origins preceding HTA.

The Cochrane Collaboration provides a global resource of evidence-based health care in the form of systematic reviews. The move to strengthen links between organisations undertaking evidence synthesis was initiated by Cochrane.

However, unlike Cochrane reviews, HTA places emphasis on application in a local context. HTA: (1) is an assessment of the 'global' evidence base; (2) includes locally adapted evidence for assessment; and (3) provides an appraisal of this evidence with recommendations and/or a decision.^{7,11} An assessment involves gathering information and analysing it. An appraisal is about decision-making, taking account of the assessment information but incorporating other local factors.¹² The linking of global evidence to local contextual information means that HTA reports can rarely be simply taken from one context and applied in another. In practice, the assessment within the HTA must be extracted, updated and adapted. The accompanying appraisal must be conducted locally in relation to the local context.

A further complexity to using HTA reports written for other contexts is that the content and focus of HTA reports can vary according to their purpose. HTAs may include primary research, systematic reviews and economic evaluations.^{8,13} Their focus can vary from simply providing generic evidence of effectiveness and cost-effectiveness to (more recently) consideration of specific political, ethical, social, organisational or legal perspectives for a local setting.⁵

To foster links between HTA agencies, the International Network of Agencies for Health Technology Assessment (INAHTA) was formed. Its primary objectives are to develop HTA methods, raise standards and share work and improve communications between HTA agencies.² Efforts to strengthen collaboration between HTA agencies across Europe began in earnest in the early 1990s.¹⁴ The EUR-ASSESS project (1994-7) was the first of three EU-funded projects set up to identify the need for and then establish co-ordinating mechanisms across European HTA agencies.¹⁵ The other two projects were HTA-Europe (1997-9) and the European Collaboration for Health Technology

Assessment/European Collaboration for Health Interventions Project (ECHTA/ECAHI) project (1999–2001).¹⁴

The European Network for Health Technology Assessment (EUnetHTA) project was initiated in 2006 to further strengthen this collaboration and create a sustainable European network on HTA.¹⁶ In the majority of member states of the EU, HTA is intrinsically linked with the Ministry of Health or equivalent.⁵ Another primary objective of EUnetHTA was to strengthen such links in Europe.¹⁷

An important benefit of such a network is the opportunity to make better use of existing HTA reports by: (1) supporting HTA agencies, and low income countries, that do not have the technical resources to undertake comprehensive HTAs; and (2) reducing the number of HTA reports that are produced on the same health technology by different HTA agencies. For instance, a search of the INAHTA database showed that 14 HTA reports on positron emission tomography for lung cancer had been published worldwide.

The preparation of HTA reports can require a great deal of time and effort and inevitably there is also a monetary cost associated with this. The aim of adaptation is to maximise the value of HTA reports by utilising the parts that can be adapted to inform policy in other countries or contexts as well as in the country or context for which the report was initially prepared, thereby saving costs and time. The extent to which this can be achieved depends on the generalisability of the topic under consideration and the different contexts in which it is to be considered.^{18,19}

Depending on the purpose, making use of all or part of an HTA report from elsewhere could be undertaken in a wide range of ways. There is a spectrum, with progressively more of the original report being used. The adaptation of a report may range from simply translating the language in which the report is written, through to adapting the entire report. Most reports require some degree of adaptation, i.e. having the need for systematic extraction of relevant HTA information from an existing report (from a whole report or from part of a report).

HTA reports should be viewed as ‘context specific’ until they have been adapted. Some parts of reports are more context dependent than others.²⁰ For instance, most safety and effectiveness

evidence for many health technologies can be readily transferred to different contexts (being context independent). However, specific attributes or acceptable trade-off levels may vary between contexts (the appraisal of evidence being context dependent). Legal and ethical information is heavily context dependent. It is unlikely that this information could be readily adopted or easily adapted without significant appraisal in relation to the local context.

Although adaptation has been undertaken in the past, there are very few published accounts of how this process has been undertaken.²¹ However, numerous collaborative projects have been undertaken between different countries assessing particular health technologies.²² Currently, the only information available relating to the direct adaptation of HTA reports from one context for use in another is anecdotal.

The EUnetHTA project was set up with the strategic objective of connecting public national/regional HTA agencies, research institutions and health ministries, enabling an effective exchange of information and providing support to policy decisions by the member states.¹⁷ It was funded by the European Commission and member states and ran for 3 years (2006–8). It aimed to develop a sustainable European network through the development of: (1) an organisational framework; and (2) practical tools to fit within this network.¹⁷

During the EUnetHTA project time frame, tools and systems were developed to support this process. These activities were undertaken via eight work packages (WP1–WP8). *Table 1* gives a brief description of each work package’s remit.

Further details of the work undertaken within each WP can be found on the EUnetHTA website.¹⁶ This report provides information on work undertaken by WP5. This WP was concerned with the adaptation of HTAs from one country to other settings. A partnership of 28 HTA agencies from across Europe was tasked with developing these products. It was led by the National Coordinating Centre for Health Technology Assessment (NCCHTA), now part of the National Institute for Health Research (NIHR) Evaluations, Trials and Studies Coordinating Centre (NETSCC), based at the University of Southampton in England. WP5’s objective was to ensure better use of existing HTA reports by developing tools for adapting the ‘core’ within assessments made for one country into advice appropriate to other contexts. To this end, a

TABLE 1 Description of work undertaken by the eight EUnetHTA work packages (WPs)

WP	Description of work
1	Co-ordination of the project
2	Communications
3	Evaluation of the project
4	Common core of HTAs
5	Adapting existing HTAs from one setting to other settings
6	Transferability to health policy
7	Monitoring development for emerging/new technologies and prioritisation for HTA
8	Systems to support HTA in member states with limited institutionalisation of HTA

toolkit for adapting HTA reports and a glossary of HTA adaptation terms were developed.

The adaptation toolkit is a collection of resources developed to help transfer data and information from one context to another. As described above, some evidence must be appraised and adapted to be relevant for a specific context. The toolkit provides resources to help make the leap from assessment to appraisal. The accompanying glossary provides descriptions of adaptation terms

from different countries and settings. Although some definitions for terms are provided, the objective of this glossary is to highlight differences in meaning.

The aim of this report is to describe how the adaptation toolkit and glossary were developed. The current versions of both documents (at the time of publication) can be found in Appendices 1 and 2, respectively, of this report.

Chapter 2

Methods

This section describes how the toolkit and glossary were developed.

Partners involved in toolkit and glossary development

A partnership of 28 HTA agencies and networks from across Europe developed the HTA adaptation toolkit and a glossary of adaptation terms. This partnership formed the EUnetHTA WP5 (as described in Chapter 1). Another agency from outside the EUnetHTA partnership also contributed to some elements of the development of the HTA adaptation toolkit and the glossary (NHS Quality Improvement Scotland). The WP5 partnership was led by NCCHTA based in England. A list of all WP5 partners can be found in the acknowledgements section of this report.

Overall toolkit and glossary development processes

A pragmatic iterative process was employed to understand partners' experiences of adaptation, identify and explore their views of its purpose, and develop the content of the toolkit and glossary. To do this a number of methods was used.

Figure 1 shows the stages of toolkit development and the methods employed at each stage:

- Stage 1 involved searching for literature on adaptation and undertaking a preliminary survey of partners to better understand their experiences of adapting HTAs.
- Stage 2 involved a Delphi survey questionnaire, which was distributed to participants to gain an initial insight into partners' requirements from a toolkit for adaptation.
- In stage 3, the results from this first round of the Delphi survey shaped both the subsequent round of the Delphi questionnaire and the discussions of the toolkit's function, structure

and content at the first face-to-face meeting of the partnership.

- Once these concepts had been agreed, stage 4 involved each partner individually drafting the initial content of specific domains of the toolkit. Partners working in the same 'domain' were then brought together through e-meetings to help reach consensus on the final content of that domain.
- Stage 5 involved a review of the domain contents by other partners. Then all partners reviewed the entire toolkit.
- The final stage (stage 6), one of quality assurance testing, was undertaken by all partners. This involved partners using the toolkit to adapt an HTA and reporting back on their experiences of using it through questionnaires and interviews.

Figure 2 shows the stages of glossary development and the methods employed at each stage:

- Stage 1 involved the identification of a list of terms for possible inclusion in the glossary from a variety of sources.
- Partners were then asked to provide descriptions for these terms (stage 2).
- These descriptions were collated (stage 3).
- For stage 4, partners were asked to comment on the descriptions.
- Stage 5 involved final editing of the glossary.
- A final review by all EUnetHTA partners formed stage 6.
- To further enhance the glossary, definitions (descriptions for the purpose of EUnetHTA) were developed for certain terms (stage 7).
- Lastly, additional descriptions were gathered for the remaining terms (stage 8).

All partners were asked to provide input into all stages of development for both resources. These methods were employed in a pragmatic fashion to achieve the goal of producing a toolkit and glossary within the allotted project time. The following sections provide details of these methods.

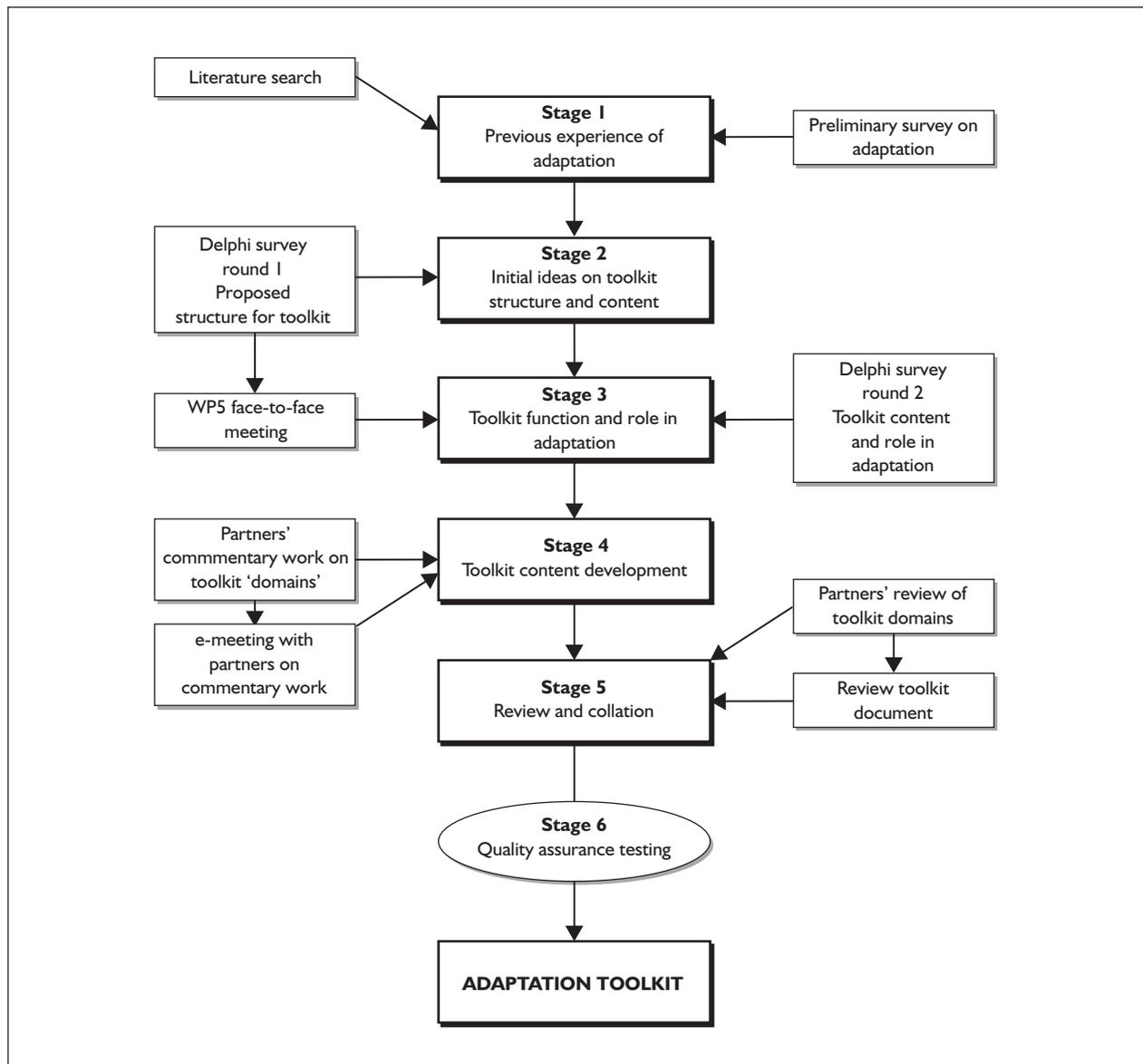


FIGURE 1 Stages of toolkit development and methods employed.

Toolkit development

Stage 1: Previous experience of adaptation

Literature review

Two electronic databases, MEDLINE and Health Management Information Consortium (HMIC), were searched from September 1996 to September 2007 for published papers on adaptation. Searches were initially limited to English language publications. This search was undertaken in January/February 2006. The search strategy is shown in Appendix 3 (e-version). Two additional papers on the transferability of economic

evaluation were identified by a referee during the editorial phase of publication of this monograph.

A list of the published papers on adaptation identified by the searches was made available to all partners. Partners were asked if any papers were missing from the list and if they were aware of any grey literature in this area (February/March 2006).

Subsequent searches were conducted without a language restriction, to identify publications with an abstract or title in English, or without any of the MeSH terms used (October 2007). INAHTA members were also asked at a later date if they were

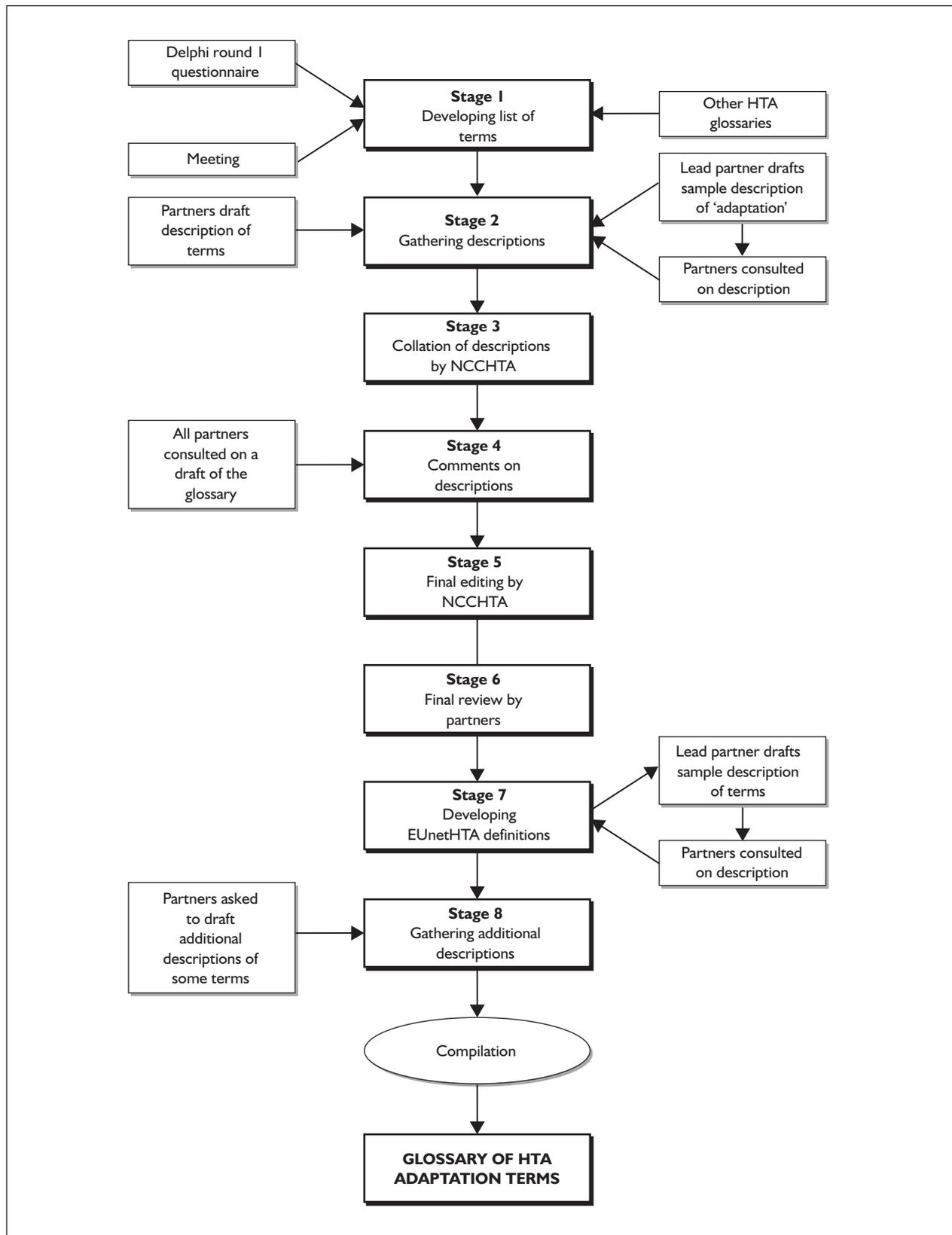


FIGURE 2 Stages of glossary development and methods employed.

aware of any grey literature in this area (October 2007).

Preliminary survey of previous experience of adaptation

A preliminary survey was conducted to gain an understanding of the previous experiences of fellow Europeans in adapting HTA reports from other countries. A total of 29 European HTA organisations/networks were asked to complete this survey in April 2006. The survey is shown in Appendix 4 (e-version).

Questionnaire

The questionnaire consisted of the following six questions:

1. Describe the work of your HTA agency for the benefit of people outside your own country.
2. How much priority does your agency give to each of these groups as a target audience – clinical staff, policy-makers, health-care providers, health-care funders, others?
3. Have you ever adapted an HTA report from another country?
4. Do you know of any of your HTA reports that have been used in other countries?
5. How useful is it for your HTA agency to make use of reports from other countries?
6. Which elements from the EUR-ASSESS¹⁵ framework should WP5 focus on?

Data analysis

Responses to questions 2–6 were expressed quantitatively in the form of frequencies and percentages. Question 1 and comments received in relation to question 5 involved a qualitative analysis of responses. These responses were assessed using a thematic analysis, which focused on looking at identifiable themes. Themes were defined as patterns that appeared across participants' responses and were identified by the careful consideration of each individual response. Quotations were chosen from the comments and were used to further elucidate each theme.

Stage 2: Initial ideas on toolkit structure and content

Delphi survey round 1

Based on information derived from literature searching and from responses to the preliminary survey, a possible toolkit structure was described in the first round of a Delphi survey questionnaire. This is shown in Appendix 5 (e-version). A total of

29 European HTA agencies were asked to complete this Delphi survey round 1 questionnaire.

Survey questionnaire

The Delphi survey round 1 questionnaire contained five questions on the toolkit:

1. The above was a description of what we (at NCCHTA) think the toolkit will consist of and achieve. What are the pros and cons of this approach? What do you think?
2. ... shows our proposed subheadings for each of the 'most important' headings (domains). What do you think of these subheadings? What are the pros and cons? Are there any missing?
3. We are thinking of asking WP5 members to work on specific 'most important' headings (domains), both to develop the associated subheadings and to identify useful links and information. Please rank your preference for working on these headings below.
4. If your agency has had experience of adapting HTA reports from other countries/settings, what words or phrases in other countries' reports cause difficulties?
5. Please provide comments on the ease or difficulty that you had in understanding the toolkit description and the questions above.

Data analysis

Responses to questions 1, 2 and 5 were assessed using thematic analysis. Responses to question 3 were used to guide the allocation of the commentary work to specific partners. Responses to question 4 provided words for the glossary. Details explaining the development of the glossary can be found later in this chapter (see Glossary development).

Stage 3: Toolkit function and role in adaptation

Partners' face-to-face meeting

Partners had a further opportunity to comment on the proposed toolkit structure and content at a face-to-face meeting. This meeting took place in June 2006 with 24 partners represented. At the meeting, participants were asked to undertake group work to further consider the role and function of the toolkit.

Delphi survey round 2

From the responses to the Delphi questionnaire round 1 and following the discussions at the face-to-face meeting, the lead partner revised the

toolkit's structure and composition. This revised structure and function of the toolkit was presented to partners in the Delphi survey round 2 (shown in Appendix 6, e-version) in which partners were asked to comment on these proposals.

A total of 29 European HTA agencies were contacted with the Delphi survey round 2. The survey consisted of four questions, each pertaining to a specific part of the toolkit:

- Question 1: Adaptation and the role of the toolkit. This question comprised a description (taking account of partners' views) of the adaptation process. It asked partners to consider at which stage of adaptation the toolkit would help.
- Questions 2 and 3: Toolkit details:
 - Speedy sifting section. This question comprised a description of the speedy sifting section of the toolkit. Partners were asked whether there were any questions missing with regard to this section.
 - Main section. This question comprised a description of the main section of the toolkit and some of the issues raised by partners. Partners were asked for their thoughts on content.
- Question 4: Any further comments.

Data analysis

Responses to these questions were assessed using a thematic analysis.

Stage 4: Toolkit content

Partners' commentary work on toolkit 'domains'

Having agreed which domains would be included within the draft toolkit, partners were asked to produce commentaries on the content of these domains. Instructions for work are shown in Appendix 7 (e-version). In essence, partners were asked to consider checklists, questions and issues within their specific domains for inclusion within the toolkit. They were asked to identify publications, draw on their own experiences and provide ideas when no existing checklists could be identified. Between three and six partners worked independently on each toolkit domain.

This work was undertaken from May to August 2006. Commentary work was allocated to partners according to their expressions of interest for working on specific domains.

e-meetings with partners

Once received the 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.

Stage 5: Review and collation

As a result of e-meeting discussions, checklists were finalised for each domain.

Partners' review of toolkit domains and review of entire toolkit

There were two stages to the review process:

1. review of domain checklists and speedy sifting questions and consideration of inclusion of recommendations and implications
2. review of draft toolkit.

For the first stage of the review, partners were randomly allocated finalised domain checklists. In addition, all 27 partners were asked to provide final agreement on the first section of the toolkit, known as the speedy sifting section. For the second phase of the review, the entire toolkit was reviewed by all 27 partners. Changes to the toolkit as a result of review were made by the lead partner.

Stage 6: Quality assurance testing

The first five stages of development and review resulted in the first version of the toolkit. This was then subjected to quality assurance testing.

All 27 partners were contacted to participate in the quality assurance testing. Testing required partners to select one or more HTA reports from a different country and test the toolkit as an aid to adapting the report to meet the needs of their own health service. They then completed a questionnaire on their experiences of using the toolkit for this adaptation. In total, 15 partners participated in quality assurance testing. Responses were submitted in June 2007. Four of these evaluators also underwent a 1-hour face-to-face or telephone interview to further explore their experiences. Changes to the toolkit as a result of quality assurance testing were made by the lead partner.

The quality assurance testing questionnaire consisted of the following questions:

1. How long did it take you to use the toolkit?

2. Did you use the speedy sifting section to assess the relevance of this report to your question? If so, how useful was it?
3. How can we improve on the speedy sifting section? What additional questions or resources would help you assess relevance?
4. Which domains in the main part of the toolkit did you use for this report (technology use and development, safety, effectiveness, cost-effectiveness, organisational aspects)?
5. Can we improve on the checklists within these domains? Is the balance of questions right (too superficial/too in-depth)?
6. What additional toolkit questions and resources would help in adaptation?
7. Did you use the glossary? If so, was it useful?
8. Did you consult anything other than the toolkit, e.g. resources, checklists, to help you adapt this report?
9. What additional work was required to adapt this report for your target setting (your local context)?
10. Is there any other information you would like to provide us with to help improve our toolkit?

Responses from both the questionnaire and subsequent interviews were analysed using a thematic approach.

Glossary development

The production of the glossary of HTA adaptation terms also involved numerous developmental stages, described in the following sections. In total, 28 partners helped to develop this glossary.

Stage 1: Developing the list of adaptation terms to be included in the glossary

This stage involved identifying terms that would be suitable for glossary inclusion. Terms were deemed suitable if they pertained to HTA, were relevant to adaptation and were subject to confusion and/or different usage in different countries. Potential terms were identified from a variety of sources:

- HTA glossaries identified during an internet search
- partners who attended the face-to-face meeting (see Toolkit development)
- partners who responded to round 1 of a Delphi questionnaire (see Toolkit development).

From these sources a list of glossary adaptation terms was assembled. It was decided to include terms if they satisfied the following characteristics:

- concerned with adaptation and
- subject to considerable confusion and/or
- used differently by different countries.

Stage 2: Gathering descriptions and examples of usage for these terms

The second stage of development involved 12 partner organisations who were each asked to prepare descriptions on several adaptation terms identified in stage 1. Descriptions were meanings, or understandings, of a term. All meanings were written in English.

Each organisation was allocated three or four terms. Some terms were stand alone (e.g. 'affordability') whereas others were grouped terms (e.g. 'efficacy' and 'effectiveness'). Terms were grouped if they were closely related and more likely to be prone to confusion. For these terms partners were asked to explain the differences between them in their descriptions. They were specifically asked to discuss possible interpretations of each of the terms and to provide examples of how these terms are used in different countries. It was specified that what were required were not definitions of the terms but rather descriptions. Partners were encouraged to use their experiences with, and understanding of, HTA to guide them.

To help the partner organisations with this task, NCCHTA developed a description of the term 'adaptation' for the glossary. This description was distributed to all partners for comment.

Stage 3: Collating the descriptions

The descriptions of the terms provided by each partner were collated and a draft glossary was compiled. Minimal editing was undertaken at this stage, mainly the correction of spelling and grammar.

Stage 4: Obtaining comments on the collated descriptions from partners

The draft glossary was made available to all partners for review.

Stage 5: Collation and editing of glossary

Final descriptions were subjected to some minor editing to eliminate contradictory information. However, any similarities between descriptions were left untouched to highlight areas of strong agreement. Descriptions for each term were then placed in the following order:

1. EUnetHTA definition
2. INAHTA definition
3. HTA organisation descriptions.

In addition to the terms circulated for stage 2 of development, four additional HTA adaptation terms were proposed by the lead partner for inclusion in the glossary at this stage of development.

Stage 6: Final review

A second review round was undertaken. All partners were asked to comment on the terms, definitions and descriptions included. Several amendments were made to the glossary as a result of this review.

Stage 7: Developing EUnetHTA definitions for certain terms

To further enhance the glossary it was decided that it would be helpful to reach some agreement on glossary entries for a few specific terms. These

would form the 'EUnetHTA descriptions' for these terms. The terms were selected because they were considered to be particularly relevant to the issues of adapting HTA reports. The terms selected were:

- clinical and policy question
- context specific and setting
- domain, speedy sifting and toolkit
- relevance and reliability
- generalisability and transferability.

NCCHTA drafted initial definitions for these terms, based in part on the various descriptions already available within the glossary. These definitions were then circulated to partners. All comments and suggestions received were considered. Based on this feedback the EUnetHTA definitions were redrafted and integrated into the glossary.

Stage 8: Gathering additional descriptions

Some additional descriptions were gathered for certain terms. To this end the 11 partners who had already submitted descriptions were allocated a further three glossary terms and asked to write descriptions for these. These were incorporated into the glossary.

The results, the final format of the glossary and details of how to use it are discussed in Chapter 3.

Chapter 3

Results

Interim results: development of the toolkit

The results from each stage of toolkit development are described below.

Stage 1: Previous experience of adaptation

Literature review

No published accounts or examples of adaptation of HTA reports were identified. Three papers^{19,23,24} on the generalisability of economic evaluations were identified, which provided guidance on adapting economic evaluations. Widening the search to include languages other than English produced no additional relevant results.

In terms of grey literature our partners identified one German language paper on the development of a decision-analytic model to facilitate adaptation. It described the parameters that need to be taken into account in the transfer of evidence in decision-analytical models. This paper was translated and provided guidance on important factors to consider when adapting HTA reports. No further reports were identified.

Preliminary survey of previous experience

Of the 29 agencies/networks contacted, 21 chose to participate in the survey, a 72% response rate. It is important to note that four of the participants did not have a formalised HTA agency in their respective countries and felt that they had insufficient experience to complete the survey. In this respect, a truer response rate for the survey of previous experience would be 21/25 agencies or 84%.

Question 1 concerned the remit of the agency. The various European HTA organisations/networks had slightly different remits. However, despite these differences, all of the agencies had the central aim of researching, or commissioning research into, the relevant aspects of new and existing health technologies. In relation to question 2, policy-makers were identified as the most important target audience for European HTA agencies. *Table 2* shows the results for questions 3 and 4 relating to the agencies' experiences of adaptation.

Question 5 was 'How useful is it for your HTA agency to make use of reports from other countries?'. In total, 17 of the 21 participants answered this question, with 14 (82%) responding that it would be very useful and the remaining 3 (18%) responding that it would be quite useful. None of the respondents felt that it would not be useful.

Participants were also asked to elaborate on why they thought it would be useful to use HTA reports from other countries. In total, 17 of the 21 participants chose to elaborate. The themes identified from their comments, as well as pertinent quotations, are shown in *Table 3*.

Based on the responses and ideas from the preliminary survey, it became clear that the adaptation of HTA reports was considered desirable. Further to this, respondents identified the need for a toolkit to facilitate this process.

