INAHTA

A checklist for health technology assessment reports

Introduction

Objective

This checklist has been prepared as an aid to furthering a consistent and transparent approach to health technology assessment. A general theme is the clear identification in an HTA report of what has been done in an assessment and of any significant limitations in the analysis. A key to improving the usefulness and generalisability of HTA reports is to aim for transparency in the assessment process. Assessments will vary considerably in their depth and scope of analysis, given differences in the types of problem being addressed, policy requirements and the time and resources available for assessment. However, readers of an HTA report need to be able to easily obtain information on the purpose of the assessment, the methods used, assumptions made and conclusions reached.

Intended audience

The checklist is intended as a guide both for those who use HTA reports as a source of information and for those who prepare such documents.

For those reading reports prepared by other organisations, the checklist gives guidance on what to look for in an HTA report and in assessing the reliability of the information provided.

For those undertaking HTA, the checklist gives points that should be considered during the planning, conducting and reporting of the assessment. It is hoped that this guidance will help to improve the quality of HTA reports.

Context of material in the checklist

The checklist contains only brief details of a number of important points relating to HTA reports and is intended for initial guidance. The checklist should be seen as complementary to the authoritative guidelines for assessment of health technologies that have been prepared by a number of agencies.

It is stressed that an HTA report may be a valid and useful source of information even if it does not include a number of elements from the checklist. It is not essential for an HTA report to include all the attributes given in the checklist.

The checklist will help those reading and preparing HTA reports in consideration of which elements have been included and which omitted. The significance of any omissions in an HTA report will depend on how it is to be used by the reader. Those needing further assurance of the nature and quality of an assessment may well have to contact those who prepared the HTA report.

Contents of the checklist

The checklist includes 14 questions to be considered by those reviewing or preparing an HTA report.

One additional question is concerned with the context of the technology assessment and relates to issues that may not be addressed in some reports ie medico-legal implications, economic impact, ethical and social implications and the wider community perspective.

The core 14 questions deal with matters that should be considered for all HTA reports. Some of

these questions cover provision of basic information; others refer to the steps taken in performing the assessment. Those dealing with selection and appraisal of information are followed by additional points for consideration, whose application will vary, depending on the scope of the report under review.

Under most of the questions, some further points and suggestions have been added in italics.

At the end of the checklist is a summary sheet that may be helpful for recording conclusions regarding the content of an HTA report.

The checklist

Preliminary information

1. Are there appropriate contact details for provision of further information?

Include a contact person or position with appropriate addresses.

2. Are those who prepared the HTA report identified as authors or in other ways?

Approaches and conventions will vary, but it will be desirable to have a clear indication of persons who were involved in preparing the report and of their roles. These persons may include authors, committee members (if that has been the approach used) and persons providing technical or administrative support.

It may be helpful to include a statement to the effect that the assessment has drawn on available published material and expert comment and is intended to be current at the date of publication.

3. Is there a statement regarding conflict of interest?

Conflict of interest is of concern here because of the perception that it could lead to unreasonable bias in an HTA report. A statement on conflict of interest would refer to those who prepared the report. There may be a need only to indicate there is no conflict of interest. It will be appropriate for reports to indicate whether funding for the assessment has been provided by sources other than those responsible for the author agency's usual budget.

It should be noted that conflict of interest may arise in relation to non-financial matters.

4. Is there a statement on whether the report has been externally reviewed?

External review of a report is generally regarded as a measure that improves its quality and credibility. Details provided regarding the review process will vary, but it is helpful to include names and affiliations of persons who have provided comment or information during preparation of the report.

5. Is there a short summary that can be understood by the non-technical reader?

This is a highly desirable feature of an HTA report. Many of the policy makers and other non-technical recipients of the report will only read the summary. This is a major aid to getting the message of the assessment across to a wider audience. The summary might cover the purpose and scope of the assessment, refer to the approach taken, give leading results and include clear conclusions. It should preferably not exceed two pages — longer summaries tend not to be read.

It is highly desirable for non-English language HTA reports to include an English version of the summary.

Inclusion of a structured abstract can be a helpful approach to concise presentation of essential details.

Why the assessment has been undertaken

6. Is reference made to the policy question that is addressed?

It is important to describe the rationale for undertaking an HTA report in order to explicitly identify factors that may have influenced the report such as health system policies and priorities, social and political influences.

Reports should specify why an assessment has been undertaken and, where appropriate, who has requested this work.

7. Is reference made to the research question(s) that is/are addressed?

It is important to clearly define the research question(s). How is this health technology to be

assessed? A well-constructed research question should contain elements of the criteria for including studies, specifically the population for whom the technology is intended, the technology or intervention of interest, the comparator (or related health services and technologies) against which the technology will be evaluated, and the outcomes that will be used to assess the technology. For example, "Is MRI screening of women at high risk of breast cancer more effective at reducing breast cancer mortality than film-screen mammography?"