Question 6 asked respondents to indicate the elements (or domains) of HTAs that should be focused on for adaptation, i.e. which domains provide data and information that are most

TABLE 2 Preliminary questionnaire responses relating to adaptation experience

Question	Number of respondents	Yes	No
3. Have you ever adapted an HTA report from another country?	19	11 (58%)	8 (42%)
4. Do you know of any of your HTA reports that have been used in other countries?	18	8 (44%)	10 (56%)

TABLE 3 Themes identified in response to question 5.

1. Aids in the comparison of results
2. Increases the volume of output: 'Given the heavy workload associated with preparing HTA reports, it is crucial to be able either to adapt HTA reports which have been prepared abroad or to share the development of HTA reports between HTA agencies'; 'Small countries cannot be as productive as those with big HTA programs'; 'We do not have enough resources to do many reports'; 'It helps to ensure the completeness of information'
3. Helps avoid duplication: 'We consider it unnecessary to duplicate work done by other agencies'; 'There is not need for duplicating'
4. Helps identify the different methods used
5. Provides data/information that can be adapted: 'We often take the HTA evidence/reports and put it in our national context'; 'Surely adapting and evolving from what has been done already is a feature of producing HTAs relevant to the healthcare system in which you operate'
6. Aids in the speed of provision of information to customers: 'It provides an easy and quick source'; 'to get the report done more quickly with less resources'; 'It is essential ... when we are asked to give quick answers'; 'Adaptation should concern aspects which are specific to each country'
7. Helps with development of own HTA programme: 'It is very important for us to have the ability to access other HTA reports, so that it can orient itself on which way to go'
8. There is a general consensus that systematic reviews are of particular importance: 'Especially the systematic review part'; 'Because the most important chapter of a report is the systematic review'; 'It is possible to utilize the international systematic reviews and their structure, references and search strategies'

readily adaptable? The 10 elements put forward were taken from previous work, the EUR-ASSESS framework. In total, 18 of the 21 participants answered this question. *Table 4* sets out each of the 10 elements and indicates the number of participants who thought that each should be focused on.

Participants were also asked to elaborate on why they thought that the elements they had highlighted were important. In total, 16 of the 21 participants chose to elaborate. A common theme

that emerged in response to this question was that the important parts of HTA reports are those concerning clinical effectiveness and efficacy, i.e. the information that can be separated from the setting of the original HTA report. Quotations in response to this question are shown in *Table 5*.

Following from this, domains such as ethical impact, legal aspects, and social and organisational aspects were rated less highly. Therefore, these domains were not incorporated into the toolkit.

TABLE 4 EUR-ASSESS framework elements – HTA domains to focus on for adaptation

Framework elements	Should be focused on, n (%)	Should not be focused on, n (%)
Definition of policy questions being addressed	8 (44%)	10 (56%)
Definition of the research questions being addressed	10 (56%)	8 (44%)
Current state of development and use of the health technology and alternative technologies	12 (67%)	6 (33%)
Technical characteristics of the device(s), such as accuracy and precision	12 (67%)	6 (33%)
Data on absolute and relative efficacy, safety and effectiveness	16 (89%)	2 (11%)
Economic evaluation (looking at both direct and indirect resource use)	15 (83%)	3 (17%)
Social and psychological implications	7 (39%)	11 (61%)
Impact on the organisation of health service generally and within settings	11 (61%)	7 (39%)
Ethical impact	7 (39%)	11 (61%)
Legal aspects and policy conclusions, options and recommendations (including implementation)	6 (33%)	12 (67%)

TABLE 5 Quotations suggesting which domains to focus on in adapting HTAs

'Only the efficacy and clinical effectiveness data may be more easily adapted from one country to another'

'General data on these themes can be easily applied to national and local settings'

'HTA from other countries can be used best, if the evidence on actual effectiveness is separated from questions of the setting'

'Close to the core that can be shared across countries and settings'

'Should focus on those areas that are most likely to be applicable across countries'

Stage 2: Initial ideas on toolkit structure and content

Delphi survey round 1

Based on information from existing literature and the preliminary survey responses, a possible toolkit structure was described in the Delphi survey questionnaire round 1 (shown in Appendix 5). This first round Delphi questionnaire was distributed to the 27 partners and two further interested organisations. In total, 19 of the 29 organisations/networks invited to participate responded (66% response rate).

The results of this survey can be summarised as follows: there was overall agreement on the sequential approach used in the toolkit and respondents felt that it provided a useful starting point; however, there was a need for clarification on the purpose of the toolkit and concern regarding the choice of included 'domains'; lastly, respondents provided suggestions for further questions.

These results were used to further develop the description of the toolkit.

Stage 3: Toolkit function and role in adaptation

Delphi survey round 2

Toolkit structure and composition was developed further by the lead partner as a result of the Delphi survey round 1 responses and discussions at the

face-to-face meeting. The structure and function of the toolkit and its place within the stages of adaptation was presented in the Delphi survey round 2 questionnaire (shown in Appendix 6, e-version).

In total, 21 of the 29 organisations/networks invited to participate responded (72% response rate).

Respondents provided comments on how to improve the various questions in the toolkit. They also requested the inclusion of examples of how the toolkit would actually work and what it should produce.

The comments, examples and suggestions received in response to the second round of the Delphi survey were used to further develop the description of the toolkit.

Stage 4: Toolkit content development

Partners' commentary work on toolkit 'domains' and e-meetings

Table 6 shows the numbers of partners allocated commentary work, producing commentaries and participating in e-meetings. These partners developed the content of the toolkit.

Decisions were made within each e-meeting on which checklists to be included within the relevant toolkit domains.

TABLE 6 Numbers of partners working on and deciding on toolkit domain content

Domain	Number of partners allocated commentary work	Number of partners producing commentaries	Number of partners participating in e-meeting
Technology use and development	5	3	3
Safety	4	3	2
Effectiveness (including efficacy)	3	2	2
Economic evaluation	6	5	3
Organisational aspects	5	4	4

Stage 5: Review and collation

In total, 21 of 26 partners reviewed a domain of the toolkit (response rate of 81%). Subsequently, 23 of the 27 partners reviewed the entire toolkit (response rate of 85%). Suggestions for improvements were taken forward by the lead partner.

Stage 6: Quality assurance testing

A total of 15 partners undertook quality assurance testing (55% response rate) using 16 different HTA reports. The types of health technologies within the reports adapted are shown in *Table 7*.

As can be seen in *Table 7*, the toolkit was more commonly used to adapt reports on drugs and surgical interventions. The origin of the reports is shown in *Table 8*. Origin in this context is the country for which the original report was produced.

As can be seen from *Table 8*, most participants chose to adapt a report produced for the UK context. Only three of the adapted reports were written in a language other than English.

It took respondents a median of 1 hour (range $\frac{3}{4}$ hour to 5 days) to use the toolkit to adapt parts of a report or an entire report (hence the wide range in responses). Question 2 asked about the

TABLE 7 Types of health technologies in HTA reports adapted using the toolkit

Drugs	5
Surgery	5
Therapeutics	2
Devices	2
Screening	1
Diagnostics	1

TABLE 8 Country of origin of HTA reports adapted using the toolkit

UK	8
Canada	3
Belgium	2
France	1
Australia	1
Unknown	1

usefulness of the speedy sifting section. This toolkit section was used by respondents to assess the relevance of all 16 adapted reports. There was general consensus that it was easy to use and fast to apply. The questions were reasonable, relevant and common sense. Only minor changes were proposed.

Question 3 asked respondents which toolkit domains they used to assess relevant parts of HTAs for adaptation. The results are shown in *Table 9*. Most respondents used the effectiveness (including efficacy) domain. The organisational aspects domain was used by the fewest respondents.

Respondents found these toolkit domains useful but asked for more information. Conversely, other respondents felt that the toolkit was too comprehensive already. One felt that the toolkit was not suitable for screening topics.

Eight respondents did not consult anything other than the toolkit to adapt their chosen HTA. Six used other sources. Additional work required to adapt their chosen HTAs included understanding how information relates to local context, updating literature searches, analysing other types of reports, rebuilding economic models and stakeholder involvement.

Four interviews were undertaken. Additional benefit gleaned from these interviews was the knowledge that at least two adapted reports (as a result of using the toolkit) are now being used in policy-making. Interviewees said that they would use the toolkit again and recommend it to others. However, one felt that it was geared towards treatment reports (less so diagnostic and screening reports). Lastly, respondents recommended that the toolkit be translated into other languages. Some of these changes have been taken forward and are included within the latest version of the toolkit (see Appendix 1 of this monograph). Other concerns, requiring further work, are being

TABLE 9 Number of respondents using toolkit domains

Technology use and development	12
Safety	11
Effectiveness (including efficacy)	15
Economic evaluation	10
Organisational aspects	5

explored in a second round of quality assurance testing (not described in this report).

Description of the toolkit

This section consists of a detailed description and instructions for the use of the toolkit. The toolkit and glossary are presented in full as appendices.

The adaptation toolkit is composed of a series of checklists, questions and issues that should be considered when adapting an HTA report, either in whole or in part, from one setting to another. It is intended that the 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. The reliability of the report, i.e. an assessment of the quality of the report.
3. The transferability of the report, i.e. guidance on issues for consideration when applying information/data to a local context.

The toolkit will aid in the adaptation of HTA reports that include 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.

The toolkit has two sections:

- *Speedy sifting* A screening tool that enables speedy sifting of existing HTA reports to assess the relevance of the HTA report for adaptation.
- *Main toolkit* A more comprehensive tool with questions on reliability and issues regarding transferability.

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 section of the toolkit. However, all users should undertake speedy sifting before using the more comprehensive tool.

Speedy sifting

The speedy sifting section of the toolkit assesses the relevance of the report for adaptation, i.e. is the

policy and/or research question posed sufficiently similar to warrant adaptation of this report? The aim is for users to be able to make a decision as to the suitability of an HTA report within 2 hours.

Main 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 is proposed that using this tool will take less than 5 days.

Currently, there are five domains within the WP5 adaptation toolkit. These domains are shown in *Box 1*.

The main part of the toolkit can be used only to adapt information and/or data contained within an HTA report that includes one or more of these five domains.

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 it can be used to adapt information/data in one or more domains. Thus, the user need only use the parts of the toolkit that are relevant to their needs.

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

How to use the toolkit

Currently, the adaptation toolkit is in the form of a document.

The flow diagram in *Figure 3* shows the stages of adaptation, from the identification of a local research/policy question to the development of an adapted HTA report. It also highlights the stages at which the toolkit will help with adaptation.

The following sections explain the processes undertaken at each of the stages shown in *Figure 3*.

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.

BOX 1 Adaptation toolkit domains

- The technology's use: current state of the health technology and alternative technologies and the technology's background
- Safety
- Effectiveness (including efficacy)
- Economic evaluation: costs, cost-effectiveness, cost-utility and cost-benefit analysis
- Organisational aspects: of health service generally and within settings

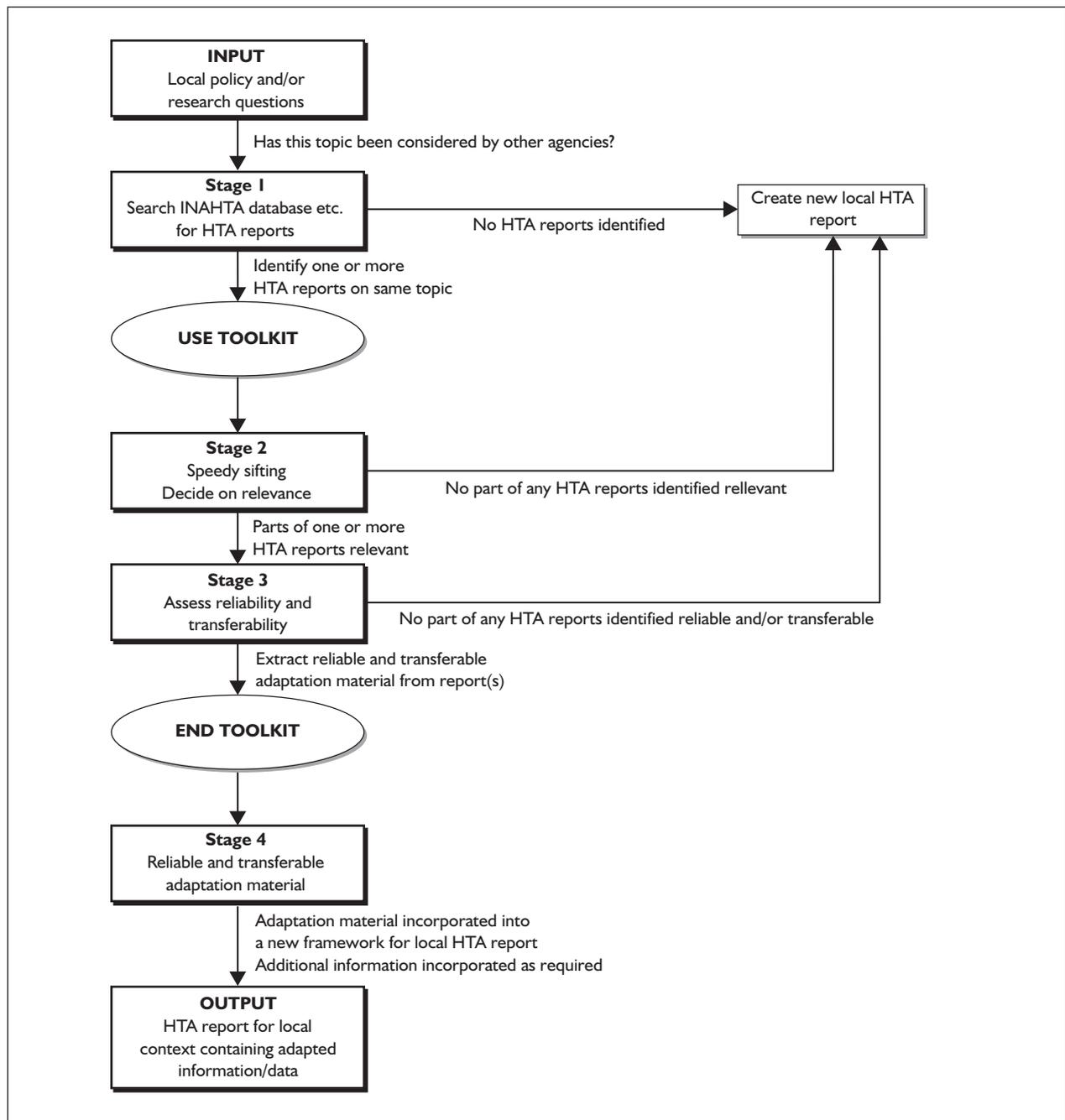


FIGURE 3 Stages of adaptation from input to output and role of the toolkit.

Stage 1: Identification of HTA reports

The INAHTA database 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.

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 can 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

The main section of the toolkit will 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

The output of the toolkit will be adaptation material, i.e. information and/or data that are relevant, reliable and transferable to a local context.

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 a local context.

Interim results: development of the glossary

The glossary was developed through a sequential approach of identifying terms, developing descriptions, developing some definitions and review. *Figure 4* shows the numbers of terms, descriptions and definitions identified and developed at each stage.

Description of the glossary

The glossary consists of 42 terms (*Box 2*) related to the adaptation of HTA reports from one setting to another along with various descriptions for each. It aims to identify and highlight key words and concepts that are easily misunderstood between countries. The series of descriptions for each term attempts to clarify areas of confusion by demonstrating the range of ways that the terms may be used depending on the setting. It also contains examples of where the usage of these terms may differ between countries.

The glossary is fundamentally different from other HTA glossaries that are available, e.g. the INAHTA glossary. First, it deals only with terms relating to adaptation. Second, it provides numerous descriptions of these terms, from a variety of different HTA organisations in the EUnetHTA project, rather than simply prescribing a single definition. Where applicable, EUnetHTA and INAHTA definitions are provided. It also includes examples of how the terms are used in different countries. Finally, the descriptions for each term have been commented on by other HTA organisations in the EUnetHTA project and these comments are accessible to readers.

The glossary can be a valuable resource for HTA organisations when adapting HTA reports produced in other countries for their own use. It can also be used to glean a better understanding of HTA reports written in a different setting from the readers' own. The glossary is shown in Appendix 2 of this report.

How to use the glossary

The glossary can be used as a stand-alone tool to aid in the understanding of HTA reports from settings throughout Europe, or as a valuable resource in the toolkit for adapting HTA reports from one setting to another.

The full version of the glossary is shown in Appendix 2. By referring to this appendix, users can see the wide range of usage of the various terms from different countries and HTA agencies across Europe. This version of the glossary can be used by all stakeholders involved in the process of HTA both to better help their understanding of HTA reports from different contexts and as a tool to aid in the adaptation of such reports.

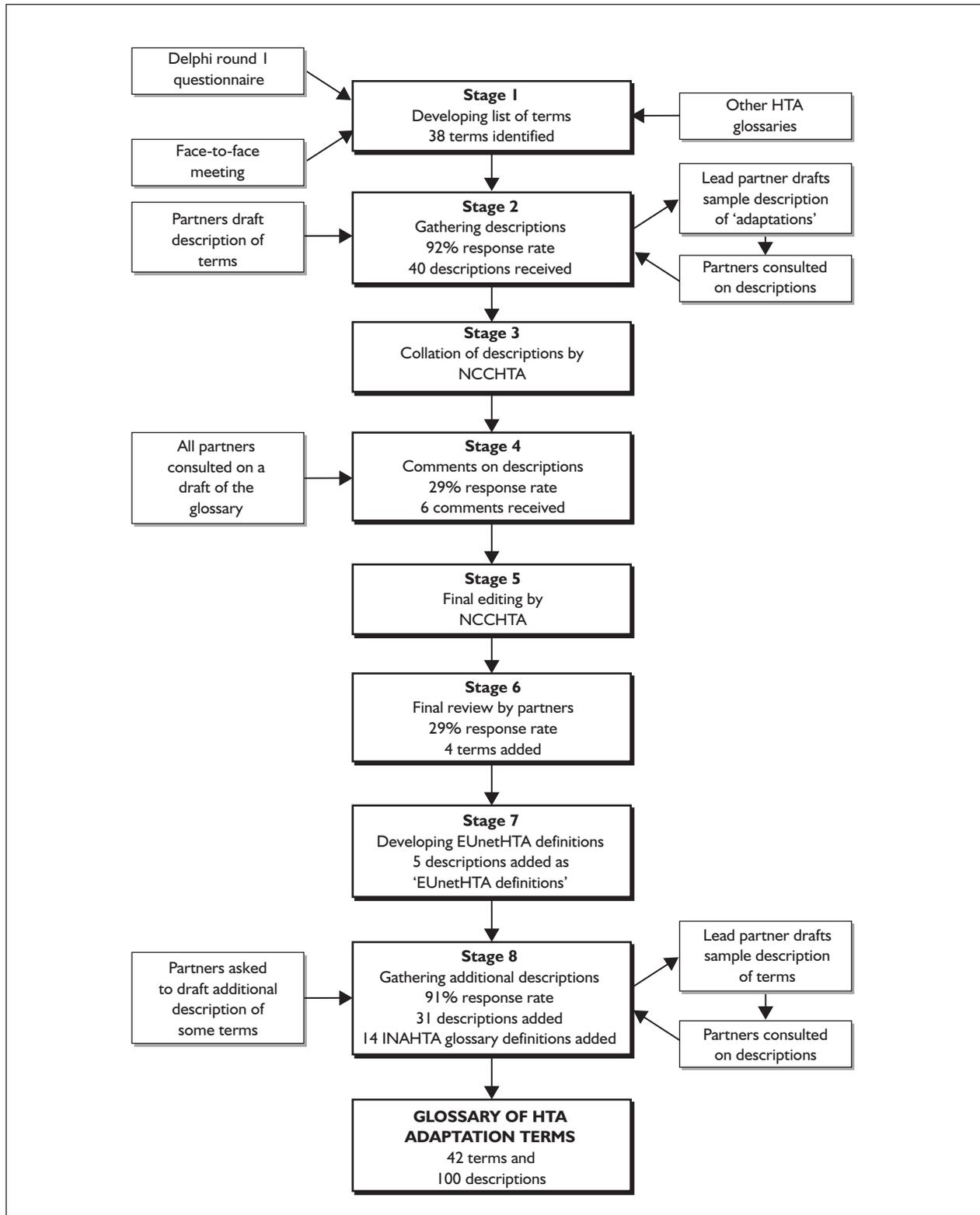


FIGURE 4 Numbers of terms, descriptions and definitions identified and developed at each stage of glossary development.

BOX 2 List of terms: the 42 terms included in the glossary of HTA adaptation terms

Adaptation	Health technology
Adoption	Health technology appraisal
Advice	Health technology assessment
Affordability	HTA core model
Applicability	Mini-HTA
Clinical question	Planning
Commissioning	Policy
Common core HTA	Policy-makers
Competing interests	Policy questions
Conflict of interest	Pre-assessment
Context specific	Primary research
Core model for HTA	Protocol
Critical appraisal	Purchasing
Domain	Rapid review
Effectiveness	Relevance
Efficacy	Reliability
Equity	Secondary research
Evidence synthesis	Setting
Generalisability	Speedy sifting
Guidance	Toolkit
Guideline	Transferability

An abbreviated version of the glossary is also included as part of the HTA adaptation toolkit. Its purpose is to provide descriptions of the terms as they are used in the toolkit. It is recommended that users of the toolkit refer to this version as they work through the toolkit.

Together, the glossary and the toolkit provide a means of ensuring better use of existing HTA reports by allowing users to adapt the 'core' within assessments made for one country into advice appropriate to other contexts. v

Chapter 4

Discussion

This report describes the development of two resources to support users in the adaptation of HTA reports: the HTA adaptation toolkit and the accompanying glossary of adaptation terms. Both resources were developed as outputs for the EUnetHTA project and are available on the internet (www.eunethta.net/) and in Appendices 1 and 2 of this report.

The toolkit supports the adaptation of information and data from an HTA report written in one context into material relevant for other contexts. It is a collection of resources that helps the user assess whether data and information in existing HTA reports should and could be adapted for their own setting. It supports the adaptation of HTA reports that are systematic reviews and which include one or all of the following domains: technology use and development, safety, efficacy and effectiveness, economic evaluation and organisational aspects. Resources contained within the toolkit are in the form of checklists of questions on relevance, reliability and transferability of data and information and links to useful websites.

The accompanying glossary provides descriptions of meanings for HTA adaptation terms from HTA agencies across Europe. It is intentionally non-prescriptive, seeking to highlight differences in the use and understanding of each word by HTA agencies. Each term has a number of meanings attached to it. For a small number of terms definitions are provided. These are terms that are specific to the toolkit and glossary. A shortened version is also available within the toolkit.

Both resources were developed by representatives from 29 HTA agencies and networks from across Europe. The majority of these representatives were members of EUnetHTA (WP5). Quality assurance formed part of the development process. In the first quality assurance round, agencies within WP5 selected HTA reports to adapt for their own setting using the toolkit. The outcome was positive, with minor changes made to the resulting toolkit and glossary. A second round of quality assurance testing was undertaken in 2007/2008 to ensure that agencies unfamiliar with the development of these resources can readily utilise them.

As a result of the pragmatic approach to its development, this work has several strengths. First, an iterative process was used. Each stage in development resulted in a further refined toolkit and glossary. The benefits of such an approach were that all partners had the opportunity to voice their ideas, develop content and have ownership of the products. In addition, the most appropriate methods could be employed at different stages of development and, in seeing these products develop, partners were motivated to further develop these resources. Another strength was the number and type of methods employed. Experience of adaptation and ideas on structure and development of content were drawn from literature reviewing, surveying and discussions at meetings. Both review of content and quality assurance testing of the final toolkit and glossary were undertaken. All of these methods involved input from the partnership of 29 HTA agencies. Finally, there was the strength of the partnership itself, which consisted of members from across Europe, each with different systems and experiences of HTA.

Potential weaknesses were, first, the lack of a systematic review of specific reliability (critical appraisal) checklists contained within the toolkit. Development relied on the expertise and experience of the partnership for input. However, partners were asked to both draw on their experiences and consult the literature to propose checklists. Second, glossary terms and meanings of terms were provided by the partnership. Clearly, the inclusion of many more terms and additional meanings for both existing and new terms would further enhance the usefulness of the glossary. Efforts to develop a wiki-glossary to support this activity are currently under way. Finally, because of the project timescale, both resources did not undergo a review or quality assurance testing by agencies outside of the WP5 partnership. In addition, a limited number of partners reviewed the toolkit. However, to address these issues, wider quality assurance testing of the toolkit outside of the partnership will be undertaken in the near future.

It could be argued that the toolkit is limited in relation to its content as it provides checklists and resources for just five HTA report domains. It does not include guidance on the adaptation of information on legal, social or ethical aspects. However, this was a considered decision; the partnership agreed that the toolkit should only contain those HTA report domains that are least context dependent and therefore more amenable to the adaptation of data.

The toolkit will also be limited in its usefulness by how systematic and quality assured its input is, i.e. the HTA report for adaptation. Clearly, HTA reports with little information on how data was collected and analysed will be more difficult to adapt than those with explicit details of the processes undertaken. The potential usefulness of this toolkit will be dependent on the quality of the HTA report for adaptation. Furthermore, the toolkit has been developed for the adaptation of HTA reports that are systematic reviews. In some countries, reports of primary research studies are also considered to be HTA reports. These reports would not be suitable for adaptation using the toolkit.

In undertaking our literature search, no published or grey literature accounts or examples of adaptation of HTA reports were identified. Other checklists and toolkits are available, for example the INAHTA checklist^{2,25} and the Equity-Oriented Toolkit for Health Technology.²⁶ However, these tools were designed as an aid to writing new HTA reports and to guide those using HTA reports as a source of information. They were not devised for the adaptation of HTA reports from another context. The toolkit described is the first collection of resources to be specially designed for this purpose. Any relevant questions and resources contained within known checklists and tools have been scrutinised for possible input within our toolkit. At the time of writing, a report was drawn to our attention that compared two reviews of vision screening, one undertaken in the UK and the other in Germany.²⁷

Glossaries of HTA terms are in abundance, the most notable and widely accepted being the INAHTA glossary of HTA terms.² The INAHTA glossary provides definitions of HTA terms. There are no HTA glossaries that attempt to facilitate understanding of different meanings of HTA words. This glossary will be the first attempt to provide clarity of meaning. It has been specifically

designed to help in understanding what different countries mean when using adaptation terms.

Globally, the resource of HTA reports is growing at a rapid pace. Many are readily available through the internet and stronger links between HTA agencies now provide the opportunity to develop and share resources, to reduce duplication of effort and to encourage sharing of information. It is timely that resources are developed to support the adaptation of reports written for other contexts.

Adaptation of existing reports requires a great deal of judgement on the part of the user. Some parts of reports can be readily adopted, being context independent, whereas other parts are more context dependent and need to be adapted to relate more readily to the new context. The adaptation toolkit and accompanying glossary of HTA adaptation terms provide guidance and information to support this process.

These resources have been designed for use by HTA agencies. Conceivably they could be used by policy-makers and clinicians to aid in understanding HTA reports written for other contexts. However, the main implications of this work for policy-makers and clinicians alike should be an increase in the number of health technologies assessed. The adaptation of HTA reports should release resources to enable the development of further HTA reports.

Since the main work described in this monograph was carried out, further work has been undertaken to support the development of the toolkit. This work included a second round of quality assurance testing between September 2007 and March 2008. Following this testing, minor amendments were made to the toolkit, which resulted in the production of a final version. This work was presented to the EUnetHTA conference in November 2008 and this version of the toolkit is now available on the EUnetHTA website.

The toolkit has implications for practice as the preparation of HTA reports requires both time and financial resources. Adaptation of an existing HTA report will reduce the cost and time incurred during the production of new reports. This may lead to an increase in the potential for HTA organisations to have the resources available to report on a greater breadth of new health technologies.

The recommendations for the further development of the toolkit are as follows:

- The toolkit is currently in a PDF version and there is the potential to develop an interactive web-based version.
- There is scope to extend the toolkit to facilitate the adaptation of HTA reports on diagnostic testing and screening.
- There is scope for further testing, review and improvement both within the EUnetHTA partnership and beyond to external organisations.

- There is the potential to develop a wiki-version of the glossary.
- There is the potential for more work to be undertaken to incorporate closer integration with other EUnetHTA outputs.

In its current form the toolkit is analogous to a drug in phase III of its clinical trial as a version is now available to a wide audience on the EUnetHTA website and it can be used in 'real' situations by a variety of HTA organisations.



Acknowledgements

This project was jointly funded by the European Commission and the NIHR Health Technology Assessment programme.

We would like to acknowledge the work of all of the WP5 partners for EUnetHTA:

Hauptverband der Österreichischen Sozialversicherungsträger, Austria

Ludwig Boltzmann Institut für Health Technology Assessment (LBI@HTA), Austria

Österreichisches Bundesinstitut für Gesundheitswesen, Austrian Health Institute, Austria

Belgian Health Care Knowledge Centre (KCE), Belgium

Servicio Canario de la Salud, Canary Islands

Danish Centre for Evaluation and HTA (DACEHTA), Denmark

Danish Institute for Health Services Research (DSI), Denmark

National Coordinating Centre for Health Technology Assessment (NCCHTA), now part of the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), England

University of Tartu, Estonia

Finnish Office for HTA (FinOHTA), Finland

Haute Autorité de Santé/French National Authority for Health (HAS), France

German Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information (DAHTA@DIMDI), Germany

Public Health Genetics European Network (PHGEN), German Center for Public Health Genetics (DZPHG), Germany

Technische Universität Berlin, Germany

University of Iceland, Iceland

Agenzia Sanitaria Regionale (ASR), Emilia Romagna, Italy

Region Veneto, Italy

Università Cattolica del Sacro Cuore, Policlinico Universitario 'A. Gemelli', Health Technology Assessment Unit and Laboratory of Health Economics (Institute of Hygiene), Italy

ZonMW, the Netherlands

Norwegian Knowledge Centre for the Health Services (NOKC), Norway

Health Technology Assessment and International Liaisons Agency for Health Technology Assessment (AHTAPol), Poland

Institute of Molecular Medicine, Portugal

Institute of Public Health of the Republic of Slovenia, Slovenia

Andalusian Agency for Health Technology Assessment (AESTA), Spain

Basque Office for Health Technology Assessment (OSTEBA), Spain

Swiss Network for Health Technology Assessment (SNHTA), Switzerland

Cochrane Collaboration, UK

Previous partner: HTA Unit Aarhus University Hospital Denmark

Contribution of authors

Debbie Chase, Claire Rosten, Nick Hicks and Ruairidh Milne led the work of the WP5 partnership. Sheila Turner supported the collation of published literature and prepared information for publication. Debbie Chase coordinated the work of agencies in relation to toolkit development, prepared survey forms, attended meetings, analysed results from each stage of

development, developed the toolkit and prepared the information for publication. Claire Rosten co-ordinated the work of agencies in relation to glossary development, analysed survey work and results from each stage of glossary development, attended meetings, developed the glossary and prepared the information for publication. Ruairidh Milne and Nick Hicks led NCCHTA's contribution to the EUnetHTA project, provided ideas for developmental processes and reviewed versions of the toolkit and glossary and information for publication.

Funding

This project was jointly funded by the European Commission and the NIHR Health Technology Assessment programme. The sole responsibility for the content of this publication lies with the authors, and the European Commission and the Department of Health are not responsible for any use that may be made of the information herein.



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Appendix I

WP5 adaptation toolkit (November 2007)

This document is version 3 of the WP5 adaptation toolkit (November 2007).

Version 3 was used in the WP5 applicability testing round 2 (December 2007–March 2008).

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Section 1 – Introduction

The objective of *Work Package 5* (WP5) is to ensure the better use of existing *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. WP5 is a partnership of 28 HTA agencies and networks across Europe who work together to accomplish this objective. A list of WP5 partners can be found in Appendix 2 of this document and on the EUnetHTA website (www.eunetha.eu/Work_Packages/WP_5/Members).

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 will be developed further as a result of the second round of applicability testing scheduled early in 2008. It is intended that the toolkit will also be developed into a user-friendly web-based toolkit by the end of the *EUnetHTA* project period.

Section 1.1 – Contents of the toolkit

This document is the current version of the toolkit (version 3). 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. *Appendices 1* and *2*, respectively, 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. The full glossary of HTA adaptation terms can be found on the EUnetHTA website (www.eunetha.eu/Members_only/Workpackages/Workpackage_5/WP5_Glossary/). Further explanation of domain questions is available in six domain explanation tables, which can be found on the EUnetHTA website.

Section 1.2 – Format of the toolkit

Some concepts in the toolkit may need further explanation. Further detail can be found within this document or in one of the six domain explanation tables (www.eunetha.eu/Members_only/Workpackages/Workpackage_5/Toolkit/).

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. 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. This definition is from the INAHTA glossary (1st edition, July 2006).

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. Some reports are 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. 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

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.
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 that would enable rapid screening of existing HTA reports to assess the relevance of the HTA report for adaptation.
- *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! (*Table 1*).

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 section* of the 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?

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, for example, 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 his 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) they are of sufficient quality and (c) 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 his needs, the new owner builds his new house and incorporates these parts where he sees fit	Having used the toolkit to decide which parts of the report meet his needs, the user 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, for example, technology use, effectiveness and cost-effectiveness (as required)

Users can assess the relevance of multiple reports on the same health technology. The aim is that users could make a decision on each HTA report within 2 hours (this is an indication of time, not a suggested time limit).

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*.

The first two questions posed in the *speedy sifting* section can result in either proceeding to the

BOX 1 *Speedy sifting questions. For further explanation of these questions see: www.eunetha.eu/WP5_documents/WP5_Toolkitv3/Table_Speedy_Sifting.pdf*

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 carried out? 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

following question (with a 'yes' response) or ending the process (with a 'no' response). The following six questions (questions 3–8) 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 the literature searches, when data for clinical or economic evaluation were gathered, and whether the technology has changed significantly.

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

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 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 (Box 2).

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

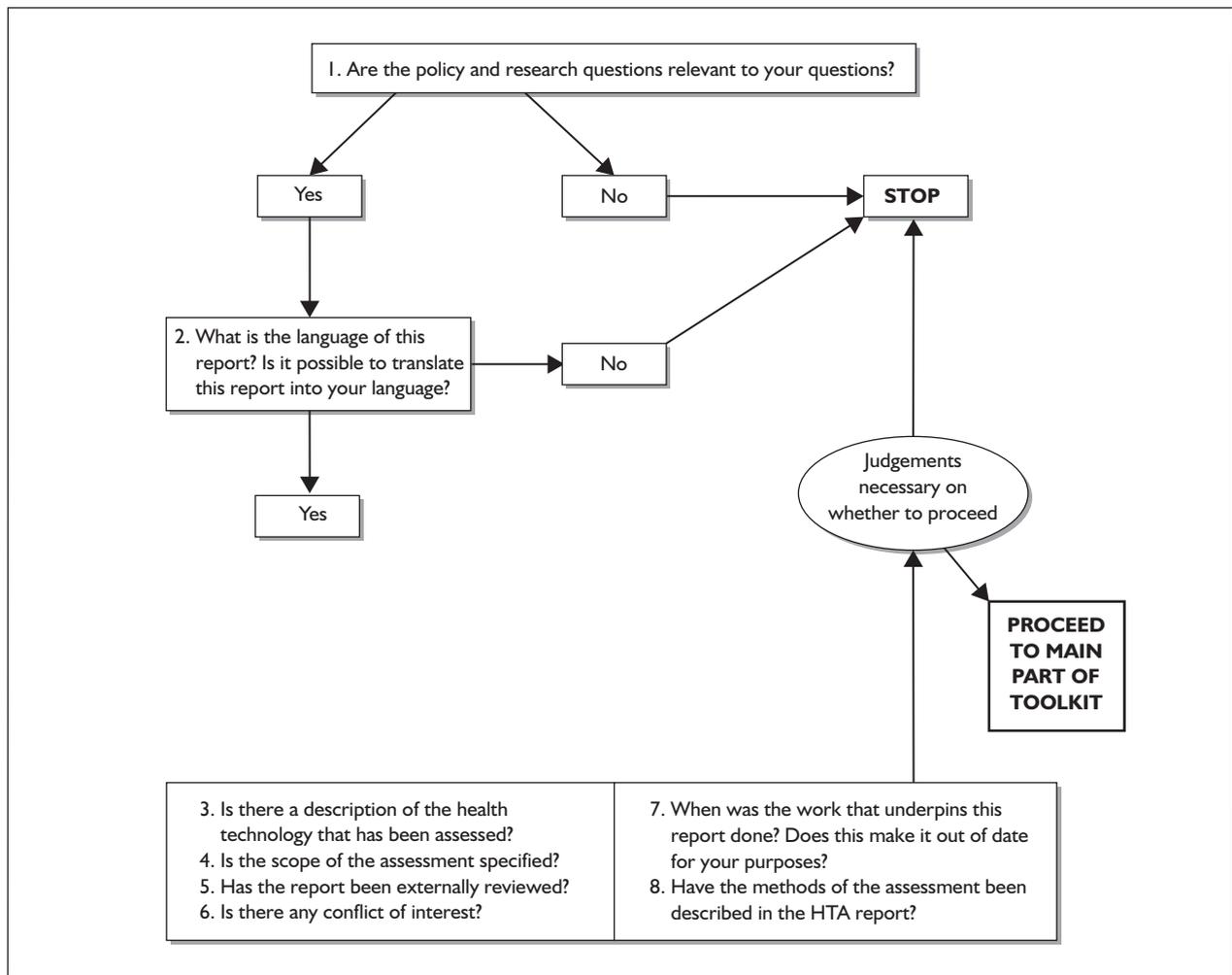


FIGURE I Pathway of questions and responses in the speedy sifting part of the toolkit.

BOX 2 Resource for speedy sifting section

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

Section 5 – Main part of the toolkit

The main part of the toolkit contains questions on reliability, specific relevance questions and questions on 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 (this is an indication of time, not a suggested time limit).

Currently, there are five domains within the WP5 adaptation toolkit (*Box 3*). The toolkit was tested through applicability testing (round 1) with these five domains. Further domains may be added, e.g. social, ethical and legal considerations, as a result of applicability testing.

The main part of the toolkit can be used only 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 aspects. Please view *Box 4* for the justification behind the choice of these domains.

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 it 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 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*).

BOX 3 Adaptation toolkit domains

- 5.1 Technology use: current state of the health technology and alternative technologies and the technology’s background
- 5.1 Safety
- 5.3 Effectiveness (including efficacy)
- 5.4 Economic evaluation: costs, cost-effectiveness, cost–utility and cost–benefit analysis
- 5.5 Organisational aspects: of health service generally and within settings

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) a Delphi survey round 1 questionnaire

Preliminary questionnaire

Members were surveyed to ask their opinions 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 aspects) 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 only these five domains. There was general agreement that these domains should be included in the toolkit

Delphi survey 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.

BOX 5 Technology 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 with the uses described in the HTA report for adaptation)?

For further explanation of these questions see: www.eunethca.eu/WP5_documents/WP5_Toolkitv3/Table_Technology_Use.pdf

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 them 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. This is followed by a list of reliability questions and a list of questions relating to transferability.

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 collected data (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 reports, randomised controlled trials, 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. 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)?
11. Which risks have been reported and how were they measured?
12. Were the study outcomes valid and 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 the technology is targeted in the target setting?
16. Are there any reasons to expect differences in complication rates [e.g. epidemiology, genetic issues, health-care system (quality of care, surveillance)]?
17. Are the requirements for the technology's 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. Is safety particularly dependent on training? Are there types of teams to whom the procedure should be limited for safety reasons? 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?

For further explanation of these questions see: www.eunetha.eu/WP5_documents/WP5_Toolkitv3/Table_Safety.pdf

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 them with local context data.

5.2.1 – Resources for the safety domain

Box 7 provides a list of 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**Reliability**

More detailed questions for the safety domain to assess reliability

See domain commentaries on EUnetHTA WP5 web page

General safety issues

Report from a World Health Organization (WHO) meeting to provide guidance and input towards the development of rapid assessment methodologies for estimating harm caused by the health-care system

www.nap.edu/books/0309090776/html/
Link last checked: 12 November 2007

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

www.dcha.org/JCAHORrevision.htm
Link last checked: 12 November 2007

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

www.ahrq.gov/clinic/ptsafety/
Link last checked: 12 November 2007

ECRI's mission is to promote the highest standards of safety, quality and cost-effectiveness in health care to benefit patient care through research, publishing, education and consulting

www.ecri.org/
Link last checked: 12 November 2007

AHRQ mission: To improve the quality, safety, efficiency and effectiveness of health care for all Americans

www.ahrq.gov/
Link last checked: 12 November 2007

The National Institute for Health and Clinical Excellence (NICE) is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health in the UK

www.nice.org.uk/
Link last checked: 12 November 2007

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

www.nap.edu/books/0309090776/html/
Link last checked: 12 November 2007

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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*).

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 them with local context data.

Section 5.3.1 – Resources for the effectiveness domain

Box 9 provides a list of useful resources to help in assessing the reliability of effectiveness data and

information and 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.

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*).

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.

BOX 8 Effectiveness questions**(a) To assess relevance:**

1. What is the research question considered? 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:^a

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 that 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 because of additional research that has been started, completed or published since this HTA report was published?

(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

For further explanation of these questions see: www.eunethta.eu/WP5_documents/WP5_Toolkitv3/Table_Effectiveness.pdf

- a 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 Med Res Methodol* 2006;6:27

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 (e.g. countries or regions) where particular laws or guidance (including policy decisions) apply.

Section 5.4.1 – Resources for the economic evaluation domain

Box 11 provides a list of useful resources to help in assessing reliability, the consideration of general issues and transferability, and 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.

Section 5.5 – Organisational aspects domain

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

1. Information and data on organisational aspects are absent from most European HTA reports.

BOX 9 Resources for the adaptation of effectiveness data and information**Reliability**

More detailed questions for the effectiveness domain to assess reliability

See domain commentaries on EUnetHTA WP5 web page

A study to assess the validity of an index of the scientific quality of research overviews, the Overview Quality Assessment Questionnaire

www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&list_uids=1834807&dopt=abstract
Link last checked: 12 November 2007

How to use an overview

www.cche.net/usersguides/overview.asp
Link last checked: 12 November 2007

How to use a systematic review about therapy

www.ebm.med.ualberta.ca/sysrev.htm
Link last checked: 12 November 2007

Critical appraisal worksheet for therapy

www.cebm.net/index.aspx?o=1157
Link last checked: 12 November 2007

Description of 'critical appraisal'

www.jr2.ox.ac.uk/bandolier/painres/download/whatis/What_is_critical_appraisal.pdf
Link last checked: 12 November 2007

The *Cochrane Handbook for Systematic Reviews of Interventions* is the official document that describes in detail the process of creating Cochrane systematic reviews

www.cochrane.org/resources/handbook/
Link last checked: 12 November 2007

The QUOROM checklist describes the preferred way to present the abstract, introduction, methods, results and discussion sections of a report of a meta-analysis. The flow diagram provides information about both the numbers of randomised controlled trials identified, included and excluded and the reasons for exclusion of trials

www.blackwell-synergy.com/doi/abs/10.1046/j.1365-2168.2000.01610.x?cookieSet=1&journalCode=bjs
Link last checked: 12 November 2007

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

www.ahrq.gov/clinic/epcsums/strengthsum.pdf
Link last checked: 12 November 2007

Descriptive method guidelines to help reviewers design, conduct and report reviews of trials in the field of back and neck pain

www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12811274&dopt=Abstract
Link last checked: 12 November 2007

Paper: The need for caution in interpreting high quality systematic reviews

www.bmj.com/cgi/content/full/323/7314/681
Link last checked: 12 November 2007

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BOX 10 Economic evaluation questions**(a) To assess relevance and reliability:^a**

1. Was a well-defined question posed in an answerable form?
2. What is the question being asked in the report? Is the economic question relevant? 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. Has the viewpoint or perspective for the analysis been stated clearly, along with the reasons for this choice? Is it a societal perspective, third-party payer perspective or patient perspective? 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. Has the evidence of the product's efficacy been established through randomised trials? Has the evidence of efficacy been supplemented by evidence of effectiveness applicable to the patient population or subgroups considered in the study? Has the latter evidence been derived from studies documenting routine use in clinical practice? Have all of 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. Are the methods and analysis displayed in a clear and transparent manner? Are the components of the numerator (cost of each alternative) and denominator (clinical outcomes of each alternative) displayed? 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)?
11. How is health-related quality of life (HRQOL) measured?
12. Is HRQOL an important component of an economic analysis for this question? 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 tree) with information derived from a variety of sources or estimated directly from specific patient population(s)?
16. Are capital costs and overhead costs included as well as operating costs? How are they measured?
17. How have indirect costs (i.e. productivity costs, cost of lost time) been identified and estimated?
18. For variables that are difficult to measure, what method is used to handle this difficulty? 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?

continued

BOX 10 Economic evaluation questions (continued)

23. What equity assumptions have been made in the analysis? For example, are quality-adjusted life-years gained by any individual considered equal?
24. 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 programmes operated by the decision-makers to whom the report is addressed? Are there other indications that have not been considered which involve a large amount of utilisation for which the ratio may be very different?
25. 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 programmes? What is the estimate of aggregate incremental costs? 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?

(b) To assess transferability:^b

27. How generalisable and relevant are the results, and validity of the data and model, to the relevant jurisdictions and populations?
28. 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 that influence incidence and prevalence
 - (x) Demographic context
 - (xi) Life expectancy
 - (xii) Reproduction
 - (xiii) Pre- and postintervention care
 - (xiv) Integration of technology in health-care system
 - (x) Incentives

If differences exist, how likely is it that each factor would impact the results? In which direction? Of what magnitude? Taken together, how would they impact the results and of what magnitude? 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?

For further explanation of these questions see: www.eunethta.eu/WP5_documents/WP5_Toolkitv3/Table_Economic_Evaluation.pdf

a Questions taken from *CCOHTA Guidelines for Economic Evaluation of Pharmaceuticals*, 2nd edition. Canada. Ottawa: Canadian Coordinating Office for Health Technology Assessment; 1997; and Drummond MF, O'Brien BJ, Stoddart GL, Torrance GW. *Methods for the economic evaluation of health care programmes*, 2nd edition. Oxford: Oxford Medical Publications; 1997

b List of factors taken from Welte R, Leidl R. Übertragung der Ergebnisse ökonomischer Evaluationsstudien aus dem Ausland auf Deutschland: Probleme und Lösungsansätze. In Leidl R, Graf von der Schulenburg JM, Wasem J, editors. *Ansätze und Methoden der ökonomischen Evaluation. Eine internationale Perspektive*. Baden-Baden: Nomos; 1999

BOX 11 Resources for the adaptation of economic evaluation data and information**Reliability**

The objective of these guidelines is to assist the 'doers' of economic evaluations to produce credible and standardised economic information that is relevant and useful to decision-makers in Canada's publicly funded health-care system

www.rees-france.com/IMG/pdf/2006_CCOHTA_EconomicGuidelines_e.pdf

Link last checked: 12 November 2007

Guidelines for economic evaluation of pharmaceuticals: Canada

www.cadth.ca/media/pdf/peg_e.pdf

Link last checked: 12 November 2007

Paper: Development and validation of a grading system for the quality of cost-effectiveness studies

www.lww-medicalcare.com/pt/re/medcare/abstract.00005650-200301000-00007.htm;jsessionid=FvHWsGYxIHVV6bvMrpj4MTyvrTLZknpmBghdv5ctppVFQjLifNjV!-1480123504!-949856144!8091!-1

Link last checked: 12 November 2007

Paper: Economic evaluations in international health technology assessments – a study of methodologies

www.sst.dk/publ/Publ2004/Sundhedsoekonomiske_evalueringer_MTV.pdf

Link last checked: 12 November 2007

Paper: Review of guidelines for good practice in decision-analytic modelling in health technology assessment

www.hta.nhsweb.nhs.uk/execsumm/summ836.htm

Link last checked: 12 November 2007

Paper: A critical review of health-related economic evaluations in Australia: implications for health policy

www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10141252&dopt=Abstract

Link last checked: 12 November 2007

Paper: The cost-benefit approach

<http://bmb.oxfordjournals.org/cgi/reprint/30/3/252.pdf>

Link last checked: 12 November 2007

Paper: Estimating costs in the economic evaluation of medical technologies

www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=2113891&dopt=Abstract

Link last checked: 12 November 2007

General issues

Policy brief: *Health technology assessment: an introduction to objectives, role of evidence, and structure in Europe*

[www.mig.tu-berlin.de/menue/publications/thematisch/hta0/\[9th item on page\]](http://www.mig.tu-berlin.de/menue/publications/thematisch/hta0/[9th item on page])

Link last checked: 12 November 2007

Paper: Standardizing methodologies for economic evaluation in health care. Practice, problems, and potential

www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8423113&dopt=Abstract

Link last checked: 12 November 2007

Paper: Guidelines for authors and peer reviewers of economic submissions to the BMJ

www.bmj.com/cgi/content/full/313/7052/275

Link last checked: 12 November 2007

Paper: Review of guidelines for good practice in decision-analytic modelling in health technology assessment

www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=15361314&dopt=Citation

Link last checked: 12 November 2007

continued

BOX 11 Resources for the adaptation of economic evaluation data and information (continued)**Transferability issues**

Paper: Generalisability in economic evaluation studies in healthcare: a review and case studies

www.ncchta.org/execsumm/summ849.htm

Link last checked: 12 November 2007

Paper: Analyzing differences in the costs of treatment across centers within economic evaluations

<http://eprints.whiterose.ac.uk/612/>

Link last checked: 12 November 2007

Paper: Extrapolation of cost-effectiveness information to local settings

www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10180659&dopt=Citation

Link last checked: 12 November 2007

Specific topics

Paper: Economic evaluations in the critical care literature: do they help us improve the efficiency of our unit?

www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8797635&dopt=Abstract

Link last checked: 12 November 2007

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

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

'Organisational aspects' 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 aspects of a care pathway are carried out by which organisations (interorganisational level), which professions are responsible for which aspects of care and whether the right skills exist to exploit the technology (intraorganisational level), and which technologies would be supported in terms of policy or funding (health-care system level).

When adapting information and data from organisational aspects sections of an HTA report, you should consider the organisational aspects matrix shown in *Box 12*.

Section 5.5.1 – Organisational aspects matrix

The purpose of the organisational aspects 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 aspects within those levels) have been considered within the report, and the type of data included and the method of analysis that has been undertaken to assess organisational aspects. A list of the dimensions of organisational aspects that can potentially be affected by the technology, and can affect the implementation of the technology, has been proposed by the EUnetHTA work package 4 (the rows of the matrix in *Box 12*).

Section 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?

On completion of this exercise, adaptation questions to ask are shown in *Box 13*.

Answers to these questions should help the user extract information and/or data from this section

BOX 12 Organisational aspects matrix.

Organisational aspects dimensions	Organisational levels	
Interorganisational level	Intraorganisational level	Health-care system
Utilisation	<p>Type of data and methods of analysis</p> <p>Data from research (quantitative and qualitative)</p> <p>Literature reviews</p> <p>Routine data</p> <p>Informal knowledge and anecdotes</p> <p>Judgements</p> <p>Models</p>	
Work processes		
Centralisation/decentralisation		
Staff		
Job satisfaction		
Communication		
Finances		
Stakeholders		

of the HTA report. This 'adaptation material' on organisational aspects can be incorporated within an HTA report in your own setting. There may be a need to update these data and supplement them with local context data.

Section 5.5.3 – Resources for the organisational aspects domain

Box 14 provides a list of useful resources to help in addressing organisational aspects issues and the

assessment of qualitative research. The user may wish to consult any or all of these resources to aid in the adaptation of organisational aspects data and information.

Section 6 – General resources

Box 15 lists general toolkit resources and links to those resources. These resources provide information on adaptation issues, transferability

BOX 13 Organisational aspects domain additional questions

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

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

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

A judgement will be necessary here

3. 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

4. Are the results applicable to my context?

A judgement will be necessary here

For further explanation of these questions see: www.eunetha.eu/WP5_documents/WP5_Toolkitv3/Table_Organisational_aspects.pdf

BOX 14 Resources for the adaptation of organisational aspects information**General documents dealing with organisational aspects**

This Danish Centre for Health Technology Assessment (DACEHTA) handbook provides an introduction to the scientific methods and instruments in HTA, in particular the four main elements of an HTA analysis – the technology, the patient, the organisation and the economy

<http://sst.dk/Applikationer/cemtv/publikationer/docs/Metodehaandbog/MethodologyHandbook180601.pdf>

Link last checked: 12 November 2007

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)

www.sst.dk/publ/Publ2005/CEMTV/Mini_MTV/Introduction_mini-HTA.pdf

Link last checked: 12 November 2007

Assessment of qualitative research

Assessment of qualitative articles (in Danish)

www.ffy.dk/graphics/PDF-filer/Metodeartikler/2002/Vurdering_af_artikler_NOF_2002.pdf

Link last checked: 12 November 2007

A checklist designed for assessing the quality of qualitative studies

<http://66.102.9.104/search?q=cache:LbXIV4sEijgJ:www.liv.ac.uk/lstm/download/guidelines.pdf+criteria+for+evaluating+qualitative+studies&hl=en&ct=clnk&cd=1&gl=ie>

Link last checked: 12 November 2007

An assessment tool developed by the Critical Appraisal Skills Programme in the UK (CASP) to deal with some of the principles and assumptions of qualitative research

www.phru.nhs.uk/casp/casp_qualitative_tool.pdf

Link last checked: 12 November 2007

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

www.bmj.com/cgi/content/full/320/7226/50

Link last checked: 12 November 2007

This is a brief review that indicates how observational methods can be used to 'reach the parts that other methods cannot'

www.bmj.com/cgi/content/full/311/6998/182

Link last checked: 12 November 2007

This article argues that three inter-related criteria can be identified as the foundation of good qualitative health research

<http://qhr.sagepub.com/cgi/content/abstract/8/3/341>

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questions and previous related EU-funded projects. These resources can be consulted if further information and guidance are required in these areas.

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.

Future toolkit development work will include two rounds of applicability testing and the development of a user-friendly web-based version.

Debbie Chase
Ruairidh Milne
Nick Hicks
Hilary Bunce
Claire Rosten
Sheila Turner
Liz Payne
November 2007

BOX 15 General toolkit resources**General adaptation issues**

1. WHO review of the literature on applicability, transferability and adaptation of guidelines www.health-policy-systems.com/content/4/1/25
Link last checked: 12 November 2007
2. Paper describing the structures and working methods of guideline programmes <http://intqhc.oxfordjournals.org/cgi/content/full/15/1/31>
Link last checked: 12 November 2007
3. 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: 12 November 2007
4. Report from the Conference on Guideline Standardization to define a standard for guideline reporting www.annals.org/cgi/reprint/139/6/493.pdf
Link last checked: 12 November 2007
5. Paper describing a framework for evaluating and adapting existing practice guidelines for local use by health-care organisations and groups. The framework presents the major issues related to guideline adaptation and breaks them down into manageable steps www.blackwell-synergy.com/doi/abs/10.1111/j.1552-6909.2002.tb00086.x
Link last checked: 12 November 2007
6. Paper based on a workshop to present and discuss an explicit approach to guideline adaptation using the PIPOH (Patient, Intervention, Professional, Outcomes, Health-care provider) tool www.g-i-n.net/download/files/Rob_Cook___Adaptation_of_guidelines.pdf
Link last checked: 12 November 2007
7. Paper reviewing the literature on the adaptation of guidelines and proposing a systematic approach for the adaptation of guidelines <http://intqhc.oxfordjournals.org/cgi/content/abstract/18/3/167>
Link last checked: 12 November 2007
8. A series of reviews of methods that are used in the development of guidelines www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=17116254
Link last checked: 12 November 2007
9. Questions relating to how generalisability can be tackled in systematic reviews www.scielo.org/scielo.php?script=sci_arttext&pid=S0042-96862005000600020&lng=en&nrm=iso&tlng=en
Link last checked: 12 November 2007
10. Clinical guidelines are only as good as the evidence and judgements they are based on. The GRADE (Grades of Recommendation Assessment, Development and Evaluation) approach aims to make it easier for users to assess the judgements behind recommendations www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=15205295
Link last checked: 12 November 2007

General adaptation issues

1. WHO review of the literature on applicability, transferability and adaptation of guidelines www.health-policy-systems.com/content/4/1/25
Link last checked: 12 November 2007
2. Paper describing the structures and working methods of guideline programmes <http://intqhc.oxfordjournals.org/cgi/content/full/15/1/31>
Link last checked: 12 November 2007
3. 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: 12 November 2007

continued

BOX 15 General toolkit resources (continued)

- | | | |
|-----|---|---|
| 4. | Report from the Conference on Guideline Standardization to define a standard for guideline reporting. | www.annals.org/cgi/reprint/139/6/493.pdf
Link last checked: 12 November 2007 |
| 5. | Paper describing a framework for evaluating and adapting existing practice guidelines for local use by health-care organisations and groups. The framework presents the major issues related to guideline adaptation and breaks them down into manageable steps | www.blackwell-synergy.com/doi/abs/10.1111/j.1552-6909.2002.tb00086.x
Link last checked: 12 November 2007 |
| 6. | Paper based on a workshop to present and discuss an explicit approach to guideline adaptation using the PPOH (Patient, Intervention, Professional, Outcomes, Health care provider) tool | www.g-i-n.net/download/files/Rob_Cook___Adaptation_of_guidelines.pdf
Link last checked: 12 November 2007 |
| 7. | Paper reviewing the literature on the adaptation of guidelines and proposing a systematic approach for the adaptation of guidelines | http://intqhc.oxfordjournals.org/cgi/content/abstract/18/3/167
Link last checked: 12 November 2007 |
| 8. | A series of reviews of methods that are used in the development of guidelines | www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=17116254
Link last checked: 12 November 2007 |
| 9. | Questions relating to how generalisability can be tackled in systematic reviews | www.scielo.org/scielo.php?script=sci_arttext&pid=S0042-96862005000600020&lng=en&nrm=iso&tlng=en
Link last checked: 12 November 2007 |
| 10. | Clinical guidelines are only as good as the evidence and judgements they are based on. The GRADE (Grades of Recommendation Assessment, Development and Evaluation) approach aims to make it easier for users to assess the judgements behind recommendations | www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=15205295
Link last checked: 12 November 2007 |

Previous EU-funded projects

- | | |
|--|---|
| ECHTA/ECAHI report <i>European collaboration for health technology assessment: developing an assessment network and HTA Europe report Health technology assessment in the European Union</i> | www.eunetha.net/Members_only/EUnetHTA_Info/Resources/
Link last checked: 12 November 2007 |
| Paper: 'EUR-ASSESS project subgroup report on methodology. Methodological guidance for the conduct of health technology assessment' | www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9194352&dopt=Citation
Link last checked: 12 November 2007 |
| 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: 12 November 2007 |

Transferability issues

- | | |
|---|---|
| Checklist for identifying guidelines requiring adaptation. It contains questions around factors that influence the applicability or transferability of guidelines across different settings. Questions relevant for the safety, effectiveness and cost-effectiveness domains of the toolkit | www.health-policy-systems.com/content/4/1/25/table/T1
Link last checked: 12 November 2007 |
|---|---|

BOX 15 General toolkit resources (continued)**General HTA resources**

NICHSR (National Information Center on Health Services Research and Health Care Technology) *HTA 101: Introduction to HTA*

www.nlm.nih.gov/nichsr/hta101/ta101_c1.html
Link last checked: 12 November 2007

CCOHTA (Canadian Coordinating Office for Health Technology Assessment) *E-text on health technology assessment (HTA) information resources*

www.nlm.nih.gov/archive//2060905/nichsr/ehta/ehta.html
Link last checked: 12 November 2007

Please let us know if you find that any of these links to web pages change or no longer work. Contact: eunetha@soton.ac.uk.

Appendix A – 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 achieved in a wide range of ways (see items 1–4). 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 1–3 require further work beyond the use of information from the original report to develop your own report.

1. *Summarising* Translating the summary and using it 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* Systematically extracting 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 which is: (a) relevant to your needs, (b) quality assessed, (c) critically appraised, and (d) 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 that 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 that 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 in *Figure 2* 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.

The following sections explain the 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 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

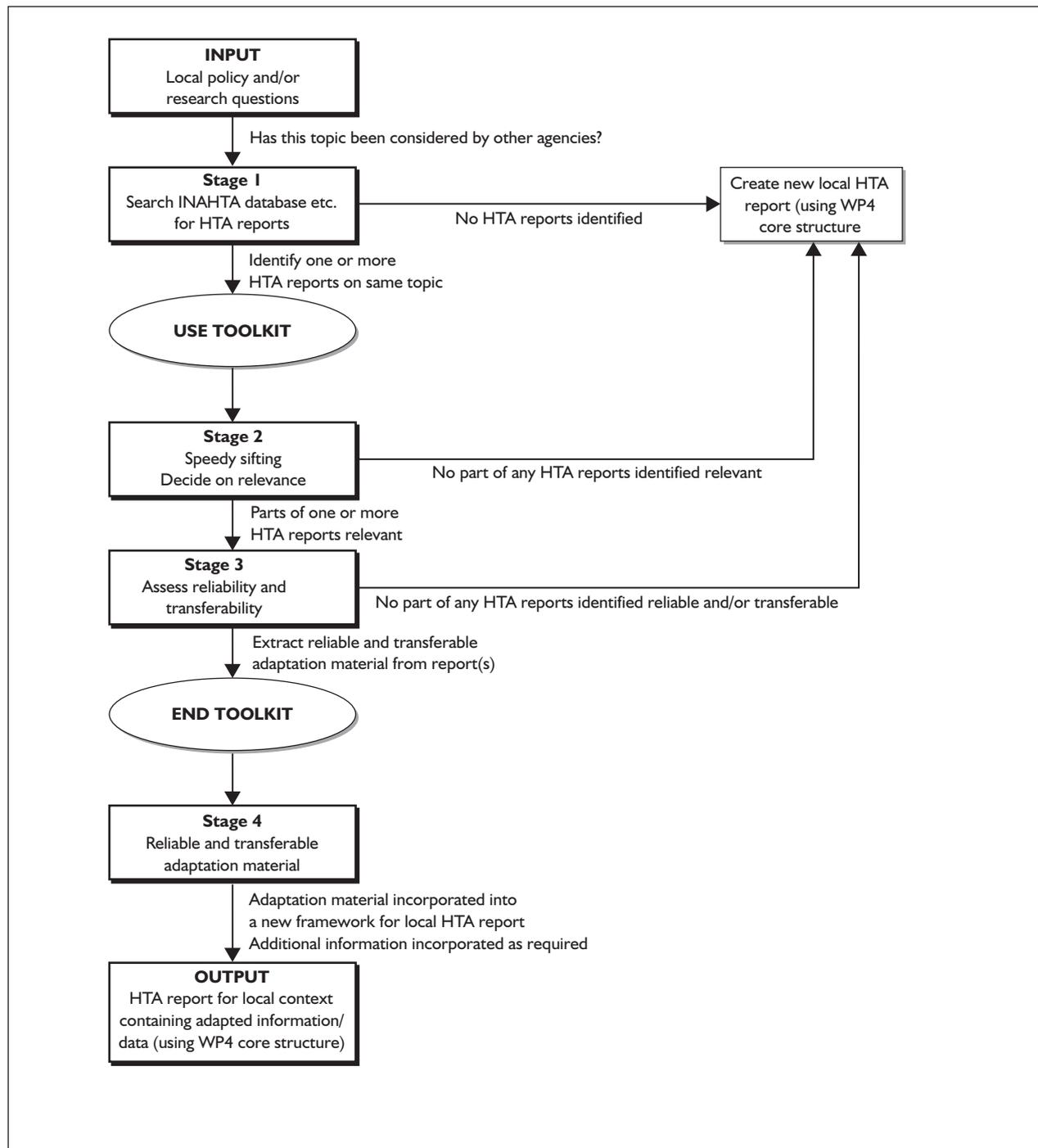


FIGURE 2 Stages of adaptation, from input to output and role of the toolkit.

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 (WP5 meeting attendees agreed that they would want to see the full HTA report(s) when speedy sifting, not just summary/other).

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 are 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.

Appendix B – 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' experiences of adaptation and to consider the purpose of 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

Nineteen associated partners

AETSA, Spain
 ASR, Italy
 Cochrane Collaboration, UK
 DACEHTA, Denmark
 DAHTA@DIMDI, Germany
 DSI, Denmark
 FinOHTA, Finland
 HAS, France
 LBI@HTA, Austria
 Università 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

Seven 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 of members' experiences of adaptation was undertaken in April 2006. A key question asked was about the HTA report headings (domains) that 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 the WP5 extranet.

Delphi survey round 1 and WP5 face-to-face meeting

Based on these ideas and the 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 survey round 1 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 in June 2006. In total, 24 of the 28 WP5 agencies

were represented at this meeting. Minutes of this meeting can be viewed at 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 survey round 2

Toolkit structure and composition were developed further by the lead partner as a result of the Delphi survey round 1 responses and discussions at the WP5 face-to-face meeting.

The structure and function of the toolkit and its place within the stages of adaptation were presented in the second round Delphi survey 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 the Delphi survey round 2 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–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 experiences and provide ideas when no existing checklists could be identified.

Between three and six 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. a review of the domain checklists and speedy sifting questions and consideration of the inclusion of recommendations and implications
2. a review of the draft toolkit.

For stage 1, members who had not undertaken 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 one round of applicability testing. A second round will be carried out (up to M29). [This was done late 2007/early 2008.] The final toolkit (incorporating the glossary) will be web based and accessible from the EUnetHTA website (M31). [Now available at www.eunethta.net.]

Appendix C – 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 from descriptions formulated by work package 5 of the EUnetHTA project.

Terms

A
Adaptation
Advice
Applicability

C
Conflict of interest

Context-specific setting

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	<p><i>EUnetHTA</i></p> <p>Issue</p> <p>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</p> <p>Different types of HTA reports</p> <p>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</p> <p>Adaptation is a part of a spectrum</p> <p>Making use of all or part of an HTA report from elsewhere could be achieved in a wide range of ways (see items 1–4 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 1–3 require further work beyond the use of information from the original report to develop your own report</p> <p>Summarising: translating the summary and using it for background information</p> <p>Updating searches: using the original search strategy to identify any more recent evidence or adding to the search strategy and extending it</p> <p>Adapting: systematically extracting relevant HTA information from an existing report (from a whole report or from part of a report)</p> <p>Adopting: making use of the report without making any changes at all (except perhaps translation into your own language)</p> <p style="text-align: right;"><i>continued</i></p>

Term	Description
	<p>Adaptation is a process</p> <p>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) 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:</p> <p>(a) checking the relevance of the question(s) addressed in the original report to the question you are facing</p> <p>(b) identifying the information in the report that is relevant and most likely to be transferable to your setting</p> <p>(c) assessing the reliability of the information under various domains (benefits, harms, cost-effectiveness, organisational aspects, social and legal issues, etc.)</p> <p>(d) identifying and setting out the problems that may occur when the extracted, relevant, quality-assessed information is transferred into a local HTA report, and deciding how to deal with them</p>
Applicability	<p><i>INAHTA glossary</i></p> <p>The degree to which the results of an observation, study or review hold true in other settings</p>
Clinical question	See Policy
Conflict of interest	<p><i>INAHTA glossary</i></p> <p>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</p>
Context-specific setting	<p><i>EUnetHTA</i></p> <p>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) and the kind of decision being made</p> <p>'Setting' in particular is commonly used in HTA to refer narrowly to an organisational dimension of health care, such as primary, secondary or tertiary care, or community care</p> <p>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</p> <p>If HTA evidence, or an HTA report, is 'context specific', this may mean that something about it cannot or should not be applied to other settings without careful adaptation. Context specific, therefore, implies 'not generalisable' and 'not transferable'</p>
Domain	See Toolkit
Effectiveness	<i>INAHTA glossary</i>
Efficacy	<p><i>Effectiveness</i> 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</p> <p><i>Clinical effectiveness</i> 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.)</p> <p><i>Efficacy</i> 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 randomised controlled trial or at a 'centre of excellence'</p>
Evidence synthesis	Please note that 'evidence synthesis' and 'secondary research' are treated here as meaning the same
Secondary research	<p><i>INAHTA glossary</i></p> <p>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</p>

Term	Description
Generalisability	<i>EUnetHTA</i>
Transferability	<p>Generalisability refers to whether the results of an HTA report can be extrapolated to other settings. This is sometimes referred to as 'external validity'</p> <p>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</p> <p>Generalisable information/data can be readily adopted. However, the 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</p> <p>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</p>
Guideline	<p><i>INAHTA glossary</i></p> <p><i>Clinical practice guideline</i> 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 policy-making that is informed or supported by HTA</p>
Health technology	<p><i>INAHTA glossary</i></p> <p>Any intervention that may be used to promote health, to prevent, diagnose or treat disease, or for rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures and organisational systems used in health care</p>
Health technology assessment	<p><i>INAHTA glossary</i></p> <p><i>HTA</i> 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 policy-making in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing on a variety of methods</p>
Relevance	<i>EUnetHTA</i>
Reliability	<p>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, it may be adopted or considered for adaptation for another setting. One way of assessing reliability in a standardised way is through the use of quality checklists, such as those that are included in the EUnetHTA toolkit</p> <p>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</p> <p>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</p> <p>A report might be very relevant even if it is not reliable, and vice versa</p>
Secondary research	See Evidence synthesis
Setting	See Context-specific setting
Speedy sifting	See Toolkit
Technology	See Health technology

continued

Term	Description
Toolkit	<i>EUnetHTA</i>
Speedy sifting Domain	<p>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 assessment of a report's relevance, reliability and transferability</p> <p>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 clearinghouse</p> <p>It consists of six modules, one generic and five specific to certain parts (or domains) of HTA reports. The generic module (speedy sifting) enables the rapid assessment of the relevance of the report</p> <p>The five specific domains relate to technology use and development, safety, effectiveness, economic evaluation and organisational aspects. The reliability and transferability of information and data within these five domains can be assessed using these parts of the toolkit</p> <p>The toolkit output is adaptation material that can be incorporated into a new framework for an HTA report in a target setting</p>
Transferability	See Generalisability

Appendix 2

Glossary of HTA adaptation terms, November 2007



The aim of the glossary of HTA adaptation terms is to identify and highlight key words and concepts that are easily misunderstood between countries. It provides a series of descriptions for such terms and contains examples of where the usage of these terms may differ between countries.

Please note: This glossary is intended to be a resource for identifying issues related to different uses and meanings of various HTA terms with a view to aiding the adaptation of HTA reports between settings.

Terms

A

Adaptation
Adoption
Advice
Affordability
Applicability

C

Clinical question
Commissioning
Common core HTA
Competing interests
Conflict of interest
Context specific
Core model for HTA
Critical appraisal

D

Domain

E

Effectiveness
Efficacy

Equity
Evidence synthesis

G

Generalisability
Guidance
Guideline

H

Health technology
Health technology appraisal
Health technology assessment

M

Mini-HTA

P

Planning
Policy
Policy-makers
Policy questions
Pre-assessment
Primary research
Protocol
Purchasing

R

Rapid review
Relevance
Reliability

S

Secondary research
Setting
Speedy sifting

T

Toolkit
Transferability

Term	Description
Adaptation	<i>EUnetHTA</i>
Adoption	<p data-bbox="427 376 481 398">Issue</p> <p data-bbox="427 421 1417 497">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</p> <p data-bbox="427 519 769 542">Different types of HTA reports</p> <p data-bbox="427 564 1417 689">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</p> <p data-bbox="427 712 817 734">Adaptation is a part of a spectrum</p> <p data-bbox="427 757 1417 855">Making use of all or part of an HTA report from elsewhere could be achieved in a wide range of ways (see items 1–4 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 1–3 require further work beyond the use of information from the report to develop your own report</p> <p data-bbox="427 878 1184 900">Summarising: translating the summary and using it for background information</p> <p data-bbox="427 922 1401 967">Updating searches: using the original search strategy to identify any more recent evidence or adding to the search strategy and extending it</p> <p data-bbox="427 990 1401 1034">Adapting: systematically extracting relevant HTA information from an existing report (from a whole report or from part of a report)</p> <p data-bbox="427 1057 1422 1102">Adopting: making use of the report without making any changes at all (except perhaps translation into your own language)</p> <p data-bbox="427 1124 689 1146">Adaptation is a process</p> <p data-bbox="427 1169 1417 1267">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) 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:</p> <p data-bbox="427 1290 1417 1550"> <ul style="list-style-type: none"> <li data-bbox="427 1290 1417 1335">(a) checking the relevance of the question(s) addressed in the original report to the question you are facing <li data-bbox="427 1357 1417 1402">(b) identifying the information in the report that is relevant and most likely to be transferable to your setting <li data-bbox="427 1424 1417 1469">(c) assessing the reliability of the information under various domains (benefits, harms, cost-effectiveness, organisational aspects, social and legal issues, etc.) <li data-bbox="427 1491 1417 1550">(d) identifying and setting out the problems that may occur when the extracted, relevant, quality assessed information is transferred into a local HTA report; and deciding how to deal with them </p>
Affordability	<p data-bbox="427 1585 619 1608"><i>DACEHTA, Denmark</i></p> <p data-bbox="427 1630 1417 1751">Here, I am afraid that we cannot give any insights from a Danish setting, as it is not a term that is often used (except perhaps in economic contexts). Also we are not sure about the specific relation to adaptation. This answer might not seem very productive, but we need to consider whether it is relevant in relation to adaptation. We endorse the general descriptions, even though it could have many different meanings (affordability of an HTA project, a technology, etc.)</p> <p data-bbox="427 1787 555 1809"><i>DSI, Denmark</i></p> <p data-bbox="427 1832 1417 1930">There is no standard definition of affordability, as it relates to the extent that a patient or a service provider can pay for it. This will, for example, depend on the funding mechanism/income level and the cost of the service. What is affordable health care in one country is not necessarily affordable in another</p>

Term	Description
	<p><i>FinOHTA, STAKES, Finland</i></p> <p>The main aim of determining affordability in the health-care sector is to evaluate whether the expenses of the intervention can be met</p> <p>In addition to an intervention's effectiveness, decision-making requires consideration of the intervention's feasibility, sustainability and affordability. Affordability also tells us something about the value of alternative health-care services</p> <p>While considering affordability, it is important to take into account all possible costs and consequences of an intervention</p> <p><i>Iceland, Editor of Clinical Guidelines, Directorate of Health</i></p> <p>Affordability describes the means that a nation/health-care system has at its disposal and could allocate to a particular purchase (service). This has nothing to do with the actual decision of whether to purchase or not, as this would depend on, amongst other things, the relative and absolute values of the goods</p> <p>In a system, such as that in Iceland, where the social security service is the main purchaser (apart from hospitals) and has a fixed budget for a defined population, affordability could be affected by changes in other services (reduced or increased demand in one sector could affect another – drug expenditure vs physician services)</p> <p><i>PHGEN</i></p> <p>Affordability is the capability to allocate financial funds to an individual or societal need. Thus, we see a need to differ between a society's capability to afford a health technology and the individual capability to afford a health technology that is not financed by the health-care system/health insurance. Affordability is closely related to the idea of choice. Affordability has different degrees, depending on the allocation and trade-offs</p> <p><i>Servicio de Evaluacion y Planificacion, Canary Islands</i></p> <p>Description of the concept</p> <p>The concept of affordability is related to the capacity of being affordable. Something is affordable when one can manage it in terms of time, money or resources</p> <p>There is another context in which this term is used, which is related to the capacity to provide something</p> <p>In HTA it should be a criterion to take into account when one has to make decisions about the inclusion or exclusion of some intervention, treatment or diagnostic procedure by the means of being able to cope within the budget and resources of each country</p> <p>Problems in interpretation</p> <p>One of the problems in interpretation could be to assume that something is not affordable because it is expensive. This would not be correct because what is affordable for one person might not be affordable for another person, even though it has the same price. It is not a question of price but of its cost in the context of the budget and resources of each health-care system</p> <p>Another problem is that one might only use it in the context of financial aspects and sometimes it refers to other aspects as affordable such as resources or time</p> <p>Examples of how this term is used in different countries</p> <p>Reading the scientific literature we can find the use of this term in different contexts, but basically it seems to have the same meaning in all countries. The references used to present examples of the use of the term of affordability come from different countries such as Germany, Sweden, India, USA, UK and Italy:</p>
	<i>continued</i>

Term	Description
Applicability	<ul style="list-style-type: none"> • financial context: frequently the word affordability is used in monetary terms • availability of time: affordability can be referred to with reference to time limits • affordability can be considered as a criterion to select interventions • affordability can be seen as a criterion related to access to services <p><i>INAHTA glossary</i></p> <p>The degree to which the results of an observation, study or review hold true in other settings</p> <p>See also Generalisability and transferability and Relevance and Reliability</p> <p><i>AETSA, Spain</i></p> <p>Applicability should be taken into account before adaptation is undertaken. One important task should be the recommendation to carry out a first judgement on the applicability of an HTA report considering epidemiological, biological, organisational and socioeconomic issues. Applicability is not the same as generalisability. Generalisability is a characteristic of a report whereas applicability is a judgement made taking into account the particular characteristics of a country. (I can judge a report as more or less generalisable but my country may have very particular circumstances that prevent its application)</p> <p><i>DSI, Denmark</i></p> <p>Issue</p> <p>Applicability is closely related to generalisability, which is a prerequisite for adapting an HTA report to a local setting. As health-care systems and patients are not the same in different countries, the approach or studies do not always apply to the local context. Therefore, the applicability of the report must be reviewed</p> <p>Process</p> <p>When testing for, or when considering, the applicability of an HTA report the researcher must decide whether the treatment effect will be similar in the population they are facing. Issues that must be considered are, for example:</p> <ul style="list-style-type: none"> • Epidemiological issues: Does the population face the same incidence and prevalence of the conditions, or is it likely that differences will significantly alter the potential benefits and risks of the treatment or screening programme? • Organisational issues: Do differences in the structure of the health-care system make the technology more or less relevant (e.g. pre-hospital care in Greenland vs pre-hospital care in Denmark)? • Socioeconomic issues: Are differences in patient or provider compliance to be expected? • Biological issues: Are there genetic or demographic differences in the illness under study that may lead to a different treatment response? <p><i>FinOHTA, STAKES, Finland</i></p> <p>Applicability, in research terminology, is used when studies conducted in one setting are assessed to determine whether their results/conclusions can be used or implemented in other settings. Examples: 'We appraise foreign results against local conditions and evaluate their applicability in Finland'</p> <p>Another example of the use of the term applicability comes from the implementation stage of a research project. Researchers should ensure that their results are communicated in such a way that they are applicable in daily practice</p>

Term	Description										
	<p>When considering the applicability of a study report, issues regarding population, intervention, settings, outcomes used and benefits or harms found should be evaluated against one's own situation or setting at hand. Specific questions on applicability are given in <i>Table 1</i></p> <p>TABLE 1 Questions on clinical applicability</p> <table border="1"> <tbody> <tr> <td>Population</td> <td>1. Are the patients described well enough to decide whether they are comparable to those that you see in your practice?</td> </tr> <tr> <td>Intervention</td> <td>2. Are the interventions described well enough so that you could provide the same for your patients?</td> </tr> <tr> <td>Settings</td> <td>3. Are the treatment settings described well enough so that you could provide the same for your patients?</td> </tr> <tr> <td>Outcome measures</td> <td>4. Were all clinically relevant outcomes measured and reported?</td> </tr> <tr> <td>Benefits worth harms</td> <td>5. Are the likely treatment benefits worth the potential harms?</td> </tr> </tbody> </table> <p>Sources: van Tulder M, Furlan A, Bombardier C, Bouter LM, the Editorial Board of the Cochrane Collaboration Back Review Group. Updated method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group. <i>Spine</i> 2003;28:1290–9; Guyatt G, Drummond R. <i>Users' guides to the medical literature. Essentials of evidence-based clinical practice</i>. Chicago: American Medical Association; 2002</p> <p><i>HTA agency, Poland</i></p> <p>What we understand by applicability is the application/use of the results from clinical trials (carried out on restricted, specially selected populations) to other groups/individual people for the use in one's own medical practice (in other words, the 'usefulness of these results in own clinical practice'). A randomised trial provides only direct evidence of causality within that specific trial. As individual characteristics will affect the outcome for this person, it takes an additional logical step to apply this result to a specific individual</p> <p>Although closely related to concepts of generalisability and external validity, applicability is broader in its scope, including issues related to the overall impact of treatment on individual patients. Wanting to make informed decisions on health care, when considering applicability it is important to take relevant individual factors/issues into consideration, such as:</p> <ul style="list-style-type: none"> • Biological issues: differences between patients, pathophysiological differences in the illness (whether the biology of the treatment effect will be similar in patients they are facing) • Social and economic issues: important differences in patients as well as in provider compliance (their own ability to deliver the intervention in a safe and effective manner) • Epidemiological issues: comorbid conditions, important differences in untreated patients' risks of adverse outcomes (their patients' risk of the target event that treatment is designed to prevent and of the side effects that may accompany treatment) <p>For full details, see Dans AL, Dans LF, Guyatt GH, Richardson S, for the Evidence-Based Medicine Working Group. <i>How to decide on the applicability of clinical trial results to your patient</i>. Centre for Health Evidence, Edmonton, Alberta. URL: www.cche.net/userguides/trials</p> <p><i>IHPRS, Slovenia</i></p> <p>Applicability of different standards or evaluations might be a problem in certain countries. Different countries have to find a criterion or a factor to apply assessments from other countries as it cannot be achieved 1:1, especially not HTA reports related to economic or epidemiological aspects. Applicability depends on the nature of certain HTA studies. Some studies (randomised controlled trials) can be transferred directly from country to country; others, such as economic evaluations or epidemiological studies, are not cross-country applicable. In Slovenia, according to experience from other countries, the Ministry of Health suggests measures for the assessment of new methods of treatment, such as medical effectiveness (necessity of medical treatment and efficiency of the programme) and economic efficiency of the programme, as well as taking a social and population view</p>	Population	1. Are the patients described well enough to decide whether they are comparable to those that you see in your practice?	Intervention	2. Are the interventions described well enough so that you could provide the same for your patients?	Settings	3. Are the treatment settings described well enough so that you could provide the same for your patients?	Outcome measures	4. Were all clinically relevant outcomes measured and reported?	Benefits worth harms	5. Are the likely treatment benefits worth the potential harms?
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Term	Description
	<p><i>NOKC, Norway</i></p> <p>The Norwegian Knowledge Centre does not currently have a structured approach to assessing the applicability of external HTA reports or reviews, although issues tied to applicability and transferability are dealt with frequently. In practice, our approach when evaluating these documents resembles processes described by other institutions, including the New Zealand Guideline Group (NZGG). These issues are also described in a recent publication coauthored by two of the Norwegian Knowledge Centre's staff members to serve as background for advice from the WHO Advisory Committee on Health Research</p> <p>As an important first step we begin by appraising the quality of the document using checklists developed for assessing the quality of systematic reviews. If the document is evaluated as being of high enough quality, we then go on to evaluate its relevance or potential transferability to the Norwegian setting. This is carried out particularly for the following areas:</p> <ul style="list-style-type: none"> • the health setting or professional groups involved in intervention delivery • the patients or consumers, the intervention targets, including their specific health conditions, baseline risk, expected compliance, etc. • the intervention, its current availability, cost, etc. • the control intervention and the degree to which the comparison is a relevant one in Norway • the outcomes and the degree to which they reflect the values and goals of Norwegian health-care users and policy-makers <p>The issue that most often hinders the applicability of an HTA report from another agency is the uncertainties regarding the methods for how the review was undertaken. Thus, developing a core model for HTA will facilitate the use of HTA reports from other agencies</p> <p>When assessing the applicability of another HTA report or systematic review we consider whether there are special circumstances that may modulate the efficacy obtained in the research setting. For instance, percutaneous coronary interventions (PCI) have proven to be better than thrombolysis in acute myocardial infarction. PCI needs to be given within a period of less than 3 hours, but if PCI is decentralised to hospitals with few annual procedures, patient outcomes are worse than in more experienced hospitals. Thus, there are certainly other factors that are unlikely to have been dealt with in the trial setting which may modulate the expected effectiveness of the technology when applied in another setting. These factors may relate to the health-care system, geography, population, need for education or special competence, etc.</p> <p>Another issue that might relate to the applicability of HTA reports is the timeliness. If an issue is emerging with great importance, exchange of information may be extremely helpful. This may not be a complete HTA report but preliminary information. We have, for example, shared a preliminary version of our HPV vaccination report so that other agencies may assess whether this report may be relevant to their question</p>
	<p><i>PHGEN</i></p> <p>The idea behind the term 'applicability' is related to the general idea of adaptation because the application of foreign HTA reports is only possible if an adaptation is possible and worth the effort</p> <p>Application as a task</p> <p>We would like to point out the key focus of the term by referring to computer sciences and the term 'application software'. According to one definition, 'application software is a defined subclass of software that employs the capabilities of a computer directly to a task that the user wishes to perform'. This should be contrasted with system software, which is involved in integrating a computer's various capabilities but typically does not directly apply them in the performance of tasks that benefit the user. The term application refers to both the application software and its implementation</p> <p>To come back to HTA, the importance of applicability is the underlining of the wishes of the user. Thus, applicability has a different notion as the focal point is opposite to that of adaptation. Adaptation calls for a general standardisation beyond the users' wishes. Applicability is reached if HTA reports are 'open' to the wishes of users</p>

Term	Description
	<p>Application as a need</p> <p>The overall need for applicability is obvious and the conceptual contrast to the term 'adaptation' will melt away if the general standardisation acknowledges the individual need of a user. Thus, we feel the term 'applicability' must be defined in the context. For HTA reports we should draw a distinction between the application of an HTA report as a science base as support for an appraisal (with the new user drawing a conclusion) and as the appraisal itself (in the sense of an adoption)</p>
Commissioning	<i>DSI, Denmark</i>
Planning	Commissioning, planning and purchasing are different stages in the process of getting from a strategy or an idea to providing a service
Purchasing	<p>In the commissioning process, an agent will be granted authority to undertake certain functions, for example determining priorities within the defined objective. The second step in the process is the planning process. In an HTA perspective, this could involve an assessment of status quo in the given country or region and a review of strategies and services that deliver the most health gains for the patient and the best value for money for the given context. Purchasing involves choosing how to deliver the strategy and services and selecting the most appropriate service providers</p>
	<i>HTA agency, Poland</i>
	<p>Commissioning</p>
	<p>Commissioning is sending or officially charging an individual or group to undertake certain functions or to complete certain tasks. Usually one commissions tasks that cannot be completed within one's own sources to people more competent for the task</p>
	Commissioning may refer to:
	<ul style="list-style-type: none"> • a report (agency for HTA commissions academic entity to produce HTA, Minister of Health commissions HTA on given subject from AHTAPol) • new research (to fill gaps in knowledge)
	<p>Planning</p>
	<p>Planning is one of the functions/activities usually carried out by top-level management/project leaders. It focuses on the preparation of plans and arrangements to design and control the development/progress of:</p>
	<ul style="list-style-type: none"> • the organisational structure • the work division/tasks (e.g. planning the work for an HTA report in a team of employees of an HTA agency) • the project • the budget, etc.
	<p>It is the process of defining goals for future organisational performance, and deciding on tasks and resources necessary to attain these goals. It answers questions on:</p>
	<ul style="list-style-type: none"> • what goals are to be achieved within a given time frame • why these goals need to be achieved • how could/should they be achieved • what actions are needed in order to achieve them • how to verify whether these goals have been achieved or not (and, if not, what other/alternative actions should be undertaken to achieve these goals)
	<p>Development of the strategic plan greatly helps to clarify the organisation's/project plans. When generating the plan it is essential to clearly define the purpose of the organisation/project and to establish realistic goals and objectives consistent with that mission in a defined time frame within the organisation's capacity for implementation</p>
<i>continued</i>	

Term	Description
	<p>Purchasing</p> <p>Purchasing is the act of buying goods (licensed medical devices, medical services) by National Health Fund or health-care practitioners/providers by entering into contractual agreements with suppliers</p> <p>The act of buying goods (devices) is carried out strictly in compliance with purchasing policy</p> <p>According to this policy, purchasing must be based on gathering information on needs from staff and patients, assessing the urgency of these needs and weighing the options, and on these bases trying to make informed decisions. Once placed, purchasing requests for items (addressed supply requirements) are acknowledged by management and a vendor/supplier is chosen by tender. Usually the vendor who presents the most cost-effective contract pricing for the items/service/medical devices is chosen to fulfil the purchase order</p> <p><i>Iceland, Editor of Clinical Guidelines, Directorate of Health</i></p>
	<p>Commissioning</p> <p>This has many meanings depending on the situation/reference. Relating to HTA adaptation it is the delegation of some task/assignment to an individual or group. This usually involves transferring some authority and responsibility to those being asked/ordered (commissioned) to perform some task</p> <p>Planning</p> <p>Describes the a priori formulation of a scheme or strategy to attain some specific accomplishment</p>
	<p>Purchasing</p> <p>The act of buying/obtaining goods (services) with money or by other means by a health funding authority. In Iceland this is usually the social security system or hospitals</p> <p><i>IHPRS, Slovenia</i></p> <p>Purchasing of health services is the process by which the most needed and effective health interventions are chosen and provided in an efficient and equitable manner, and the providers are paid appropriately from the pooled financial resources for delivering defined sets of services and interventions. Purchasing has three interwoven elements: allocating 'financial resources', establishing 'provider payment options' and 'contracting' with providers</p> <p><i>Institute of Molecular Medicine, Portugal</i></p>
	<p>Commissioning</p> <p>We usually use it for someone (or an institution) who has been put in charge of a specific project or designated to lead a project, e.g. Infarmed has been commissioned to perform a thorough inspection on pharmacies; the Ministry of Health is commissioning the Health Observatory to find out why there is a huge waste on drugs</p> <p>Planning</p> <p>The word planning is somewhat more vague in Portuguese than commissioning. Planning is mostly used when a plan is still in its first steps and nothing has really been delineated yet. Nevertheless it can also mean a real plan, and planning, in fact, by definition, is the act of producing a plan. I think that the best word to define Portuguese 'planning' is the English expression 'thinking of'. Planning is best described as 'delineating a plan' or 'building a plan' or 'building a project'</p>
	<p>Purchasing</p> <p>By purchasing we usually mean the act of acquiring something, be it real estate, other objects or services. Considering this last aspect, in Portuguese you can say 'we purchased John for this specific task' (highly used in football). It means an exchange that involves money</p>

Term	Description
	<p><i>TU Berlin, Germany</i></p> <p>The term 'commissioning' can be applied to both commissioning an HTA report and commissioning services</p> <p>In the first sense it is related to the process of HTA. In Europe there are HTA agencies that have a so-called general mandate which allows them to identify priorities and conduct assessments on their own initiative. However, many HTA agencies in Europe perform assessments in the context of a formalised decision-making process in which an institution may (or should, or must) commission the agency with the assessment of a relevant topic to inform a specific deliberative process. The commissioning institution assigns the HTA agency with the task of assessing a specific topic</p> <p>The second sense – commissioning services – is more closely related to the term 'purchasing'. These terms can be best understood in a model of a health system in which there is an institutional separation between the health services and the institution ultimately responsible for the health of a population (i.e. community). In such a model, the providers of primary health care, hospitals, rehabilitation services, etc., represent in a way the means by which the institution accountable for health care (i.e. the local health authority, the regional government, etc., depending on the organisation and on the degree of decentralisation of the system) tries to achieve its ultimate goal: the production of population health. For example, a regional health authority is responsible for the health of the population living within its administrative borders and has to reach agreements for service delivery with providers in order to address the health needs of its population as well as guaranteeing equal access. Commissioning can thus be understood as the action of assigning tasks to providers. In addition, the term 'purchasing' implies a money flow between the commissioning institution and the provider of health services, i.e. an amount of money is allocated to the provider in relation to the task assigned. Purchasing usually implies a greater degree of separation between both actors</p> <p>Planning refers more to the action of elucidating the health needs of a given population and allocating resources in order to meet them. In a model of separation between provider and purchaser/ commissioner planning can be considered to be the necessary step previous to commissioning and/ or purchasing</p> <p>The three terms are closely inter-related and it may be difficult to draw a clear conceptual border between them when there is no clear separation of roles (provider, purchaser, etc.) in the health system. Thus, in some situations they may be used interchangeably</p>
Core model for HTA	<p><i>FinOHTA, STAKES, Finland</i></p> <p>The core model for HTA defines and standardises elements of assessment. It supports the production of HTAs that are independent of specific context and identifies issues relevant for adaptation in national settings</p> <p>The elements within the HTA core model have been evaluated for two key characteristics: importance and transferability. In this context importance indicates how essential the element is from the view point of decision-making. Transferability indicates how easy it is to transfer the results from one setting to another. The importance and transferability of each element of assessment – and hence the inclusion in the HTA core model – have been agreed on within the EUnetHTA project</p> <p><i>Institute of Molecular Medicine, Portugal</i></p> <p>Common core HTA is best translated as 'apreciação de tecnologia nuclear da saúde' or 'apreciação de tecnologia central da saúde'. The first suggests more the main core of the system, whereas the second can be a little broader</p> <p><i>NOKC, Norway</i></p> <p>The HTA core model describes how HTAs are produced. Therefore, it can be described as either the method for producing an HTA or the content of an HTA. The core model can also be viewed as the product resulting from an HTA</p>
	<i>continued</i>

Term	Description
	<p><i>Servicio de Evaluacion y Planificacion, Canary Islands</i></p> <p>Essential common parts in the reports of HTAs, independent of the subject of the reports</p> <p><i>TU Berlin, Germany</i></p> <p>The core model can be understood as the minimum components of an HTA report and thus it may vary from country to country. The core model can also be understood as the agreement on the minimum components of an HTA report from an international perspective, thus representing a kind of European standard. For core model definitions please refer to the EUnetHTA definition</p>
Conflict of interest	<p><i>INAHTA glossary</i></p>
Competing interests	<p>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</p> <p><i>DSI, Denmark</i></p> <p>A conflict of interest is a situation in which a corporation or individual is in a position to exploit a professional or official capacity for their corporate or personal benefit. Competing interests can make it difficult to act impartially. Even if there is no evidence of improper actions, a conflict of interest can undermine confidence in the ability of that person to use his/her position with proper ethics. Common forms of conflicts of interest or competing interests in HTA are when outside employment or privately held business interests are in some way related to the subject of the HTA or are interested in its outcome</p> <p><i>IHPRS, Slovenia</i></p> <p>A conflict of interest is a situation in which someone in a position of trust has competing professional or personal interests. Such competing interests can make it difficult for a person to fulfil their duties impartially. Even if there is no evidence of improper actions, a conflict of interests can create an appearance of impropriety that can undermine confidence in the ability of that person to act properly in his/her position. For example, a conflict of interest might exist when a person working for one organisation does research for a pharmaceutical company and presents the results at a congress. The payment of the person's trip by the pharmaceutical company in question might cause a conflict of interests. To avoid it, no direct link between the researcher and the pharmaceutical company in financial terms should exist. A conflict of interests can occur when, for example, researchers or experts in a randomised controlled trial in a special field (e.g. neurology) carry out the research, write the final report and present the trial and its outcomes and then also sit on the board where the adoption of the application for the specific treatment is being decided</p> <p>Conflict of interests can increase into competing interests when there is a priority list of treatments or medication. The experts in question might vote against one other proposed treatment or medication so that 'theirs' does not lose a spot in the priority list. Pharmaceutical companies and the doctor who travels with the company have to sign a statement which states that the medical doctor will not favour the specific pharmaceutical company and its products</p> <p>A competing interest exists when the interpretation of data or presentation of information may be influenced by a personal or financial relationship with other people or organisations. Often researchers are asked to disclose any financial and non-financial competing interests that may cause them embarrassment were they to become public. Declaring their competing interests does not prevent an evaluation from being published</p>

Term	Description
	<p><i>Institute of Molecular Medicine, Portugal</i></p> <p>Conflict of interest</p> <p>There has been a little arguing about what 'conflito de interesses' in Portuguese really means. We used to use this term when a person or a group had a particular (economic or professional) interest in a task or product and was part of a party designated to assess the utility of this product. But its range can be wider, especially when we are speaking of health professionals, who should have different scopes for the same path; for instance, physicians should use the patient perspective in some aspects of health, but should also take into account the Ministry of Health perspective or the Medical Society perspective in others, not think of their own personal perspective. Therefore, we now tend to consider 'conflict of interest' as the personal perspective against the party or group perspective, as the most important 'conflict' of all the interests at stake</p> <p>Competing interests</p> <p>Competing interests add a temporal vector to the possible conflicting interests. However, competing interests may not be conflicting. Sometimes they compete for the same window of opportunity. Therefore, the success of one project (one interest) may jeopardise the success of the other. Sometimes the interests can be conflicting, e.g. 'The interests of the population go against the interests of the army, competing for the ownership of the land on the east side of the river'</p>
	<p><i>FinOHTA, STAKES, Finland</i></p> <p>Development and research activities should always be based on the principle of transparency. Internationally, financial and other conflicts of interest are being declared with increasing openness. Especially in research projects it is important to declare any financial or other interests that might influence the approaches taken by the researchers in the project or while drafting the final report. A person's own assessment in this matter should be trusted and the information given should be dealt confidentially</p> <p>Declaring financial and other conflicts of interest does not mean that the person would not be in a position to participate in the research, or that his or her conclusions would be incorrect or biased. A significant financial or other interest may, however, constitute a reason for the person concerned to decide to withdraw from participation. Unclear cases should be negotiated. If the expert has financial or other interests that he or she does not want to declare, it is preferable to withdraw from participation</p>
	<p><i>NCCHTA, UK</i></p> <p>The BMJ editors and the International Committee of Medical Journal Editors define competing interests as including financial relationships with industry (e.g. through employment, consultancies, stock ownership, honoraria and expert testimony), either directly or through immediate family; personal relationships; academic competition; and intellectual passion</p> <p>Source: BMJ editors (http://bmj.bmjournals.com/advice/editorial_policies.shtml#competing) and the International Committee of Medical Journal Editors (www.icmje.org/index.html#conflict)</p>
	<p><i>NOKC, Norway</i></p> <p>In HTA conflict of interest relates to two issues:</p> <ul style="list-style-type: none"> • conflict of interest in published studies (authors, sponsors) and • conflict of interest of the people involved in the HTA <p>The issue of conflict of interest in published studies may interfere with the objectivity of the study. All studies should declare conflicts of interest from all authors and how the study was sponsored</p>
	<i>continued</i>

Term	Description
Context specific Setting	<p>How does the issue of conflict in publications apply to HTA?</p> <p>Conflict of interest relates to the fact that sponsoring from industry has been associated with restricted or selective publication of data. Thus, such studies may introduce bias if industry-sponsored studies tend to more often report positive results (which they actually do) and withhold data from studies showing no or harmful effects. Thus, studies may introduce the bias of overestimating the effectiveness of the technology</p> <p>Conflict of interest may also apply to those involved in an HTA, whether researchers or clinical experts. This conflict of interest should be declared in the final HTA report and is referred to in the INAHTA checklist</p> <p>When considering conflict of interest the issue relates not only to financial interests but also to other issues such as allocation of money for research, etc.</p> <p>In Norway, conflict of interest is declared by all involved in the HTA process</p> <p>The issue of competing interests could be viewed in relation to the issue of conflict of interest and the fact that different interests may compete with each other; thus relating to the comments above. On the other hand, competing interests may also apply to the process of HTA</p> <ul style="list-style-type: none"> • Do we have competing interests in HTA? If yes, how do competing interests apply to the HTA process? • Do we have competing interests when prioritising technologies for assessment (for instance, do we prioritise questions from our payers and are these questions the important questions for society?) • Do we have competing interests when selecting studies for assessment (for instance, use of confidential data vs open access data)? • Do we have other competing interests? <p><i>EUnetHTA</i></p> <p>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) and the kind of decision being made</p> <p>Setting, in particular, is commonly used in HTA to refer narrowly to an organisational dimension of health care, such as primary, secondary or tertiary care, or community care</p> <p>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</p> <p>If HTA evidence or an HTA report is context specific, this may mean that something about it cannot or should not be applied to other settings without careful adaptation. Context specific, therefore, implies 'not generalisable' and 'not transferable'</p> <p><i>INAHTA glossary</i></p> <p><i>Context</i> The conditions and circumstances that are relevant to the application of an intervention, for example the setting (in hospital, at home, in the air), the time (working day, holiday, night-time), type of practice (primary, secondary, tertiary care; private practice, insurance practice, charity), whether routine or emergency</p> <p><i>NOKC, Norway</i></p> <p>Context applies to the local setting in which the output of the HTA process should apply, and may be viewed as the brokering of science into decision-making processes. In this process issues to consider are the facilitators or restrictions for applying the HTA conclusions into the local setting. These issues are financial restrictions/facilitators, organisational issues such as hospital structure, education, speciality services, and legal issues such as patients access to treatment</p> <p>Clinical efficacy may be influenced by the context (trial setting). This may be especially important when assessing surgical procedures, but other contextual factors such as organisational issues and sociodemographic issues may influence the overall measured effect</p>

Term	Description
	<p><i>TU Berlin, Germany</i></p> <p>Setting</p> <p>In general, the term 'setting' seems to be understood as the place where something occurs. The setting, for example, is the place where a technology is implemented</p> <p>There seems to be some confusion over this term as sometimes it is a geographical concept (national setting, regional setting, local setting), sometimes a concept related to the type of health system (NHS setting, SHI setting) and sometimes a concept related to the type of care or institution (ambulatory setting, hospital setting, academic setting)</p> <p>When a sentence such as 'In our setting ...' is found, it is not clear to which of the above it refers when further information is not provided. Thus, the term should not be used alone as it might be difficult to interpret. A more accurate description of what is meant in each case (i.e. geography, health system, institutions, etc.) should be clearly preferred</p> <p>Context specific</p> <p>The term 'context' seems to refer to the same issues as the term 'setting' and in general the terms are being used interchangeably. Context, however, seems to be used with the intention of referring more explicitly to further aspects that characterise 'where' a technology is applied, such as cultural issues, preferences, interests, etc. In contrast, setting seems to be used when referring only to the characteristics of the place, discussed previously</p> <p>Context seems to cover more than setting and to be used when referring to the whole environment</p> <p>The term 'context specific' seems to be used to describe such aspects or issues relating to the implementation of technology that vary depending on 'where' it is the technology is applied. The term is frequently used to highlight that a piece of evidence might not be transferable to one's own situation as the findings could have been different had the evidence been produced elsewhere. In this form context specific seems to be used as an equivalent to saying 'not generalisable' or 'not transferable'</p>
Critical appraisal	<p><i>INAHTA glossary</i></p> <p>The process of assessing and interpreting evidence by systematically considering its validity, results and relevance</p> <p><i>DACEHTA, Denmark</i></p> <p>The process of assessing and interpreting evidence by systematically considering its validity, results and relevance is a central part of carrying out HTA. This definition is clear and should be preserved. The specific process of critical appraisal is probably carried out in different ways in different organisations/projects, but the main request must be that the process is reliable and is documented in a transparent way</p> <p><i>DSI, Denmark</i></p> <p>Critical appraisal is the process of systematically examining research evidence to assess its validity, results and relevance before using it to inform a decision. Critical appraisal is one step in the process of evidence-based decision-making. Critical appraisal skills are necessary to determine what the evidence is for the local context. The relevance of health-care research might be related to the country, as different countries have organised their health-care systems differently. Most health-care research is not perfect or perfectly relevant for a specific decision context and critical appraisal is not an exact science, but systematically applied it can guide decisions on whether a reported piece of research is good enough to be used in decision-making. If research has flaws it is up to readers to use their critical appraisal skills to decide whether and how this affects the usefulness of the research paper</p>

continued

Term	Description
	<p><i>IHPRS, Slovenia</i></p> <p>Critical appraisal is the process of systematically examining research evidence to assess its validity, results and relevance before using it to inform a decision. In Slovenia, both assessment and critical appraisal have the same meaning and they are used for closing the gap between research and practice. Critical appraisal means that bias needs to be avoided and the most appropriate design for studying the effectiveness of an intervention or treatment has to be implemented. Systematic reviews are particularly useful because they usually contain an explicit statement of the objectives, materials and methods, and should be conducted according to explicit and reproducible methodology. Randomised controlled trials and systematic reviews are not automatically of good quality and should be appraised critically</p> <p><i>NCCHTA, UK</i></p> <p>The process of deciding whether a piece of research can help you in answering your clinical question. There are three questions you need to ask about any kind of research:</p> <ul style="list-style-type: none"> • Is it valid? • Is it important? • Is it applicable to the patient? <p>Source: Centre for Evidence-Based Medicine, Oxford</p>
Efficacy	Please note: The term 'efficacy' has a specific definition when used by drug licensing companies
Effectiveness	<p><i>INAHTA glossary</i></p> <p><i>Effectiveness</i> 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</p> <p><i>Clinical effectiveness</i> 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.)</p> <p><i>Efficacy</i> 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 randomised controlled trial or at a 'centre of excellence'</p> <p><i>HTA agency, Poland</i></p> <p>Effectiveness and efficacy</p> <p>As for effectiveness and efficacy, we do not think that there can be a problem with mistaking these two terms</p> <p>As efficacy refers strictly to the trial setting it is difficult to even assume to what extent the effects obtained in such an 'ideal' setting can be generalised outside to clinical practice, in which the conditions as well as characteristics of the treated population differ</p> <p>Although high-quality randomised clinical trials provide the most reliable evidence on the benefits of a new treatment over the standard treatment, the Polish guidelines for conducting HTA reports suggest that the effectiveness of the medical technology should be taken into consideration, as it reflects the effects of an intervention as measured in a situation similar to or very similar to common clinical practice</p>

Term	Description
	<p data-bbox="403 327 938 353"><i>Iceland, Editor of Clinical Guidelines, Directorate of Health</i></p> <p data-bbox="403 365 502 392">Efficacy</p> <p data-bbox="403 403 1374 495">Describes how well or badly some input (intervention/health technology such as drugs, screening programmes, etc.) works under ideal circumstances, whether artificial (research setting) or natural (created by, for example, geography, captive population)</p> <p data-bbox="403 506 560 533">Effectiveness</p> <p data-bbox="403 544 1353 636">Describes how well or badly some input (specific intervention/health technology such as drugs, screening programmes or other services) works under usual circumstances (real world or usual practice)</p> <p data-bbox="403 656 555 683"><i>NOKC, Norway</i></p> <p data-bbox="403 694 1390 808">Efficacy refers to the trial setting and thus any HTA needs to consider whether the results obtained in clinical trials can be generalised outside to clinical practice. In some instances 'real world' studies are conducted to evaluate real world effectiveness; such studies are, however, often registry based and thus are not of a design comparable with study designs most often used to analyse efficacy</p> <p data-bbox="403 819 1394 934">We and probably other HTA agencies are often faced with the question 'What is sufficient documentation of effectiveness? This question would be important to discuss within EUnetHTA, and one might consider some approaches that include consideration of the amount and quality of clinical trials, use of surrogate measures, time for follow-up, etc.</p> <p data-bbox="403 945 1378 1037">Another potential problem arises when efficacy is derived from confidential information. How do we handle the fact that agencies within Europe have different approaches to the use of confidential information and how would this influence the sharing and using of reports from other agencies?</p> <p data-bbox="403 1057 486 1084"><i>PHGEN</i></p> <p data-bbox="403 1095 1370 1187">Efficacy is the extent to which a specific intervention, programme or service produces a beneficial result under ideal conditions. The definition of ideal conditions is based on the results of a randomised controlled trial</p> <p data-bbox="403 1198 1404 1256">Effectiveness is the extent to which a specific intervention, programme or service, when developed in the field, does what it is intended to do for a defined population</p> <p data-bbox="403 1276 890 1303"><i>Servicio de Evaluacion y Planificacion, Canary Islands</i></p> <p data-bbox="403 1314 1394 1464">In a medical context it indicates that the therapeutic effect for a given intervention (e.g. intake of a medicine, an operation or a public health measure) is acceptable. Efficacy in this context refers to a consensus that it is at least as good as other available interventions to which it will have ideally been compared to in a clinical trial. For example, an efficacious vaccine has the ability to prevent or cure a specific illness in an acceptable proportion of exposed individuals</p> <p data-bbox="403 1476 1366 1534">In strict epidemiological language, efficacy refers to the impact of an intervention in a clinical trial, differing from effectiveness, which refers to the impact in real world situations</p> <p data-bbox="403 1545 724 1572">Effectiveness: doing things 'right'</p> <p data-bbox="403 1583 711 1610">Efficacy: doing the 'right' things</p> <p data-bbox="403 1630 592 1657"><i>TU Berlin, Germany</i></p> <p data-bbox="403 1668 1401 1906">The terms 'effectiveness' and 'efficacy' seem to be used as synonyms and to be quite interchangeable, despite formal conceptual differences between them. To my knowledge this might be due to translation difficulties (in German, for example, 'efficacy' is usually translated as 'Wirksamkeit' and 'effectiveness' as 'Wirksamkeit unter Alltagsbedingungen', which is then too often shortened to 'Wirksamkeit' alone again). The confusion might be also due to a lack of clarity on interpreting whether the conditions of a trial were so far away from conditions in everyday practice. Thus, in front of a piece of evidence it might be difficult to separate both terms clearly, leading to the interchangeable use of both</p>
	<i>continued</i>

Term	Description
Equity	<p>Some separate these concepts depending on how the evidence was gathered, speaking of efficacy when they refer to the effect measured in a randomised controlled trial and of effectiveness when the effect has been measured based, for example, on routinely collected data (epidemiological, administrative, etc.). Another way to separate these concepts might be along the phases of drug development, i.e. depending on the results from a phase II, III or IV trial; however, this could only be applied to drugs as the phase differentiation does not apply to other kinds of interventions</p> <p>Other differentiations can be made on the basis of whether the data analysed refer only to the persons who got the intervention (analysis per protocol) or in contrast to the persons who did not get the intervention (intention to treat analysis). The former would give an estimate of efficacy, the latter would be closer to the concept of effectiveness</p> <p>To facilitate adaptation, the following simplified definitions of both concepts could be taken as a starting point:</p> <ul style="list-style-type: none"> • efficacy: effects of an intervention as measured in a situation unlikely to be widely found • effectiveness: effects of an intervention as measured in a situation similar to or very similar to common practice <p>Following this understanding, a report should speak about efficacy when referring to evidence of effects gathered in studies whose conditions are very artificial and not likely to be found in common practice (independently of whether they are randomised controlled trials or other kinds of studies)</p> <p>Effectiveness should be used when referring to evidence of effects gathered in studies in which the conditions are similar to or very similar to common practice (independently of whether they are randomised controlled trials or other kinds of studies). One can also speak about efficacy when the assessment has modelled the effect taking evidence from studies on efficacy as the starting point and adding evidence from other sources to other terms of the equation (e.g. compliance, diagnostic accuracy, etc.)</p> <p><i>INAHTA glossary</i></p> <p>Fairness in the allocation of resources or treatments among different individuals or groups</p> <p><i>FinOHTA, STAKES, Finland</i></p> <p>Within an HTA project equity can be defined as fairness when allocating resources and interventions among individuals or groups. Equity issues are important in both relation to needs and access to services. Equity as an ethical imperative has to be taken into account when organising health-care systems, setting goals and allocating health-care resources</p> <p>It is important that decision-makers understand that they hold equity assumptions, which are likely to have implications for their decisions. They have to think which individuals or population groups may benefit from a health intervention or perhaps be penalised by that intervention. Population characteristics such as age, gender, ethnicity, geographical area, socioeconomic conditions or health status may be relevant for equity purposes</p> <p>Because of limited health-care resources it is not possible to afford everything. Equity also includes the right to get effective and safe treatment</p> <p>Choosing outcome measures may have equity implications. For example, the use of quality-adjusted life-years (QALYs) as an outcome measure implies that each unit of measurement is considered equal regardless of who gains. By using QALYs, it is assumed that a small gain to many people is equally as desirable as a large gain to a few as long as the QALY totals are the same</p> <p>One example of the use of equity is reported by Teperi <i>et al.</i> (www.stakes.fi/verkkokajulkaisut/raportit/M233-VERKKO.pdf) who concluded that allocating services has not happened according to equity principles. In relation to needs, well-paid people get more surgical treatments, physical examinations and psychotherapy</p>
<See comments on these description>	

Term	Description
	<p><i>NOKC, Norway</i></p> <p>The Norwegian Knowledge Centre has paid little attention to the issue of equity in our work in general and in the use of external HTA reports and reviews in particular. Our responsibility for an international conference on the issue of equity in 2006 has, however, raised our awareness of this issue. The conference also led to a publication that serves as background for advice from the WHO Advisory Committee on Health Research. Here, the authors give recommendations on how issues of equity should be addressed in the development of systematic reviews and guidelines</p> <p>The authors make use of Braveman and Gruskin's definition of equity as 'the absence of disparities in health that are systematically associated with social advantage or disadvantage'. In addition, they refer to Whitehead's definition of inequity: 'differences in health which are not only unnecessary and avoidable but, in addition, are considered unfair and unjust'</p> <p>The authors point to a number of dimensions that can influence a person's access to health care and health, including economic status, occupation, gender, ethnicity, class, caste, religion, status grouping, age, disability, place of residence, geographical location and manifest sexual orientation'. All of these dimensions are of relevance in Norway, although some aspects may be more important than others</p> <p>The Norwegian Knowledge Centre does include ethical considerations in selected HTA reports, and equity is dealt with as part of the ethical assessment</p>
	<p><i>PHGEN</i></p> <p>The idea of equity in health services must be seen in close relation to the principles of justice, fairness and non-discrimination. Equity can refer to both the level of health care provided and the access to health care. Equity therefore can be outcome or 'opportunity' oriented. Equity also requires health literacy as health-care users must be empowered to use the health-care system. From an individual point of view, equity describes what the individual can reasonably expect from a solitary health-care system</p>
	<p><i>Servicio de Evaluacion y Planificacion, Canary Islands</i></p>
	<p>Issue</p> <p>Equity, together with efficiency, are two of the main driving principles in health-care planning and provision of care in publicly financed health-care systems. The concept of equity is a complex concept, but most would agree with the definition of 'equal access to equal treatment for people with similar level of need'. One of the main objectives of the policy-makers is to reach an adequate balance between equity and efficiency</p>
	<p>Relevance and dimensions of equity in HTA</p>
	<p>Equity has a relevant role in different stages of HTA:</p>
	<ol style="list-style-type: none"> 1. Allocating resources according to economic evaluation results from, for example, cost-effectiveness analysis. It is important to note, however, the lack of consensus about the adequacy of cost-effectiveness analysis to promote equity in health-care resource distribution 2. Fair distribution of health technologies, ensuring 'equal access' once the incorporation of a specific technology has been decided
	<p>Example</p>
	<p>A good example of a health technology that increases equity in access to care is telemedicine, given its capabilities to provide a wide range of health-care services to underserved people in remote places. Telemedicine is also a good example of a technology that adequately combines equity and efficiency</p>
	<p><i>TU Berlin, Germany</i></p> <p>For this term I cannot think of many conflicts or misunderstandings in its use. To my knowledge it is predominantly used according to existing definitions. Sometimes it might be confused with 'equality' or with 'justice'. To my knowledge most of the HTA reports to date have not dealt with equity, at least formally or in a systematic way</p>
	<p style="text-align: right;"><i>continued</i></p>

Term	Description
Evidence synthesis Secondary research	<p>Please note: Evidence synthesis and secondary research are treated here as meaning the same</p> <p><i>INAHTA glossary</i></p> <p>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</p> <p><i>NCCHTA, UK</i></p> <p>Using scientific methods to summarise knowledge in an area. HTA evidence synthesis usually includes a systematic review (based on a clearly formulated question, using systematic and explicit methods to identify, select and critically appraise relevant research and to collect and analyse data from the studies included in the review). It may also include meta-analysis (statistical methods to combine research) and economic evaluations based, for example, on decision modelling</p>
Generalisability Transferability	<p>Please note: There is no consensus agreement as to the exact definition of the word ‘transferability’ with reference to HTA. Please be aware that your personal views as to the exact meaning of this term are likely to differ from those of the author(s) of an HTA report in which you read it</p> <p>See also Applicability and Relevance and Reliability</p> <p><i>EUnetHTA – WP5 toolkit</i></p> <p>Generalisability refers to whether the results of an HTA report can be extrapolated to other settings. This is sometimes referred to as external validity</p> <p>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</p> <p>Generalisable information/data can be readily adopted. However, the 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</p> <p>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</p> <p><i>INAHTA glossary</i></p> <p>Generalisability is the degree to which the results of a study or systematic review can be extrapolated to other circumstances, in particular to routine health-care situations</p> <p><i>DACEHTA, Denmark</i></p> <p>Generalisability and transferability both refer to the degree to which results of an HTA can be extrapolated to other circumstances or settings. The two terms are often seen as having the same meaning and are very closely related. It could, however, be desirable to ascribe different meanings to the terms. One possible way of separating the two terms is as follows:</p> <p>Generalisability basically refers to the external validity of an HTA. In general, this refers to interventions, outcomes, units and settings. Generalisability as a concept grows out of research methodology</p> <p>Transferability refers to the organisational context-dependent questions. Is it possible to envision transfer to another setting based on the information in the HTA? Transferability grows out of policy analysis/political science</p> <p>Transferability can be seen as a subcategory of generalisability. It is, however, extremely important to focus on the transferability (setting) question when it comes to adaptation (especially concerning organisational questions) as the selection of relevant HTAs (or other parts of HTAs than the core) for adaptation relies heavily on an assessment of the context-dependent parts of the HTA. Furthermore it is important to stress that the question of generalisability includes both statistical and analytical generalisation and external validity and construct validity</p> <p>Another interpretation of transferability (often used in organisational theory) could be that it is not as closely related to generalisability but rather related to the description of the process of transferring one idea, in this case the HTA report, from one field to another</p>

Term	Description
	<p><i>FinOHTA, STAKES, Finland</i></p> <p>In our view transferability should not be understood as being something related to 'organisational context' only. Two countries may have similar organisational structures, but transferability may still be an issue (if, for example, the genetic profile of the populations is different)</p> <p><i>HTA agency, Poland</i></p> <p>Generalisability</p> <p>Generalisability is the extension of specific research findings and conclusions from a study conducted on a (relatively limited) sample population to the population at large (e.g. to the whole population of the country)</p> <p>In many ways, generalisability amounts to nothing more than making predictions based on a recurring experience. Having collected sufficient data to support a hypothesis, a premise regarding the behaviour of those data can be formulated, making it generalisable to similar circumstances</p> <p>There is a small but significant difference between applicability and generalisability – the more generalisable a finding (e.g. multinational RCT) the better regarded it is; however, the more generalisable a result the less applicable it is to specific populations (e.g. specific race)</p> <p>Transferability</p> <p>Transferability is the ability to apply something that has already been implemented in another context with regard to consequences resulting from certain differences, for example:</p> <ul style="list-style-type: none"> • transferring chosen (applicable) data, results/conclusions on the medical technology in question from an existing HTA report • the ability to transfer experience, results, conclusions from one research population to another (different but comparable) population <p>This term may refer to the possibility of 'transferring' data (economic, clinical results/published evidence), methods, principles and policies</p> <p>Transferability of economic data in HTA defines key variable economic data and defines guidelines for acceptance data from outside a country taking into consideration existing national guidelines. Transferability of cost (and cost-effectiveness) estimates between populations/countries remains problematic. When transferability of data is doubtful/limited because of their specificity, calculations and even conclusions may need to be reworked for the different setting</p> <p>Transferability can be considered in regard to developing organisations (such as AHTAPol), where it enables them to set their own principles, their own objectives (although based on the best practice/ experience of other agencies), their own priorities, to have control over institutional building and to evaluate progress in development from their own perspective rather than from that of an external agency</p> <p>Transferability can be understood as the process performed by readers of research (doers of HTA reports among them). This process is based on comparing the specifics of the research situation to the specifics of an environment or situation that is familiar to the reader. If there are enough similarities between the two situations, it is possible to infer that the results of the research would be the same or similar in the other situation</p> <p>Whereas generalisability is based on the extension of the use/application of conclusions, transferability is carried out based on the parallel transfer/application of these conclusions to other but comparable settings</p> <p>1. <i>Overview: generalisability and transferability</i>. Colorado State University website – http://writing.colostate.edu/guides/research/gentrans/index.cfm</p>
	<i>continued</i>

Term	Description
Guideline Guidance advice protocol	<p><i>IPHRS, Slovenia</i></p> <p>Generalisability is the degree to which the results of a study or systematic review can be extrapolated to other circumstances, in particular to routine health-care situations. Measurements can be used for different purposes. The same measurements will be used for the introduction of new programmes or new technologies, such as equipment, medical-technical devices and pharmaceuticals, the extension of the current programmes and treatments (as well as a reduction in waiting times) and the organisational and other changes in the health-care system. In controlled clinical trials some research or the introduction of new pharmaceuticals or technologies might look efficient; however, it may not be when applied to real life, with no control and different knowledge of the staff having to deal with other factors. If the study is transferable with no major problems, the degree of generalisability is high</p> <p>Transferability is the ability to use knowledge appropriately and fruitfully in a new or different context from that in which it was initially learned. For example, the new technological solution can be applied to other hospitals in the country or even into other countries</p>
	<p>Please note: In the UK, the term 'guidance' in the context of HTA refers to the reports produced by NICE. In France, the term 'advice' in the context of HTA refers to whether health insurers are required to reimburse the cost of a health technology</p> <p>See also Health technology appraisal</p> <p><i>INAHTA glossary</i></p> <p><i>Clinical practice guideline</i> 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 policy-making that is informed or supported by HTA</p> <p><i>FinOHTA, STAKES, Finland</i></p> <p>What is a guideline?</p> <p>The purpose of a guideline is to assist practitioners and patients in making decisions about health-care interventions in a specific situation (IOM 1990?)</p> <p>Different types of guidelines</p> <p>Guidelines are produced through different processes and their quality varies. Evidence-based guidelines are based on a systematic analysis of existing literature and appraisal of the evidence. Guidelines can also be based on a consensus of clinical experts, stakeholders, etc.</p> <p>The level of evidence for each existing guideline depends on the quality and amount of the existing studies and on the uniformity of this evidence</p> <p>Guidelines need to be updated at regular intervals. New research may either strengthen or weaken the evidence</p> <p>What is guidance?</p> <p>Guidance is information or counselling as to how or where a particular disease or situation can be handled. Guidance can be given orally, in written documents or through the media (television, internet, videos). In clinical practice the purpose of guidance is to help people make their own decisions based on their values. Within health care the purpose of guidance is to instruct the health-care providers in the optimal use of resources</p> <p>Guidance is a spectrum</p> <p>Guidance includes information on a range of topics. Guidance can, for example, give information to pregnant women on the content, meaning and consequences of participating in screening for fetal abnormalities. Guidance provides information on how to calculate your personal risk for a disease (e.g. heart diseases: blood pressure, age, cholesterol level, etc.). Guidance can also include recommendations on reducing your risk (e.g. how to stop smoking, reduce drinking, etc.)</p> <p>The legal status of guidance varies from country to country and may also be dependent on the context of the issue in question. It may provide legally binding boundaries for those patient groups that are to receive a specified treatment (e.g. reimbursement of a drug for only specified types of patients with the same disease). It may also give various options as to how a specified issue should be handled within a health-care system (e.g. alcohol abuse)</p>

Term	Description
	<p>Guidance is a process</p> <p>Guidance does not give straightforward answers to the patient but helps the person to understand the process or intervention. The person should be given as much guidance as she/he needs in order to make her/his own decision</p> <p>Guidance is changed with increasing knowledge, changes in existing resources, etc.</p> <p>What is advice?</p> <p>Advice is a statement or opinion as to how one should proceed. The purpose of advice is to influence</p> <p>Advice can be based on research evidence, professional experience, personal opinion/experiences or even societal norms</p> <p>As advice tries to influence, it includes clear recommendations as to what to do, where to go, what to decide, etc. The advisor has already made the value-laden weighing of different options</p> <p>What is protocol?</p> <p>Protocol is a set of directions or rules regarding a sequence of activities in a specified situation or setting. The directions are formulated in advance and are recorded in some way. The purpose of a protocol is to give a general structure for the activities and by doing so to help collaboration between persons, organisations and societies</p> <p>Different types of protocol</p> <p>As a protocol has been devised for a special operational environment, it varies from one context to another. A protocol can direct a clinical procedure. Other examples are research protocols (including those for HTA) and specified rules regarding data transmission</p> <p>Updating of protocol</p> <p>A protocol should be amended when it becomes necessary, e.g. to improve functioning of an organisation</p> <p><i>HTA agency, Poland</i></p> <p>Protocol</p> <p>In terms of HTA, a protocol is a detailed plan that, by providing a list of steps or procedures, guides the development of a full HTA report. A protocol usually contains an introduction, the objectives of the report, the methodology to be followed (e.g. inclusion criteria for clinical trials, methodology of data extraction and analysis), the role of each person involved in the process, a detailed search strategy and the time frame for all stages of the developing full HTA process. The objective of a protocol is to inform all stakeholders and other HTA agencies about the undertaken HTA report and avoid unnecessary doubling of the work. A protocol also enables a reviewer to verify whether the whole process has been carried out properly and, if yes, it enables others to update the search on the topic in question by using the search strategy determined in the protocol</p> <p>In accordance with the Order of the Director of the AHTAPol of 27 March 2007 on preparing recommendations regarding financing medical technologies from public sources, a protocol shall constitute a fixed step in the procedures for developing a full HTA report, implemented by the AHTAPol</p> <p>We have no good examples of a protocol developed by the AHTAPol yet, but we consider that the best example of a protocol would be any protocol regarding systematic reviews provided by the Cochrane Collaboration</p> <p>Guidelines</p> <p>There is no doubt that the purpose of a guideline is to assist practitioners and patients in making decisions about health-care interventions for managing a specific health condition. Guidelines are produced through different processes and their quality varies. Evidence-based guidelines are (usually published) documents based on a systematic review of existing literature and an appraisal of the evidence, which are updated regularly. The level of evidence for each existing guideline depends on the quality and amount of existing studies and on the uniformity of this evidence. Guidelines need to be updated at regular intervals as the results of new research may either strengthen or weaken the evidence on effectiveness or safety of the medical technology in question</p>

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Term	Description
	<p>In terms of HTA, the AHTAPol has developed the guidelines for conducting HTA that have recently been implemented into practice with the Order of the Director of the AHTAPol of 27 March 2007. The basic objective of these guidelines is to assure a high-quality standard of conducting HTA in Poland, namely a high reliability and credibility of assessments carried out in accordance with the guidelines. The second equally important objective is to assure the highest possible repeatability of results and to limit differences occurring in assessments of the same technology by different authors, as well as to increase the verifiability of the results of assessments made for the use of the agency</p> <p>The guidelines for conducting health technology assessments are aimed at:</p> <ul style="list-style-type: none"> • enabling the Consultative Council to formulate their recommendations according to transparent and open principles, based on reliable and credible assessments of medical technologies • enabling decision-makers, on the basis of presented recommendations, to establish to what extent they can rely on those recommendations, i.e. to what extent the recommendations are justified and credible <p>Guidance</p> <p>In Poland there are few clinical practice guidelines; the most common document that serves as assistance for practitioners in making decisions on the adequate management of specific conditions is guidance. The guidance is usually developed by a consensus of clinical experts, usually based on the reference guidelines developed in other countries, for which the quality of evidence for making recommendations has been approved and acknowledged</p> <p>Guidance refers to best practice used in a local setting (sometimes region, sometimes hospital). For instance, the practice used in treating one condition may differ slightly from one hospital to another, although both are accepted and in accordance with guidelines</p> <p>Example</p> <p>One hospital may treat a mild relapse of multiple sclerosis with regard to its severity and use 0.5 g of methylprednisolone administered intravenously for 5 consecutive days for mild relapse and 1.0 g of methylprednisolone administered intravenously for 3 consecutive days for medium and severe relapses, whereas another hospital may administer 1.0 g of methylprednisolone intravenously for 3 consecutive days with no regard to the severity of the relapse</p> <p>Advice</p> <p>In our hierarchy of sources of recommendations for medical technology, advice is placed at the very bottom, as often it is a recommendation made by an individual, who is guided by his/her subjective opinion and beliefs based on his/her own experience and not necessarily based on evidence-based medicine</p> <p><i>Institute of Molecular Medicine, Portugal</i></p> <p>Guidance is best translated as 'orientação' or 'guias'. The first term is closer to the English version. Nevertheless, it is very similar lexically to the term 'guidelines', which in Portuguese has been translated as 'normas de orientação' for some time now</p> <p>Guidelines has been translated as 'normas de orientação' and the term is well consolidated in our country</p> <p>Protocol has long been translated into 'protocolo' in our country</p> <p>Advice is best translated to 'aconselhamento', which literally means counselling in Portuguese and is much nearer the English version than 'conselhos'</p> <p><i>NCCHTA, UK</i></p> <p>Guidance in the UK context is the generic term for advice given to health services. It may have the force of law or it may be more optional; it may be produced by NICE or by other national bodies, or it may be produced locally</p>

Term	Description
	<p>NICE guidance aims to ensure that the promotion of good health and patient care in local health communities is in line with the best available evidence of effectiveness and cost-effectiveness. NICE produces guidance in three main areas:</p> <p>Guidelines</p> <p>Health technologies (there are two kinds of guidance here, technology appraisals and interventional procedures guidance)</p> <p>Public health (there are two kinds of guidance here, intervention guidance and programme guidance)</p> <p>NICE guidelines are recommendations on the appropriate treatment and care of people with specific diseases and conditions within the NHS. 'They are based on the best available evidence. While clinical guidelines help health professionals in their work, they do not replace their knowledge and skills. Good clinical guidelines aim to improve the quality of health care. They can change the process of health care and improve people's chances of getting as well as possible'</p> <p>Source: NICE website (www.nice.org.uk)</p> <p><i>PHGEN</i></p> <p>The interconnection of the given terms</p> <p>Guidance is the concept involved when an HTA reports guides the new user through a certain field. We feel that this term is rather far from the core of HTA as HTA reports should either empower the user to make his/her own decision or offer the user an option that the user can either adopt or modify. Guidance might refer to HTA reports as a science base but because of the other terms mentioned we assume that this is not meant here</p> <p>Guidelines are used as a very broad concept in Germany, which makes it difficult to apply it directly to HTA. Guidelines are widely used as a checklist, which puts a duty for justification on anybody who wants to withdraw from the guidelines. Guidelines in the sense that we use it are part of a normative, regulatory concept and we do not see how HTA is connected to this normative concept. Guidelines may follow from the results of an HTA report but an HTA report is not a guideline itself as the guideline must be approved by a relevant, democratically legitimised body</p> <p>The term 'protocol' is used very seldom in Germany with reference to HTA. In the computer sciences protocols are used to prove who has been working on which issue at what time. We do not see any connection between a protocol and adaptation except for the possibility of informing a foreign user who has reviewed or modified the HTA report at what time. Usually only the group of scientists, the institution and the dates when the literature review and the submission were performed are highlighted. We would not call this a protocol</p> <p>Advice is one layer of the HTA report as we understand the concept of HTA in Germany. Many HTA reports do not include straight advice but rather deduce certain advice from the science base as described in the report. Advice in its core sense would refer to appraisal as a final step of an HTA report. We would not use the term 'advice' directly with regard to the science base of a report, neither the medical nor the health economic evidence presented</p> <p>How to link the terms for the purpose of HTA</p> <p>From the German perspective we would not use these terms at all. As already mentioned the protocol is far from being HTA relevant. Guidelines are a normative concept and therefore do not fit into HTA reports. Guidance is somewhat too neutral and refers to an idea of HTA that is not shared in Germany. Advice seems to be limited to the appraisal and this is the part of the HTA report that should have the least impact on other health-care scientists and decision-makers, as advice only works in a situation in which the foreign state can adopt the HTA report. Because of the different health-care systems and the different spreadsheet models used we assume that adoption is rather unrealistic in most cases. Thus, we would not use these terms for the adaptation process as they might be misleading</p>
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Term	Description
	<p><i>TU Berlin, Germany</i></p> <p>These terms may be used as synonyms in many situations, especially by non-native English speakers. In some languages, the translations for guideline, guidance and protocol may refer to the concept of clinical practice guidelines and may thus be completely interchangeable. However, the terms may have slightly different meanings, especially concerning the degree of legal binding. In some countries a guideline has to be followed, otherwise some kind of sanction may be the consequence (i.e. no reimbursement of a procedure). Guidance can be interpreted as 'orientation', i.e. as something that can or should be followed, but without any sanctioning enforcement (i.e. it is not legally binding). Protocol can be understood as a road map on how to act in the face of a specific clinical situation (e.g. fever of unknown origin, weight loss). Protocols are often illustrated with a flow chart in which the different steps as well as the decision nodes are shown. In some countries/contexts protocols may refer to local (e.g. hospital or primary health-care centre) action plans that should be followed when a clinical problem presents</p> <p>Advice can be translated as recommendation or orientation. Thus, it can be considered to have no legal binding character. In contrast to guidance – which may refer more to providers or clinical decision-making – advice refers more to decision-making at the macro- or meso-level</p>
Health technology	<p><i>INAHTA glossary</i></p> <p>Any intervention that may be used to promote health, to prevent, diagnose or treat disease, or for rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures and organisational systems used in health care</p>
Health technology assessment	<p><i>INAHTA glossary</i></p> <p>See also Guidance</p>
Health technology appraisal	<p><i>Health technology assessment</i> 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 policy-making in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods</p>
	<p><i>Austrian Health Institute</i></p> <p>We agree with the definition from the European Parliament (1998): Health technology assessment is the comprehensive evaluation and assessment of existing and emerging medical technologies including pharmaceuticals, procedures, services, devices and equipment in regard to their medical, economic, social and ethical effects</p> <p>Source: www.europarl.europa.eu/workingpapers/saco/pdf/101_en.pdf</p>
	<p><i>DACEHTA, Denmark</i></p> <p>HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and scientific methods</p> <p>The content of HTA</p> <p>HTA is currently being carried out in a lot of different ways, partly because of political demands and traditions in different countries. In some places HTAs consist of systematic reviews and economic evaluations, whereas other organisations do more broad-spectrum assessments. However, the concept of HTA has traditionally been defined by multidisciplinary and inclusion of a wide number of issues, which can contribute to the assessment of prerequisites/conditions for and consequences of the use of technologies in health care</p>

Term	Description
	<p>HTA vs health technology appraisal</p> <p>HTA is a general term which is used in all organisations that are working with HTA, whereas health technology appraisal seems to be used mainly in the UK. The two terms relate to the fact that HTA, when it successfully meets its aim of informing policy, is taken into a political process with (possible) recommendations and policy advice. In some countries, the UK being the best example, the actual assessment and the policy advice is (organisationally) separated into assessment (the scientific evaluation) and appraisal (the policy advice or perhaps even the actual policy based on the assessment). In other countries the term HTA also includes the process of recommending and giving policy advice, even though the active involvement in this part of the policy process is limited in most HTA organisations</p> <p><i>Institute of Molecular Medicine, Portugal</i></p> <p>HTA can be translated as 'descrição de tecnologias da saúde' or 'avaliação de tecnologias da saúde'. The first stresses more the descriptive part of the assessment, without critical evaluation. The second takes into account some type of basic evaluation, which sometimes does not include judgement. The second is the closest to the English version</p> <p>HTA is more like 'There is a health technology that ...'</p> <p>Health technology appraisal is best translated as 'apreciação de tecnologias da saúde' or 'análise crítica de tecnologias da saúde'. Both imply some kind of judgement. The first is more polite, whereas the second is more rude and direct. The first is perhaps closest to the English version</p> <p>Health technology appraisal is more like 'There should be' or 'There should also be provided' or 'There is but shouldn't'</p> <p><i>NCCHTA, UK</i></p> <p>The aim of HTA is to ensure that high-quality information about the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, provide care in, make policy for and manage the NHS</p> <p>In the UK context, the distinction between assessment and appraisal is (put simply) the difference between information and guidance. HTA is the analytical process of gathering and summarising information and then presenting it. Health technology appraisal, by contrast, is the political process of producing guidance, taking into account the assessment information but also other factors (e.g. values, political factors, the availability of resources). The term 'appraisal' is also used to refer to a particular kind of guidance, specifically NICE guidance on technologies</p> <p><i>Servicio de Evaluacion y Planificacion, Canary Islands</i></p> <p>HTA is concerned with the evaluation of medical, organisational, economic and societal consequences of implementing health technologies or interventions within health systems. To do so, a high degree of multidisciplinary co-operation and scientific (methodological) competence is required</p> <p>Health technology appraisal is a more recent concept and still not well enough known and implemented in countries other than the UK. Health technology appraisal is a process that follows after some specific health technology assessment has been made. Its main concern is about guiding the use of the technology. Although the aim of health technology appraisal is attractive, the process (methods) to develop the appraisal as well as its expected outcomes are still in a very early stage of development. Moreover, to perform the appraisal, a different group profile is needed, with the presence of clinicians and patients</p> <p>Both terms are clearly additive</p>
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Term	Description
Policy	<p data-bbox="427 331 523 353"><i>EUnetHTA</i></p> <p data-bbox="427 376 1372 425"><i>Clinical question</i> In the field of evidence-based health care, the patient–intervention–comparison–outcome (PICO) formula is widely used to construct a clinical question:</p> <p data-bbox="427 443 845 470">P – patient, population of patients, problem</p> <p data-bbox="427 488 774 515">I – intervention (e.g. a therapy, test)</p> <p data-bbox="427 533 989 560">C – comparator or control (e.g. another therapy, placebo)</p> <p data-bbox="427 577 558 604">O – outcome</p> <p data-bbox="427 622 1404 694">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</p> <p data-bbox="427 712 1388 761">An HTA research question is the question that the HTA report seeks to answer in a scientific way. Typically, it will include a number of different PICO questions and other research questions</p> <p data-bbox="427 779 1380 884">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 donepezil be prescribable on the NHS?’)</p> <p data-bbox="427 902 1380 952">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</p> <p data-bbox="427 985 550 1012"><i>DSI, Denmark</i></p> <p data-bbox="427 1030 1404 1079">A policy is an overall plan embracing general goals or ideas. It will almost always include an objective and some method of action selected among alternatives to guide decisions</p> <p data-bbox="427 1097 1412 1176">A policy question is the object for the overall policy or related one of the alternatives. For example, a health policy could be the treatment of patients’ diabetes and a policy question related to that policy could be how often patients with type II diabetes should be screened for retinopathy</p> <p data-bbox="427 1193 1420 1299">Policy-makers are individuals who make decisions at the policy level that have a political impact. Often these individuals have reached office via the electoral process (or are appointed by those who did). From an HTA perspective, it could just as easily be leading doctors or hospital departments who are so respected among their peers that other professionals generally follow their policies or guidelines</p> <p data-bbox="427 1332 550 1359"><i>NCCHTA, UK</i></p> <p data-bbox="427 1377 1356 1404">A policy is a course or principle of action adopted or proposed by an organisation or individual</p> <p data-bbox="427 1422 1173 1449">A policy-maker is a person responsible for or involved in formulating policies</p> <p data-bbox="427 1467 734 1494">Source: <i>Oxford English Dictionary</i></p> <p data-bbox="427 1523 901 1550"><i>Servicio de Evaluacion y Planificacion, Canary Islands</i></p> <p data-bbox="427 1568 494 1594">Policy</p> <p data-bbox="427 1612 1364 1740">A policy is a predefined plan of action to guide decisions and actions. The term may apply to governments, private sector organisations, groups or individuals. The policy process includes the identification of different alternatives, programmes or priorities, and choosing among them on the basis of the evidence about the impact they will have. Policies can be understood as political, management, financial and administrative mechanisms arranged to reach explicit goals</p> <p data-bbox="427 1758 1404 1832">The goals of policy may vary widely according to the organisation and the context in which they are made. Policies are typically instituted in order to avoid some negative effect that has been noticed in the organisation or to seek some positive benefit</p>

Term	Description
	<p>The policy cycle is a tool used for the analysis of the development of a policy item. It includes the following stages:</p> <ol style="list-style-type: none"> 1. agenda setting 2. policy formation 3. decision-making 4. policy implementation 5. policy evaluation (continue or terminate) <p>Policy typology</p> <p>Policies may be classified in many different ways. The following is a sample of several different types of policies broken down by their effect on members of the organisation:</p> <ol style="list-style-type: none"> 1. Distributive policies extend goods and services to members of an organisation, as well as distributing the costs of the goods/services amongst the members of the organisation. Examples include government policies that impact on spending for welfare, public education, highways and public safety, or a professional organisation's policy on membership training 2. Regulatory policies, or mandates, limit the discretion of individuals and agencies, or otherwise compel certain types of behaviour. These policies are generally thought to be best applied in situations in which good behaviour can be easily defined and bad behaviour can be easily regulated and punished through fines or sanctions. An example of a fairly successful public regulatory policy is that of a speed limit <p>Policy-maker</p> <p>A person with power to influence or determine policies and practices at an international, national, regional or local level. Policy-makers have the responsibility and commitment for making the appropriate use of the best available evidence for policy-making and decision-taking</p> <p>The policy-maker is someone who sets the plan pursued by a government or organisation, a person whose actions and opinions strongly influence the course of events</p> <p>Frequently, in many situations and contexts, the term 'policy-maker' may be interchangeable with the term 'decision-maker'. In some other instances policy-making might be closer to health planner or policy developer activities</p> <p>Policy question</p> <p>This is a relevant question (gap) concerning policies and/or strategic issues or directions in a specific context (governments, organisations, etc.) that has to be addressed by a policy-maker (decision-maker) and affects the 'real' world by guiding the decisions that are made. These policy questions may be formally written or not. Most organisations identify their gaps (policy questions) and define policies to solve them</p> <p><i>NOKC, Norway</i></p> <p>The success of HTA is its impact on decision-making processes. Thus, the concept of HTA was developed to suit the demand for policy-making by applying the context-specific analysis for brokering science into policy</p> <p>Whether the HTA process meets the demand from policy-makers is an important question, and there is a tension between the need for rigorous and high-quality assessments on the one hand, and relevant and timely outputs to feed into decision-making processes on the other</p> <p>International collaboration might enable more HTA reports to be in time with policy-making processes</p>
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Term	Description
	<p><i>TU Berlin, Germany</i></p> <p>Policy</p> <p>In a restrictive way, policy may be understood as norms issued by governmental institutions and it seems to be equivalent to 'laws' (independently of these need to be approved in a parliament or directly issued by a Ministry – i.e. decree). It can also be used to refer to the rules that govern the functioning of the health system in general, including both the ones issued from governmental institutions and the ones issued by non-governmental institutions (i.e. self-governing institutions, sickness funds, professional associations, etc.). Common to both understandings of the term 'policy' is that it refers to the regulatory framework of the health system</p> <p>Another meaning of the term 'policy' that is frequently found is that it refers to any rules at any level of the health system, independently of whether they are legally binding or not. In this context, the area of application of a policy might be as small as a ward of a hospital or a single surgery. In these cases the term 'policy' is understood as a set of statements aiming to providing guidance on how to act in some situations. So, for example, one may find 'The policy of this hospital for avoiding deep vein thrombosis after major surgery is to ...' or 'From this point of view clinical practice guidelines are also considered a kind of "policy"'</p> <p>Compared with the former, the latter understanding of policy is much broader and implies many more types of policy and many more types of individuals involved (see Policy-makers)</p> <p>Policy-makers</p> <p>The general understanding is that this term refers to the persons involved in the process of formulating policies. Which persons are actually meant under the term will depend on the understanding of the term 'policy' (see Policy). As the latter shows some variation, so too will the term 'policy-maker' vary. Related to HTA, policy-makers can be understood as the ones who are supposed to make use of or take into account evidence from assessments (i.e. the persons for whom HTA reports are written). The term may be understood restrictively meaning persons operating only in a macro level (i.e. institutions with influence at the national level) or persons operating in governmental institutions. To some extent it might be confused with politicians (i.e. persons elected) or persons occupying political positions (ministers, etc.)</p> <p>Frequently the terms 'policy-maker' and 'decision-maker' are used as synonyms. In fact, policy-makers are also decision-makers, as the process of policy formulation implies making decisions (i.e. making choices among available options). However, not all decision-makers should be considered to be policy-makers too. As said before, decision-makers are the ones who make choices among available options to solve a problem, thus a patient or a clinician is considered a decision-maker. As their decisions affect only the individual situations and are not intended to guide the actions of a group or to establish a general rule, they cannot be considered policy-makers</p> <p>The following persons can be considered to be policy-makers in different countries: politicians (MPs, ministers, etc.), civil servants in national, regional or local authorities, managers (hospital managers, PHC [primary health care] managers, sickness fund managers, private health insurance managers), (clinical) staff involved in formulating CPGs [clinical practice guidelines] (including local use CPGs), persons operating in provider associations (e.g. medical associations, hospital associations) or in purchaser associations, persons operating in self-governing institutions (e.g. joint committees of provider and purchasers)</p> <p>Policy question</p> <p>The term 'policy question' seems to be mostly understood as the problem motivating the initiation of an HTA project. Some refer to the term as the questions that policy-makers have concerning a technology, assuming that policy-makers have formulated concise questions, which can be found in, for example, the commissioning document</p> <p>The term can also be understood more generally as the problem that policy-makers face and for which information from HTA is required/can be provided. Similarly it may mean the policy process in which the assessment is/should be embedded. In those cases no questions have actually been worded by policy-makers</p> <p>In some HTA reports, policy question refers to a section in which, besides the problem/policy process that has motivated the assessment, the circumstances surrounding the assessment are also described. These include the sources of funding of the report, who commissioned the assessment and to whom is it addressed</p>

Term	Description
Primary research	<p><i>INAHTA glossary</i></p> <ol style="list-style-type: none"> 1. 'Original research' in which data are first collected. The term 'primary research' is sometimes used to distinguish it from secondary research (reanalysis of previously collected data), meta-analysis and other ways of combining studies (such as economic analysis and decision analysis). However, because systematic reviews can provide answers not possible from individual studies they can also be considered to be primary research 2. An investigation that collects original (primary) data from patients, e.g. randomised controlled trials, observational studies, series of cases, etc. <p><i>NCCHTA, UK</i></p> <p>Original research conducted to collect new data to answer a question. HTA primary research aims to test the real-life impact of an intervention by comparing it with another intervention. This is most often, but not always, in the form of a randomised controlled trial</p>
Rapid review	<p><i>DACEHTA, Denmark</i></p> <p>Rapid review (or rapid HTA or rapid assessment) is a designation of HTAs that are carried out within a shorter time frame than 'regular' HTAs. However, it is not easy to give a clear definition as rapid has been used as a concept for HTAs carried out within the time frame of a few days and up to a year</p> <p>Mini-HTA</p> <p>This is a management and decision support tool for the hospital service based on the reasoning involved in HTA. A mini-HTA is a form or a checklist with a number of questions concerning the prerequisites and consequences of introducing new technology. The purpose is to provide part of the basis for decision-making related to a proposal to introduce a specific new technology or in connection with changes in the indication for the use of an existing technology. Both the preparation and the use of mini-HTAs may take place at a local or regional level and be adapted to local/regional objectives, decision criteria and time schedules</p> <p>Brief HTA</p> <p>Equivalent to rapid HTA</p> <p>Pre-assessment</p> <p>This is the preparation of a potential HTA project. The pre-assessment may include a preliminary literature search, a preliminary review of the literature and possibly a pre-assessment report if the assessment indicates that it is not possible (or desirable) to do an HTA</p> <p><i>FinOHTA, STAKES, Finland</i></p> <p>Rapid review is an HTA report produced through an accelerated process. The form and contents of the review may vary according to the needs of stakeholders and the availability of resources. A rapid review addresses only select aspects of a full HTA, and the methods used to gather and analyse the data may be limited. Rapid reviews may be limited in one or more ways:</p> <ul style="list-style-type: none"> • question framing: the scope of the assessment may be narrowed to a narrow aspect • identifying relevant literature: the search may be based only on databases of systematic reviews or HTA reports • quality assessment: may be omitted or may rely on previous quality assessments made by other parties • evidence summary: the assessment may be based on only a few or the best available systematic reviews/HTA reports • interpreting the findings: as all available information has not been systematically assessed, the findings should be regarded as preliminary or interpreted with caution <p>Different kinds of technology assessments that are not comprehensive exist. Mini-HTAs, brief HTAs or pre-assessments are examples of such assessments</p>

continued

Term	Description
	<p data-bbox="427 315 603 338"><i>HTA agency, Poland</i></p> <p data-bbox="427 360 603 383">Pre-assessment</p> <p data-bbox="427 405 1358 450">In AHTAPol, pre-assessment constitutes the initial stage in the procedure of developing an HTA report (recently implemented by the Order of the Director of the AHTAPol of 27 March 2007)</p> <p data-bbox="427 472 1358 539">Pre-assessment of a health technology is a summary of information that is relevant for making a recommendation regarding the terms of funding a specific technology from public sources, for example:</p> <ul data-bbox="427 562 1422 965" style="list-style-type: none"> <li data-bbox="427 562 1422 741">• The description of a technology and alternative technologies, also taking into consideration the availability and accessibility of those technologies for a specific disease, health condition or indication, the description of disease, health state or indication, to which the technology referred for analysis is to be applied, mainly taking into consideration the significance for the health of the society, basic health priorities, prevalence, incidence or morbidity and significance of the consequences of the disease (e.g. partial or total incapacity for work, inability to live unaided, reduced quality of life or even death) <li data-bbox="427 763 1422 965">• Scientific evidence (on clinical effectiveness and safety, the levels of cost-effectiveness or cost-utility for analysed technologies, the budget impact) obtained from secondary sources – systematic reviews, HTA reports, meta-analyses or clinical practice guidelines – either submitted by the applicant together with the request for the analysis of a specific health technology (in accordance with the Order of the Director of the AHTAPol of 27 March 2007) or found through a search of available databases for the purposes of the pre-assessment report. The material is verified and appraised by the AHTAPol with regard to its consistency with guidelines and the reliability of the material and evidence <p data-bbox="427 987 906 1010"><i>Costs of analysed technologies and their components</i></p> <p data-bbox="427 1032 1422 1077">Decisions made in other countries regarding terms of funding/financing of the technology referred for analysis from public sources (with special regard to countries of comparable national income level)</p> <p data-bbox="427 1099 1422 1368">A pre-assessment report is prepared by the AHTAPol and their is consultation with clinical experts before submitting it to the Consultative Council for discussion. It enables the Consultative Council to provide the Minister of Health with an informed recommendation for the terms of financing the analysed technology from public sources (either consider starting or ceasing financing referred technology or just changing the level of its financing). If the Consultative Council decides that there is not enough information to make a recommendation, the scope of the HTA report that is to be undertaken is considered (especially indications and technologies compared, perspective of the analysis, type of analysis: cost-effectiveness analysis, cost-utility analysis, BIA, clinical safety). It is then discussed together with the representatives of appropriate departments of the Ministry of Health and the National Health Fund and clinical experts</p> <p data-bbox="427 1391 571 1413">Rapid review</p> <p data-bbox="427 1435 1422 1771">Generally, the term rapid review concerns any type of analysis that is carried out under a time limitation (through an accelerated process) when urgent needs or the official procedure require a very quick response to a given problem. The aim of this analysis is to help authorities to make good decisions based on reasonable arguments which are consistent with social and economic needs. Similarly, a rapid review of a health technology (or rapid HTA report) is carried out within a shorter time frame than a 'regular' HTA report. It means that the process of producing this report is accelerated. There is no specific scheme for a rapid HTA report. It depends on the aim of the analysis, needs and previous analyses available. For example, when government is going to protect people against an epidemic of a fatal disease, and the problem is very urgent, an economic analysis does not matter. Sometimes, when the evidence on effectiveness and safety of a specific medical technology is established and commonly acknowledged (e.g. other HTA agencies have carried out a full review), authorities dealing with political urgency need only consider economic analysis or budget impact analysis to make a decision on the financing (and terms of such financing) of the technology</p> <p data-bbox="427 1794 539 1816">Mini-HTA</p> <p data-bbox="427 1839 1023 1861">Poland does not have any experience in producing mini-HTAs</p> <p data-bbox="427 1883 1422 2107">A mini-HTA has an analogous purpose, which is to serve as support in decision-making on the introduction of a new technology and, resulting from this introduction, the need for resource allocation. We would expect a mini-HTA to be a tool that is based on reasoning involved in HTAs. The main difference between a full HTA and a mini-HTA is the target group and the time frame for this type of analysis. A mini-HTA is carried out rather for the purposes of local-scale (not national-scale) decision-making processes. The tool for carrying out mini-HTAs should be adapted, so its form would allow this type of assessment to be made within a short time frame, and to easily adapt its outcome to a local or regional budget and planning process (e.g. resembling the form of EUnetHTA's HTA adaptation toolkit)</p>

Term	Description
	<p>Taking into consideration the centralised health-care system in Poland, in which all of the decisions on financing medical technologies are made at national level, we would rather expect that mini-HTAs should prove useful for health-care professionals at Polish hospitals, e.g. when considering investing in a new technology for one of its wards, to provide justification for its acquisition expenditures</p> <p>Similar to a full HTA, a mini-HTA would need a multidisciplinary team comprising personnel from different departments involved in providing the service (clinicians and nurses) under the leadership of the consultant in the specific specialty and economists</p> <p><i>Institute of Molecular Medicine, Portugal</i></p> <p>Rapid review</p> <p>This usually means a draft, more than a summary or abstract, of a main report. 'Quick view' might be a better term if the objective is to express the main issues of the report</p> <p>Mini-HTA</p> <p>This seems to be a small 'concentrated' resumé assessment. It does not imply a 'not so important' HTA</p> <p>Pre-assessment</p> <p>This really means a draft or a first approach to a subject. It may mean an already performed 'pilot study', but usually means a draft of something to be thoroughly performed later on</p> <p><i>Servicio de Evaluacion y Planificacion, Canary Islands</i></p> <p>Issue</p> <p>'Rapid reviews' is a term used to group a variety of health technology assessment procedures that have to be performed in a reduced time frame. If a usual systematic review takes 1 year or more for at least two full-time people, these kinds of rapid reviews are delivered in 6 months or less. The purpose of the rapid reviews is to give support to relatively urgent health policy decision-making</p> <p>Different types of rapid reviews</p> <p>The requirement of health technology assessors to inform all possible policy, managerial or even clinical decision-making has forced methodological simplifications to answer to the urgent need for information. Not all rapid reviews are designed and performed in the same way. So, depending on the degree of urgency and/or the human resources available, these rapid reviews have evolved towards mini-HTAs, brief HTAs or technology briefs, pre-assessment, etc.</p> <p>The wide range of rapid reviews</p> <p>As rapid reviews have been developed to support real-life decision-making, assessors have been trying to meet the needs of decision-makers (assuming that no informed decision-making could be worse than an informed decision supported by a rapid review). So the available time frame and, as previously said, the availability of technical staff affects the kind of assessment that is delivered. HTA agencies located in governmental organisations have different commitments to decision-makers that could force them to submit rapid reviews with the presence of methodological limitations: restriction of literature searches to just one database (usually MEDLINE) and/or abstract-based assessment, single person process, etc.</p> <p>In my opinion, although some kind of criteria have been set to define what a rapid review is, informing health policy decision-making about HTA sometimes requires a flexible interpretation of these criteria with the aim of ensuring some support for decision-makers</p> <p>Consensus development</p> <p>Academic and governmental HTA organisations have to revise the limits and risks of the flexible answers provided through a wide variety of rapid reviews, as well as the risk of losing the opportunities of informing decisions in this way</p>
	<i>continued</i>

Term	Description
Relevance	<i>EUnetHTA</i>
Reliability	<p data-bbox="427 376 826 398">See also Applicability and Generalisability</p> <p data-bbox="427 421 1417 521">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, it may be adopted or considered for adaptation for another setting. One way of assessing reliability in a standardised way is through the use of quality checklists, such as those that are included in the EUnetHTA toolkit</p> <p data-bbox="427 544 1417 678">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</p> <p data-bbox="427 701 1417 824">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</p> <p data-bbox="427 846 1114 869">A report might be very relevant even if it is not reliable, and vice versa</p> <p data-bbox="427 902 587 925"><i>INAHTA glossary</i></p> <p data-bbox="427 947 1417 1025"><i>Reliability</i> The extent to which an observation that is repeated in the same stable population yields the same result (i.e. test–retest reliability). Also, the ability of a single observation to distinguish consistently among individuals in a population</p> <p data-bbox="427 1059 619 1081"><i>DACEHTA, Denmark</i></p> <p data-bbox="427 1104 1417 1182">Relevance refers to the extent to which an HTA is applicable for decision-makers and addresses an essential policy question. The main issue is whether the topic of a report is usable and needed by HTA users</p> <p data-bbox="427 1193 1273 1216">Reliability refers to the degree to which results from an HTA report can be replicated</p> <p data-bbox="427 1249 571 1272"><i>IPHRS, Slovenia</i></p> <p data-bbox="427 1294 539 1317">Relevance</p> <p data-bbox="427 1339 1417 1440">Relevance is a term used to describe how pertinent, connected or applicable some information is to a given matter. Some diseases might need additional measurements. One has to see if the current measurements are sufficient or if there have to be some new measurements implemented for special diseases. There are various perspectives of relevance: objective, subjective and a mixed perspective</p> <p data-bbox="427 1462 539 1485">Reliability</p> <p data-bbox="427 1507 1417 1585">In general, reliability is the ability of a system to perform and maintain its functions in routine circumstances as well as in hostile or unexpected circumstances. In natural language it may also denote people who act efficiently at proper moments/circumstances</p> <p data-bbox="427 1597 1417 1789">In statistics, reliability is the consistency of a set of measurements or measuring instrument. Reliability does not imply validity. That is, a reliable measure is measuring something consistently, but not necessarily what it is supposed to be measuring. For example, although there are many reliable tests, not all of them would validly predict job performance. In experimental sciences, reliability is the extent to which the measurements of a test remain consistent over repeated tests of the same subject under identical conditions. An experiment is reliable if it yields consistent results of the same measure. It is unreliable if repeated measurements give different results</p>

Term	Description
	<p data-bbox="411 327 539 353"><i>NCCHTA, UK</i></p> <p data-bbox="411 371 528 398">Relevance</p> <p data-bbox="411 416 1401 546">In the context of the WP5 adaptation toolkit, relevance is about similarities between the HTA report for adaptation and the needs of the user, i.e. is the policy and/or research question posed sufficiently similar to warrant adaptation of this report? And do parts of this report address areas that the user wishes to address in their report, i.e. technology use and development, safety, effectiveness, cost-effectiveness and/or organisational aspects?</p> <p data-bbox="411 564 1393 640">Questions relating to the relevance of the entire HTA report are posed in the speedy sifting section of the toolkit. Relevance questions specifically relating to parts of the HTA report are posed within the relevant toolkit domains</p> <p data-bbox="411 658 528 685">Reliability</p> <p data-bbox="411 703 1385 833">In relation to the WP5 adaptation toolkit, reliability is an assessment of the extent to which the findings of the report can be relied on, i.e. critical appraisal. This is usually in the form of a checklist of questions. The types of questions asked are: What methods have been followed? Are they good enough? Are the results generally plausible? And are graphs, figures and models correct and easy to follow?</p> <p data-bbox="411 851 1345 904">Reliability questions, specific to certain parts (or domains) within the HTA report, can be found within the relevant domains of the toolkit</p> <p data-bbox="411 936 488 963"><i>PHGEN</i></p> <p data-bbox="411 981 866 1008">The interconnection between the terms</p> <p data-bbox="411 1025 1401 1285">The terms 'relevance' and 'reliability' both refer to the quality of an HTA report. Therefore, the terms are very important in the context of adaptation as foreign users would assess the quality of a report before they chose to adapt it. Still, there is a substantial difference between the concepts behind the two terms as they point in a different direction. The relevance of a report is conceived as relative or subjective, which means that the relevance is the relevance for the user and not a general overall relevance. The relevance therefore depends on the setting, the knowledge of the adapting person and the policy question. In contrast to that, reliability is an issue that users can assess in a standardised way, as a report is reliable if the science basis and the spreadsheet models are of high quality. Relevance and reliability must be seen in different matrices, as a report might be very relevant even if it is scientifically outdated and vice versa</p> <p data-bbox="411 1303 759 1330">How to link the terms in HTA?</p> <p data-bbox="411 1348 1409 1559">According to our experience and the way that HTA reports are used in Germany, it is very important that these terms are not mixed up. We have many reliable reports that are totally irrelevant and we have many unreliable reports that are still used and therefore relevant (sometimes as negative examples). The reliability depends on the scientific quality of the report whereas the relevance depends on the policy question and its relevance in a given setting. The relevance might be different from country to country, but we should strive for unified standards of reliability measures as the reliability is the key to adaptation. Reliability and not relevance is the key incentive to use a foreign HTA report</p>
	<i>continued</i>

Term	Description
Toolkit	<i>EUnetHTA</i>
Speedy sifting	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 assessment of a report's relevance, reliability and transferability
Domain	<p>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 clearinghouse</p> <p>It consists of six modules, one generic and five specific to certain parts (or domains) of HTA reports. The generic module (speedy sifting) enables the rapid assessment of the relevance of the report</p> <p>The five specific domains relate to technology use and development, safety, effectiveness, economic evaluation and organisational aspects. The reliability and transferability of information and data within these five domains can be assessed using these parts of the toolkit</p> <p>The toolkit output is adaptation material that can be incorporated into a new framework for an HTA report in a target setting</p>

Appendix 3

Search strategies for papers on adaptation

Search strategies for HTA knowledge transfer between countries (evaluation studies), searched 8 February 2006
Database: Ovid MEDLINE® 1996 to February Week 1 2006

1. ((health technolog\$adj3 assessment\$) or hta).mp. (588)
2. exp *Technology Assessment, Biomedical/ (1585)
3. 1 or 2 (1920)
4. Evaluation study.ti.ab. (541)
5. ((“benefit\$” or “utili#ation” or “impact” or “influenc\$” or “gain\$2”) adj4 health technolog\$.ti.ab. (27)
6. (implement\$or disseminat\$or transfer\$.ti.ab. (191465)
7. 3 and 6 (184)
8. evaluation studies.pt. (64985)
9. 7 and 8 (10)
10. (transfer\$adj5 (knowledge or policy or practice)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (763)
11. between countr\$.mp. (884)
12. 11 and 12 (2)
13. *”Health Policy”/(7284)
14. “International Cooperation”/(11994)
15. (12 or 16 or 11) and 3 (39)
16. *”Diffusion of Innovation”/(1692)
17. “Cooperative Behavior”/(7175)
18. 12 or 16 or 18 or 19 (21454)
19. (knowledge or policy or practice).ti.ab. (224331)
20. 6 and 25 (19942)
21. 26 and 24 (769)
22. 27 and 3 (8)
23. 12 or 16 or 19 (19826)
24. 30 and 14 (274)
25. 31 and 3 (1)
26. generaliza\$.ti.ab. (5263)
27. (share\$or sharing).ti.ab. (56007)
28. 37 or 38 (61134)
29. 39 and 25 (5825)
30. 40 and 3 (12)
31. (12 or 16) and 11 (13)
32. (12 or 16 or 19) and 11 (21)
33. 39 or 11 (61856)
34. 46 and (16 or 12) (325)
35. (model\$or questionnaire\$or survey\$or recommendation\$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (848325)
36. 48 and 47 (66)
37. 9 or 13 or 17 or 28 or 32 or 41 or 43 or 44 or 49 (download file)

Database: HMIC Health Management Information Consortium January 2006

1. health technolog\$.ti.ab. (312)
2. (health technology assessment\$or hta).ti.ab. (191)
3. exp *Technology Assessment, Biomedical/(0)
4. 1 or 2 or 3 (318)
5. between countr\$.mp. (7122)
6. “International Cooperation”/(188)
7. 5 or 6 (7260)
8. *”Health Policy”/(0)
9. generaliza\$.ti.ab. (43)
10. (share\$or sharing).ti.ab. (4141)
11. ((implement\$or disseminat\$or transfer\$) adj5 (knowledge or policy or practice)).mp. (2111)
12. 9 or 10 or 11 (6214)
13. (model\$or questionnaire\$or survey\$or recommendation\$.mp. [mp=title, other title, abstract, heading words] (39786)
14. 12 and 13 (1638)
15. 4 and 7 and 12 (9)

Appendix 4

Preliminary survey of previous experience of adaptation



eunetha

Dear WP5 members,

This questionnaire will provide us with an understanding of your experiences of adaptation and act as a pilot for our Delphi survey. Please ensure that your reply reflects the views of your organisation and spend no more than 15 minutes completing this questionnaire.

Please send your response by Wednesday 12 April

Identification:

HTA agency	<input type="text"/>	Country	<input type="text"/>
Name of respondent	<input type="text"/>	Email	<input type="text"/>

1. Please describe the work of your HTA agency for the benefit of people outside of your country (within 200 words)

2. How much priority does your agency give to each of these groups as a target audience?

Mark your choices (one or more)

		<i>Importance</i>			
		<i>High</i>	<i>Medium</i>	<i>Low</i>	<i>None</i>
	Clinical staff (doctors, nurses, etc.)				
	Policy-makers (national or regional)				
	Health-care providers (hospital and health-care managers)				
	Health-care funders/reimbursement agencies				
	Others (please specify the name of the group here)				

Please comment on your choices as you wish

3. Have you ever adapted an HTA report from another country?

	Yes		No
--	-----	--	----

Please give recent examples (within 200 words)

--

4. Do you know of any of your HTA reports that have been used in other countries?

	Yes		No
--	-----	--	----

Please specify which report(s) and by which other countries (within 200 words)

--

5. How useful is it for your HTA agency to make use of reports from other countries?

Very useful

Quite useful

Not so useful

Not at all useful

--	--	--	--

And why? (within 200 words)

--

6. The objective of WP5 is to facilitate adaptation of HTA reports from one country to another. With this in mind, please comment on which elements from the EUR-ASSESS framework (below) you think WP5 should focus on?

Make your choices (one or more)

a)	Definition of policy questions being addressed	
b)	Definition of the research questions being addressed	
c)	Current state of development and use of the health technology and alternative technologies	
d)	Technical characteristics of the device(s), such as accuracy and precision	
e)	Data on absolute and relative efficacy, safety and effectiveness	

f)	Economic evaluation (looking at both direct and indirect resource use)	
g)	Social and psychological implications	
h)	Impact on the organisation of health services generally and within settings	
i)	Ethical impact	
j)	Legal aspects and policy conclusions, options and recommendations (including implementation)	

And why? (within 200 words)

--

7. Please provide us with your comments on the ease or difficulty you had in understanding the questions above

--

Thank you for your contribution.

Please email this form as an attached file to Debbie Chase (dla1@soton.ac.uk) by Wednesday 12 April.

We will circulate a summary of all of the answers to the Group

Appendix 5

Delphi survey round 1 questionnaire

Section A: Information about you

Please complete:

HTA agency

Country

Name of respondent

Email

Section B: Description of the toolkit

What follows (*in italics*) are our ideas on what the toolkit will contain and achieve.

The critical appraisal toolkit

Overview

This toolkit will help HTA agencies adapt HTA reports from another country for their own use. It will serve two objectives: (1) to enable the critical appraisal of reports and (2) to provide advice to aid adaptation.

The toolkit will have two sections:

- *a screening tool that would enable ‘speedy sifting’ of other countries’ reports*
- *a more comprehensive critical appraisal tool with questions on relevance and reliability and links to useful resources.*

The screening tool

This first section of the toolkit will help users to determine whether the HTA report should be considered further for adaptation. The aim is that users could make a decision within 1–2 hours.

Questions that could be posed in this section of the toolkit would be:

- *What is the policy question being addressed?*
- *What is the research question being addressed?*
- *The language of the report (and ease of translation)?*
- *Has the report been peer-reviewed?*
- *When was the report published?*

Based on answers to the above questions, the users considering adaptation of a report would then make a judgement on whether to proceed to the main section of the toolkit.

Critical appraisal tool

This main section of the toolkit would help users assess the relevance and reliability of a report from another setting and decide how to use it. Using this tool would take less than 1 week.

The toolkit will contain questions under each of the HTA report headings considered to be ‘most important’. The proposed ‘most important’ headings (as determined by results from the WP5 preliminary survey) are shown in Box 1.

BOX 1 Proposed 'most important' headings

1. *The technology's use: current state of the health technology and alternative technologies*
 2. *The technology's background (e.g. phase I/II/III or accuracy/precision)*
 3. *Benefits and harms: absolute and relative efficacy, safety and effectiveness*
 4. *Economic evaluation: costs, cost-effectiveness and cost-utility*
 5. *Organisational impact: of health service generally and within settings*
-

For each of these five headings, the following information, questions and resources will be described (subheadings A–E), as shown in Box 2.

BOX 2 Subheadings for the five 'most important' headings

- A. *Statement about what this heading is*
 - B. *Is the starting point the same as in the report (what is current practice – is yours more or less the same)? If not, does it matter?*
 - C. *What methods have been followed? Are the methods good enough?*
 - D. *Results. Are these generally plausible? Are graphs and figures correct and easy to follow? What about conclusions and/or executive summary – any worries?*
 - E. *Suggestions for key websites to help with – understanding the heading, background information, checklists and examples where this has been done well.*
-

Users would work through the subheadings (A–E) for each of the five 'most important' headings. Thus, information and data under these 'most important' headings (from the HTA report being adapted) would be critically appraised and ready for application into other contexts.

Debbie Chase
Nick Hicks
Ruaridh Milne
NCCHTA, April 2006

1. The above was a description of what we (at the NCCHTA) think the toolkit will consist of and achieve. What are the pros and cons of this approach? What do you think? (please limit your answer to 300 words or less)

Section C: Toolkit details

2. Box 2 shows our proposed subheadings for each of the ‘most important’ headings. What do you think of these subheadings? What are the pros and cons? Are there any missing? (please limit your answer to 300 words or less)

3. We are thinking of asking WP5 members to work on specific ‘most important’ headings, both to develop the associated subheadings and to identify useful links and information. Please rank your preference for working on these headings below (1 = most desirable, 5 = least desirable)

	Current state of development and use of the health technology and alternative technologies	
	Technical characteristics of the device(s), such as accuracy and precision	
	Data on absolute and relative efficacy, safety and effectiveness	
	Economic evaluation (looking at both direct and indirect resource use)	
	Impact on the organisation of health services generally and within settings	

Section C: Ideas for the glossary

We are particularly interested to find out if you have encountered words or phrases in other countries' HTA reports that have caused difficulties in understanding.

4. If your agency has had experience of adapting HTA reports from other countries/settings, what words or phrases in other countries' reports cause difficulties? (please list as many terms as you can think of)

Feedback

5. Please provide us with your comments on the ease or difficulty you had in understanding the toolkit description and the questions above

Appendix 6

Delphi survey round 2 questionnaire

Dear WP5 members,

This document is the second round Delphi survey questionnaire. The purpose of this questionnaire is to get your views on the further developed toolkit – its purpose and content, what it will finally look like and where it fits in the stages of adaptation.

In the first round of the Delphi survey, members were provided with a description of the toolkit as developed by the lead partner (NCCHTA). The description provided in this questionnaire takes account of many of the ideas and suggestions made by WP5 members in response to this first round survey and at the face-to-face meeting in London on 5 and 6 June.

This questionnaire has three sections (A–C):

Section A: Information about you

Section B: Adaptation and the role of the toolkit

Section C: Toolkit details

Please answer the four questions shown under section B (question 1) and section C (questions 2–4). Please send one response per WP5 agency no later than 6PM CET Tuesday 18 July. We would greatly appreciate the views of all WP5 members. If this deadline will prove difficult for your agency because of vacation time please contact us. Thank you.

Section A: Information about you

Please complete:

HTA agency

Country

Name of
respondent

Email

Section B: Adaptation and the role of the toolkit

What is adaptation?

Issue

The issue here is how an HTA agency in one country (or region or setting) can 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 primary research and some are reports of secondary research, i.e. reviews of primary research. Some are produced very quickly, in a few days; some take a year or more to produce.

The focus in WP5 will be, initially at least, on adapting the information part of HTA reports that are reviews of primary research.

What is the spectrum that adaptation sits on?

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

1. *Summary*: translating the summary and using it for background information.
2. *Searches*: using these and other information in the report as background for your own report.
3. *Other*: application of methods or other approaches from the report to tackle a different research/policy question.
4. *Adaptation*: systematically extracting relevant HTA information from an existing report (from a whole report or from part of a report).
5. *Complete adoption*: making use of the report without making any changes at all
(except perhaps translation into your own language).

Adaptation

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 and (c) 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) deciding on the relevance of the question addressed in the original report to the question you are facing
- (b) identifying in the report the information that is most likely to be transferable to your setting
- (c) assessing the reliability of the information under various headings (benefits, harms, cost-effectiveness, organisational impact, social and legal issues, etc.)
- (d) considering the problems that 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 and where does it fit in the stages of adaptation?

The toolkit

This toolkit will help HTA agencies adapt HTA reports from another country for their own use. It will achieve this 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 a local context.

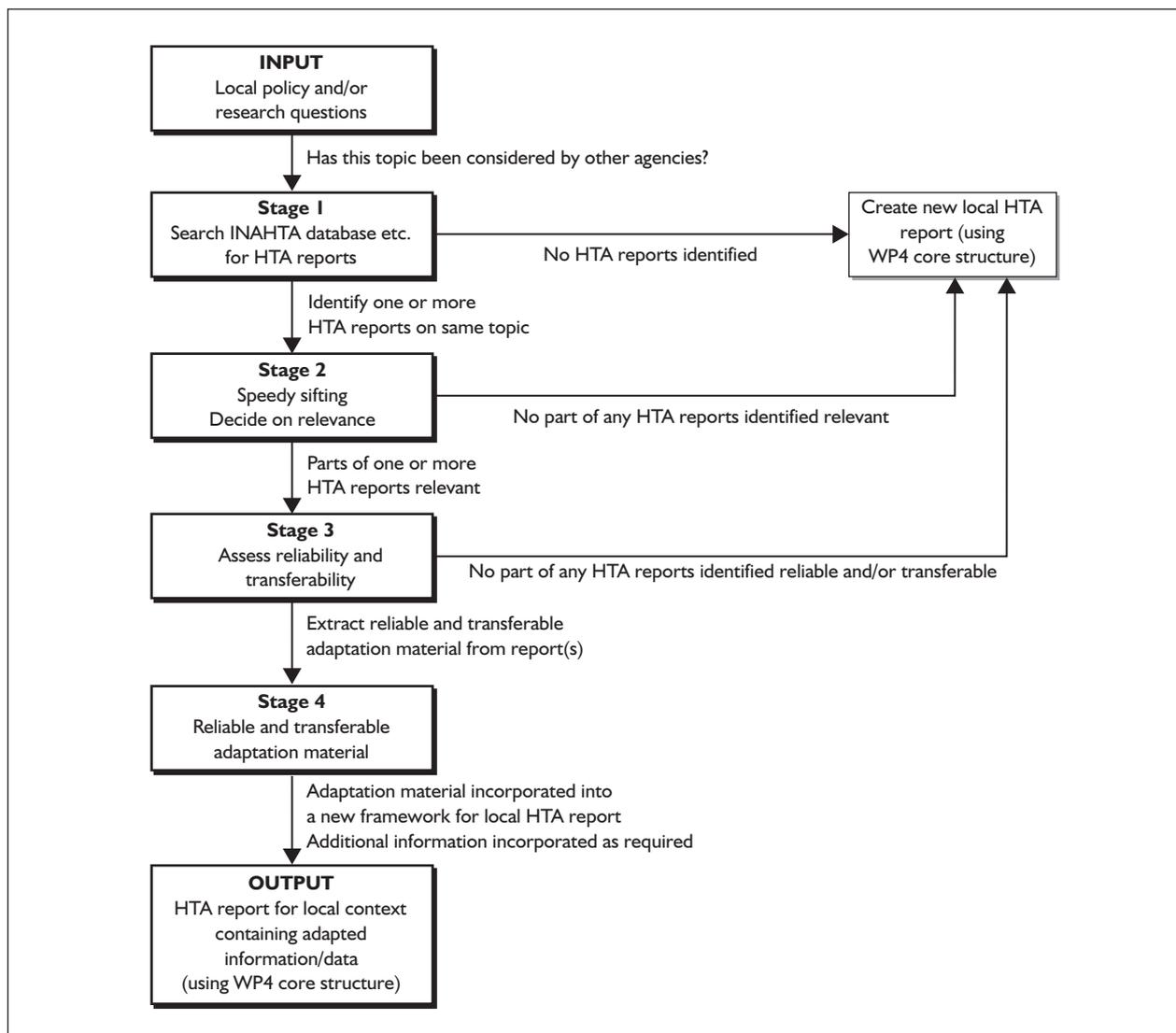
The toolkit will have two sections:

- a screening tool that would enable 'speedy sifting' of other countries' reports
- a more comprehensive tool with questions on reliability and issues regarding transferability.

Where does it fit in the stages of adaptation?

The flow diagram in *Figure 1* 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 1 Stages of adaptation, from input to output and role of the toolkit



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

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 relevance 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 are relevant, reliable and transferable to a local context. This toolkit output will be supplemented by further information and/or data by the user in order to develop an updated HTA report specific for a local context.

1. *The above was a description (taking account of WP5 members' views) of the stages of adaptation and at which stages the toolkit will help with adaptation. Do you agree with this description? What are your thoughts about the role of the toolkit in adapting HTA reports? (please limit your answer to 300 words or less)*

Section C: Toolkit details

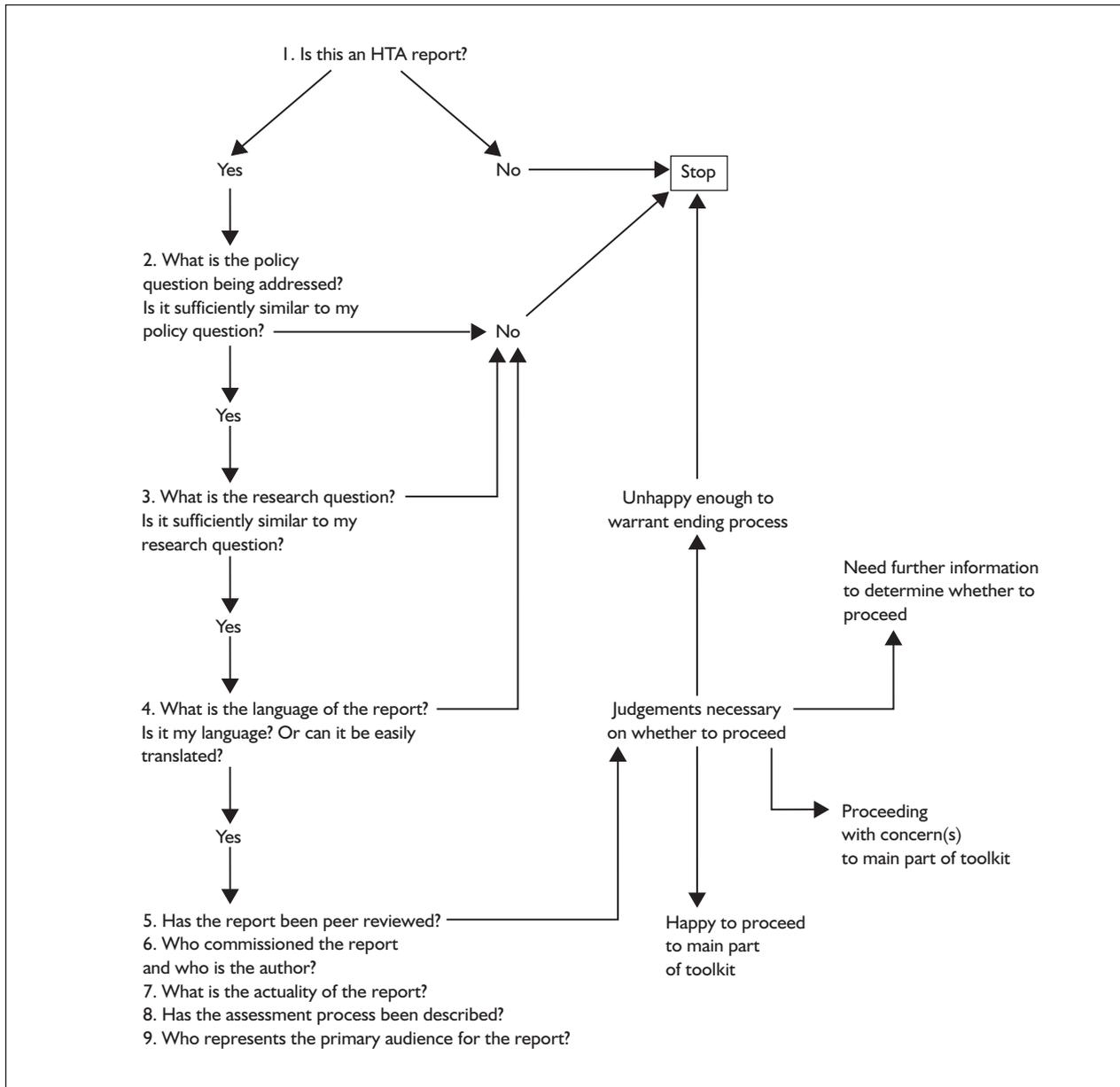
As described above, the toolkit will have two sections:

1. a screening tool that would enable 'speedy sifting' of other countries' reports
2. a more comprehensive tool with questions on reliability and issues regarding transferability.

(A) Speedy sifting

The 'speedy sifting' section of the toolkit will assess the relevance of the report for adaptation, i.e. is the policy and/or research question posed sufficiently similar to warrant adaptation of this report? The aim is that users could make a decision on each HTA report within 2 hours (this is an indication of time not a suggested time limit). *Figure 2* shows the questions that will be posed in this part of the toolkit and how the user uses the information as a result of their answers.

FIGURE 2 Pathway of questions and responses in the speedy sifting part of the toolkit



The first three 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 five questions (questions 5–9) require judgements to be made by the user. Collectively, as a result of responses to these questions, the user must decide whether to (1) end the adaptation process, (2) seek further information, to determine whether to proceed, or (3) 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.

WP5 members may recommend that this section of the toolkit includes specific questions for dealing with multiple HTA reports on the same topic and questions on how to assess the relevance of different types of HTA reports, e.g. mini-HTAs. We would welcome your views on the additional questions required to assess the relevance of multiple and/or different types of HTA report, e.g. if the conclusions of multiple HTA reports are different, would this affect which report/s are chosen for adaptation?

2. The above was a description of the speedy sifting section of the toolkit. Are there any questions regarding relevance that you think are missing from Figure 2? (please limit your answer to 300 words or less)

(B) Main part of toolkit

The main part of the toolkit will contain questions on reliability and issues regarding transferability of the HTA report. It is proposed that using this tool would take less than 5 days (this is an indication of time not a suggested time limit).

Initially, these questions will be posed under each of the HTA report headings considered to be 'most important'. [The toolkit will be tested through applicability testing (round 1) with these five headings. Further headings may be added, e.g. social, ethical and legal considerations as a result of applicability testing.] The proposed 'most important' headings (as determined by results from the WP5 preliminary survey and clarified at the WP5 face-to-face meeting) are shown in *Box 1*.

BOX 1 Proposed 'most important' headings

The technology's use: current state of the health technology and alternative technologies and the technology's background (e.g. phase I/II/III or accuracy/precision)

Benefits and harms: efficacy and safety

Effectiveness

Economic evaluation: costs, cost-effectiveness, cost-utility and cost-benefit analysis

Organisational impact: of health service generally and within settings

For each of these five headings, questions regarding reliability will be described as shown in *Box 2*.

BOX 2 Questions regarding reliability for each heading

What methods have been followed? Are the methods good enough? *Using an agreed European standard checklist for each heading (e.g. INAHTA checklist). Consider minimal requirements/criteria*

Results. Are these generally plausible? Are graphs and figures correct and easy to follow? *Again, using an agreed European standard checklist for each heading.*

WP5 members will be asked to identify checklists for assessing methods and results for each of the five headings and to recommend which of these checklists (or questions from a number of checklists) should be included in the main part of the toolkit.

Members will also be asked to consider issues regarding the transferability of information and data under each of the five headings. *Box 3* shows some of the questions and issues for consideration.

BOX 3 Issues regarding transferability

What are the transferability issues? What are the differences between the two settings? How has the context affected the decisions and recommendations? *Need a checklist of issues and problems to consider – e.g. think about event rate, cost, organisational*

As described above, the output of the toolkit is adapted material from an HTA report that can be incorporated into a report for a local context. Further work by the user, to identify local-based information and data, may be required before the local context HTA report is completed.

Other issues raised by members

Members identified the need for the toolkit to: (1) allow quick (less comprehensive) and slow (more comprehensive) adaptation, (2) support users at different levels, (3) suggest contacting other groups – economic models, etc., (4) have a standard data extraction sheet for input of data (studies, search strategies, economic models – for import into Clearinghouse database), and (5) consider the format of the final HTA report – in particular, that different users want different types of HTA report – e.g. mini-HTA reports.

3. The above was a description of the main section of the toolkit and some of the issues raised by WP5 members. What are your thoughts? Do you have any ideas of ways that we can incorporate 'other issues raised by members' into the toolkit? (please limit your answer to 300 words or less)

4. We want the toolkit to be practical, useable and user friendly! Imagine you have the toolkit in front of you, on your computer screen. How do you picture the toolkit looking and operating? e.g. a set of checklists and tick boxes, sections for inputting data, search strategies and/or text? (please limit your answer to 300 words or less)

**Thank you for your contribution.
Please email this form as an attached file to Debbie Chase
(dla1@soton.ac.uk) by 6PM CET Tuesday 18 July.**

Appendix 7

Instructions for commentary work on toolkit domains

General information

We need to develop a draft toolkit by December this year.

As discussed at the WP5 meeting in London, the task before you is the main work requirement for WP5 members for this year – developing the content of the toolkit.

The second round Delphi survey questionnaire (sent to WP5 members on 4 July) described the toolkit and its role within the adaptation process. We now have a framework for the toolkit and need to fill the gaps!

In the first round Delphi questionnaire we asked you to rank your preferences for working on developing content under specific headings/domains within the toolkit. (Members have expressed concern with the use of the word ‘headings’ to describe parts of HTA reports as described in the EUR-ASSESS paper. Therefore, what were ‘headings’ will be described as ‘domains’ from here onwards.) We have allocated commentaries on specific ‘domains’ with respect to preferences expressed in your responses, funding commitments to WP5 activities, glossary activities and information attendees provided at the WP5 London meeting. The Excel spreadsheet attached to the accompanying email shows the allocation of tasks to members. If you are unhappy with the selection made for your agency please contact us by Monday 17 July.

You should spend no more than a total of 3 days working on and producing this commentary. **The deadline for this work is Monday 1 September.**

Instructions for writing commentaries

You have been allocated the domain:

Organisational impact

With the EUR-ASSESS/ECHTA brief description of:

Health-care technology both affects and is affected by the organisational structure and other aspects of health services. The nature of the interaction of technology and organisation is strongly influenced by one or more of six factors. For each of these factors, one has to consider the health service as it exists before the introduction of a technology and changes that are needed by or resulting from its introduction: centralisation/decentralisation of information, technology/procedure, clinical decision power, economic decision power; differentiation on personal level (experts), organisational level; flexibility/vulnerability to internal effects and external effects; staff requirements: quantitatively and qualitatively; job satisfaction: physically and psychologically; and channels of communication: clinical data and administrative data

Your tasks are as follows

To identify questions to assess the reliability of information and data in the HTA report for adaptation

1. To identify quality assessment checklists/tools/guidance to assess the reliability of methods used and results described within a HTA report under your allocated domain.
2. To determine which, or which part(s), of these quality assessment checklists should be included in the toolkit, i.e. which are the most widely used and/or well validated of these checklist questions?
3. If there are not any checklists/tools/guidance for assessing reliability for this 'domain' or if you feel that further quality assessment questions are required, please suggest other evidence-based medicine tools or new questions that could be applied to this context.

To identify questions and issues to assess the transferability of information and data in the HTA report for adaptation

4. To identify checklists/tools/guidance to assess the transferability of methods and results described within a HTA report under your allocated domain.
5. To suggest some questions and/or issues for consideration when thinking about transferring information from one context to another.

Other information

6. Lastly, we also ask that you consider some of the more practical toolkit issues raised by WP5 members when producing your commentary (as described in the Delphi round 2 survey questionnaire):

'Members identified the need for the toolkit to (a) allow quick (less comprehensive) and slow (more comprehensive) adaptation, (b) support users at different levels, (c) suggest contacting other groups – economic models, etc., (d) have a standard data extraction sheet for input of data (studies, search strategies, economic models – for import into Clearinghouse database), and (e) consider the format of the final HTA report – in particular, that different users want different types of HTA report – e.g. mini-HTA reports.'

Appendix 1 is a proposed template for your commentary. Please write your commentary using the template structure. As noted above, please spend no more than 3 working days working on and producing your commentary. We recommend that your commentary is no more than 10 pages in length (including any appendices). However, if you wish to submit more information please feel free to do so. Please remember though that the objective of this exercise is to identify questions and issues for incorporation into a practical, usable toolkit.

You will notice from the accompanying Excel spreadsheet (allocation of work to partners) that we have allocated your topic domain to several other WP5 partners as well as to you. There is no need for you to contact these other partners to discuss your commentaries whilst you are working on them.

However, if you feel it would be of benefit please do so (contact information is available on the contact database or the members only site of www.eunetha.net or please contact me, dla1@soton.ac.uk).

All commentaries will be collated by the lead partner early in September. **Please ensure that your commentary is emailed to the NCCHTA by 1 September.** We will contact all organisations undertaking commentary work in mid- to late August to monitor progress and provide advice and support where needed. There may be the need for e-meetings in September after the commentaries have been received (to discuss any misunderstandings, need for further information and/or clarification); e-meetings will not be scheduled during July and August.

Good luck! We eagerly await your ideas, suggestions and issues. Please do not hesitate to contact us if you require further information and/or clarification of the task.

Kind regards,
Debbie Chase
Nick Hicks
Ruairidh Milne

June 2006



Health Technology Assessment reports published to date

Volume 1, 1997

No. 1

Home parenteral nutrition: a systematic review.

By Richards DM, Deeks JJ, Sheldon TA, Shaffer JL.

No. 2

Diagnosis, management and screening of early localised prostate cancer.

A review by Selley S, Donovan J, Faulkner A, Coast J, Gillatt D.

No. 3

The diagnosis, management, treatment and costs of prostate cancer in England and Wales.

A review by Chamberlain J, Melia J, Moss S, Brown J.

No. 4

Screening for fragile X syndrome.

A review by Murray J, Cuckle H, Taylor G, Hewison J.

No. 5

A review of near patient testing in primary care.

By Hobbs FDR, Delaney BC, Fitzmaurice DA, Wilson S, Hyde CJ, Thorpe GH, *et al.*

No. 6

Systematic review of outpatient services for chronic pain control.

By McQuay HJ, Moore RA, Eccleston C, Morley S, de C Williams AC.

No. 7

Neonatal screening for inborn errors of metabolism: cost, yield and outcome.

A review by Pollitt RJ, Green A, McCabe CJ, Booth A, Cooper NJ, Leonard JV, *et al.*

No. 8

Preschool vision screening.

A review by Snowdon SK, Stewart-Brown SL.

No. 9

Implications of socio-cultural contexts for the ethics of clinical trials.

A review by Ashcroft RE, Chadwick DW, Clark SRL, Edwards RHT, Frith L, Hutton JL.

No. 10

A critical review of the role of neonatal hearing screening in the detection of congenital hearing impairment.

By Davis A, Bamford J, Wilson I, Ramkalawan T, Forshaw M, Wright S.

No. 11

Newborn screening for inborn errors of metabolism: a systematic review.

By Seymour CA, Thomason MJ, Chalmers RA, Addison GM, Bain MD, Cockburn F, *et al.*

No. 12

Routine preoperative testing: a systematic review of the evidence.

By Munro J, Booth A, Nicholl J.

No. 13

Systematic review of the effectiveness of laxatives in the elderly.

By Petticrew M, Watt I, Sheldon T.

No. 14

When and how to assess fast-changing technologies: a comparative study of medical applications of four generic technologies.

A review by Mowatt G, Bower DJ, Brebner JA, Cairns JA, Grant AM, McKee L.

Volume 2, 1998

No. 1

Antenatal screening for Down's syndrome.

A review by Wald NJ, Kennard A, Hackshaw A, McGuire A.

No. 2

Screening for ovarian cancer: a systematic review.

By Bell R, Petticrew M, Luengo S, Sheldon TA.

No. 3

Consensus development methods, and their use in clinical guideline development.

A review by Murphy MK, Black NA, Lamping DL, McKee CM, Sanderson CFB, Askham J, *et al.*

No. 4

A cost-utility analysis of interferon beta for multiple sclerosis.

By Parkin D, McNamee P, Jacoby A, Miller P, Thomas S, Bates D.

No. 5

Effectiveness and efficiency of methods of dialysis therapy for end-stage renal disease: systematic reviews.

By MacLeod A, Grant A, Donaldson C, Khan I, Campbell M, Daly C, *et al.*

No. 6

Effectiveness of hip prostheses in primary total hip replacement: a critical review of evidence and an economic model.

By Faulkner A, Kennedy LG, Baxter K, Donovan J, Wilkinson M, Bevan G.

No. 7

Antimicrobial prophylaxis in colorectal surgery: a systematic review of randomised controlled trials.

By Song F, Glenny AM.

No. 8

Bone marrow and peripheral blood stem cell transplantation for malignancy.

A review by Johnson PWM, Simnett SJ, Sweetenham JW, Morgan GJ, Stewart LA.

No. 9

Screening for speech and language delay: a systematic review of the literature.

By Law J, Boyle J, Harris F, Harkness A, Nye C.

No. 10

Resource allocation for chronic stable angina: a systematic review of effectiveness, costs and cost-effectiveness of alternative interventions.

By Sculpher MJ, Petticrew M, Kelland JL, Elliott RA, Holdright DR, Buxton MJ.

No. 11

Detection, adherence and control of hypertension for the prevention of stroke: a systematic review.

By Ebrahim S.

No. 12

Postoperative analgesia and vomiting, with special reference to day-case surgery: a systematic review.

By McQuay HJ, Moore RA.

No. 13

Choosing between randomised and nonrandomised studies: a systematic review.

By Britton A, McKee M, Black N, McPherson K, Sanderson C, Bain C.

No. 14

Evaluating patient-based outcome measures for use in clinical trials.

A review by Fitzpatrick R, Davey C, Buxton MJ, Jones DR.

No. 15

Ethical issues in the design and conduct of randomised controlled trials.

A review by Edwards SJL, Lilford RJ, Braunholtz DA, Jackson JC, Hewison J, Thornton J.

No. 16

Qualitative research methods in health technology assessment: a review of the literature.

By Murphy E, Dingwall R, Greatbatch D, Parker S, Watson P.

No. 17

The costs and benefits of paramedic skills in pre-hospital trauma care.

By Nicholl J, Hughes S, Dixon S, Turner J, Yates D.

No. 18

Systematic review of endoscopic ultrasound in gastro-oesophageal cancer.

By Harris KM, Kelly S, Berry E, Hutton J, Roderick P, Cullingworth J, *et al.*

No. 19

Systematic reviews of trials and other studies.

By Sutton AJ, Abrams KR, Jones DR, Sheldon TA, Song F.

No. 20

Primary total hip replacement surgery: a systematic review of outcomes and modelling of cost-effectiveness associated with different prostheses.

A review by Fitzpatrick R, Shortall E, Sculpher M, Murray D, Morris R, Lodge M, *et al.*

Volume 3, 1999

No. 1

Informed decision making: an annotated bibliography and systematic review.

By Bekker H, Thornton JG, Airey CM, Connelly JB, Hewison J, Robinson MB, *et al.*

No. 2

Handling uncertainty when performing economic evaluation of healthcare interventions.

A review by Briggs AH, Gray AM.

No. 3

The role of expectancies in the placebo effect and their use in the delivery of health care: a systematic review.

By Crow R, Gage H, Hampson S, Hart J, Kimber A, Thomas H.

No. 4

A randomised controlled trial of different approaches to universal antenatal HIV testing: uptake and acceptability. Annex: Antenatal HIV testing – assessment of a routine voluntary approach.

By Simpson WM, Johnstone FD, Boyd FM, Goldberg DJ, Hart GJ, Gormley SM, *et al.*

No. 5

Methods for evaluating area-wide and organisation-based interventions in health and health care: a systematic review.

By Ukoumunne OC, Gulliford MC, Chinn S, Sterne JAC, Burney PGJ.

No. 6

Assessing the costs of healthcare technologies in clinical trials.

A review by Johnston K, Buxton MJ, Jones DR, Fitzpatrick R.

No. 7

Cooperatives and their primary care emergency centres: organisation and impact.

By Hallam L, Henthorne K.

No. 8

Screening for cystic fibrosis.

A review by Murray J, Cuckle H, Taylor G, Littlewood J, Hewison J.

No. 9

A review of the use of health status measures in economic evaluation.

By Brazier J, Deverill M, Green C, Harper R, Booth A.

No. 10

Methods for the analysis of quality-of-life and survival data in health technology assessment.

A review by Billingham LJ, Abrams KR, Jones DR.

No. 11

Antenatal and neonatal haemoglobinopathy screening in the UK: review and economic analysis.

By Zeuner D, Ades AE, Karnon J, Brown J, Dezateux C, Anionwu EN.

No. 12

Assessing the quality of reports of randomised trials: implications for the conduct of meta-analyses.

A review by Moher D, Cook DJ, Jadad AR, Tugwell P, Moher M, Jones A, *et al.*

No. 13

'Early warning systems' for identifying new healthcare technologies.

By Robert G, Stevens A, Gabbay J.

No. 14

A systematic review of the role of human papillomavirus testing within a cervical screening programme.

By Cuzick J, Sasieni P, Davies P, Adams J, Normand C, Frater A, *et al.*

No. 15

Near patient testing in diabetes clinics: appraising the costs and outcomes.

By Grieve R, Beech R, Vincent J, Mazurkiewicz J.

No. 16

Positron emission tomography: establishing priorities for health technology assessment.

A review by Robert G, Milne R.

No. 17 (Pt 1)

The debridement of chronic wounds: a systematic review.

By Bradley M, Cullum N, Sheldon T.

No. 17 (Pt 2)

Systematic reviews of wound care management: (2) Dressings and topical agents used in the healing of chronic wounds.

By Bradley M, Cullum N, Nelson EA, Petticrew M, Sheldon T, Torgerson D.

No. 18

A systematic literature review of spiral and electron beam computed tomography: with particular reference to clinical applications in hepatic lesions, pulmonary embolus and coronary artery disease.

By Berry E, Kelly S, Hutton J, Harris KM, Roderick P, Boyce JC, *et al.*

No. 19

What role for statins? A review and economic model.

By Ebrahim S, Davey Smith G, McCabe C, Payne N, Pickin M, Sheldon TA, *et al.*

No. 20

Factors that limit the quality, number and progress of randomised controlled trials.

A review by Prescott RJ, Counsell CE, Gillespie WJ, Grant AM, Russell IT, Kiauka S, *et al.*

No. 21

Antimicrobial prophylaxis in total hip replacement: a systematic review.

By Glenny AM, Song F.

No. 22

Health promoting schools and health promotion in schools: two systematic reviews.

By Lister-Sharp D, Chapman S, Stewart-Brown S, Sowden A.

No. 23

Economic evaluation of a primary care-based education programme for patients with osteoarthritis of the knee.

A review by Lord J, Victor C, Littlejohns P, Ross FM, Axford JS.

Volume 4, 2000**No. 1**

The estimation of marginal time preference in a UK-wide sample (TEMPUS) project.

A review by Cairns JA, van der Pol MM.

No. 2

Geriatric rehabilitation following fractures in older people: a systematic review.

By Cameron I, Crotty M, Currie C, Finnegan T, Gillespie L, Gillespie W, *et al.*

No. 3

Screening for sickle cell disease and thalassaemia: a systematic review with supplementary research.

By Davies SC, Cronin E, Gill M, Greengross P, Hickman M, Normand C.

No. 4

Community provision of hearing aids and related audiology services.

A review by Reeves DJ, Alborz A, Hickson FS, Bamford JM.

No. 5

False-negative results in screening programmes: systematic review of impact and implications.

By Petticrew MP, Sowden AJ, Lister-Sharp D, Wright K.

No. 6

Costs and benefits of community postnatal support workers: a randomised controlled trial.

By Morrell CJ, Spiby H, Stewart P, Walters S, Morgan A.

No. 7

Implantable contraceptives (subdermal implants and hormonally impregnated intrauterine systems) versus other forms of reversible contraceptives: two systematic reviews to assess relative effectiveness, acceptability, tolerability and cost-effectiveness.

By French RS, Cowan FM, Mansour DJA, Morris S, Procter T, Hughes D, *et al.*

No. 8

An introduction to statistical methods for health technology assessment.

A review by White SJ, Ashby D, Brown PJ.

No. 9

Disease-modifying drugs for multiple sclerosis: a rapid and systematic review.

By Clegg A, Bryant J, Milne R.

No. 10

Publication and related biases.

A review by Song F, Eastwood AJ, Gilbody S, Duley L, Sutton AJ.

No. 11

Cost and outcome implications of the organisation of vascular services.

By Michaels J, Brazier J, Palfreyman S, Shackley P, Slack R.

No. 12

Monitoring blood glucose control in diabetes mellitus: a systematic review.

By Coster S, Gulliford MC, Seed PT, Powrie JK, Swaminathan R.

No. 13

The effectiveness of domiciliary health visiting: a systematic review of international studies and a selective review of the British literature.

By Elkan R, Kendrick D, Hewitt M, Robinson JJA, Tolley K, Blair M, *et al.*

No. 14

The determinants of screening uptake and interventions for increasing uptake: a systematic review.

By Jepson R, Clegg A, Forbes C, Lewis R, Sowden A, Kleijnen J.

No. 15

The effectiveness and cost-effectiveness of prophylactic removal of wisdom teeth.

A rapid review by Song F, O'Meara S, Wilson P, Golder S, Kleijnen J.

No. 16

Ultrasound screening in pregnancy: a systematic review of the clinical effectiveness, cost-effectiveness and women's views.

By Bricker L, Garcia J, Henderson J, Mugford M, Neilson J, Roberts T, *et al.*

No. 17

A rapid and systematic review of the effectiveness and cost-effectiveness of the taxanes used in the treatment of advanced breast and ovarian cancer.

By Lister-Sharp D, McDonagh MS, Khan KS, Kleijnen J.

No. 18

Liquid-based cytology in cervical screening: a rapid and systematic review.

By Payne N, Chilcott J, McGoogan E.

No. 19

Randomised controlled trial of non-directive counselling, cognitive-behaviour therapy and usual general practitioner care in the management of depression as well as mixed anxiety and depression in primary care.

By King M, Sibbald B, Ward E, Bower P, Lloyd M, Gabbay M, *et al.*

No. 20

Routine referral for radiography of patients presenting with low back pain: is patients' outcome influenced by GPs' referral for plain radiography?

By Kerry S, Hilton S, Patel S, Dundas D, Rink E, Lord J.

No. 21

Systematic reviews of wound care management: (3) antimicrobial agents for chronic wounds; (4) diabetic foot ulceration.

By O'Meara S, Cullum N, Majid M, Sheldon T.

No. 22

Using routine data to complement and enhance the results of randomised controlled trials.

By Lewsey JD, Leyland AH, Murray GD, Boddy FA.

No. 23

Coronary artery stents in the treatment of ischaemic heart disease: a rapid and systematic review.

By Meads C, Cummins C, Jolly K, Stevens A, Burls A, Hyde C.

No. 24

Outcome measures for adult critical care: a systematic review.

By Hayes JA, Black NA, Jenkinson C, Young JD, Rowan KM, Daly K, *et al.*

No. 25

A systematic review to evaluate the effectiveness of interventions to promote the initiation of breastfeeding.

By Fairbank L, O'Meara S, Renfrew MJ, Woolridge M, Sowden AJ, Lister-Sharp D.

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