8. Is the scope of the assessment specified?

The report should indicate which attributes of the technology are addressed and preferably also clearly indicate areas that are not included in the assessment.

9. Is there a description of the health technology that has been assessed?

A short description of the technology will be helpful for the general reader. Details of what the technology does and how it works will be useful but should be concise - a text book approach is not needed. Brief reference to alternative or competing technologies may also be helpful.

How the assessment has been undertaken

10. What sources of information have been used?

- Details of the literature search should be provided. These should include key search terms and combination of search terms, databases used, years covered, and any language restrictions.
- Details of the use of primary data and other sources of information should also be given.
- Details of the source and basis of any cost data should be given, preferably with comment on their accuracy.
- Inclusion and exclusion criteria should be provided. The report should indicate who has undertaken the selection and how this processing was done.
- A complete reference list of included studies/bibliography should be included.
- A list of studies that met the inclusion criteria but were eventually excluded, and reason for exclusion, should be provided.

Some reports will include more extensive details of the literature search. It is suggested that full details of the literature search should be available on request, but not necessarily included in the report. Quality and relevance of cost data will vary with their source and nature, which may range from administrative data collected for other purposes to a bottom up approach specifically directed towards the assessment being undertaken. If arbitrary values have been assigned to costs, appropriate justification should be provided.

Material may be selected for inclusion in the report to address the following:

- *Technical issues*
  (If these are addressed, include the source of material, and the basis for selection.)

- *Safety (For example, regulatory decisions; information on adverse effects. The basis for selection of material should be indicated.)*

- *Efficacy/effectiveness (Details of the basis for selection should be given — for example, consideration of study design, numbers of subjects. Is it made clear why the selected papers have been chosen and not others?)*

Some attributes (for example, safety of the technology) may not be covered in some reports.

Usually, only references selected for inclusion in the analysis or commentary will be cited in the report. However, details of rejected references should be available on request. Use of an internationally recommended diagram (such as eg. CONSORT) to summarise what has been included and excluded in the literature selection process would be a helpful feature.

11. Is there information on the basis for the assessment and interpretation of selected data and information?

- Has the method of data extraction been described? *Accuracy and consistency in data extraction are extremely important. Errors can be minimised by designing data extraction forms with clear instructions and using at least two reviewers to perform data extraction independently.*
- Has the critical appraisal method (for quality assessment of the literature) been provided? *Appraisal of the quality of the available material should be an important component of an HTA report. Assessment of quality of life studies should consider whether valid instruments have been used. For these and other types of study attention should be paid to whether there is good comparison between groups.*
- Has the method of data synthesis been described? *There will be a synthesis from the analysis of the material selected for assessment — quantitative or non-quantitative. Details of the method should be described.*
- Are the results of the assessment clearly presented, eg in the form of evidence tables? *Tabular presentation of material is a commonly used and helpful approach.*

  Absolute values should be presented, not just relative values. Estimates or indications of uncertainty and potential bias should be included.

Context *(may or may not apply to each HTA)*

- Are medico-legal implications considered?

  Have the medico-legal implications of using this particular health technology been considered? Information on litigation risks and professional indemnity insurance may be of relevance in this section, should it be discussed.
- Is an economic analysis provided?
  Has there been an analysis of the economic impact? May include cost or economic studies of similar applications; the basis for selection should be given.

  The approach to any synthesis and extrapolation of results from the literature selected should be described. If the HTA report includes cost or economic analysis, details of methods used and assumptions made are required. The quality of available studies should be considered. There should be adequate sensitivity analysis.
- Are ethical implications considered?
  Any specific issues relevant to the technology should be included. This may include issues of access, equity and informed consent concerning use of the technology in the local health care system and community. There should be a description of what has been done in the analysis, including the arguments and approaches used. The basis for discussion should be clearly outlined.
- Are social implications considered?
  Any specific issues relevant to the technology should be included. This may include issues of the impact of this technology on carers, family dynamics, social isolation, ability to stay in the home longer, early return to work, relevance of particular sub-cultures, likelihood of employment, "disease labelling", among others.
- Is a wider perspective (stakeholders, patients, consumers) considered?
  Any organisational issues specific to the national, regional or local health care system that are related to the acquisition, implementation and operation of the technology may be discussed. This might include the impact of the technology on hospital provision of services, provision of services in rural and remote areas, or workload and workforce implications. Issues regarding training and credentialing of people operating the technology, along with patient compliance and uptake might also be considered. Sources of information should be clear and analysis transparent.

What then? - Implications of the assessment results and conclusions

12. Are the findings of the assessment discussed?

Discussion of the findings should include:

- The relationship of the results obtained to the question being addressed by the assessment. (Information from the literature may help only to a limited extent.)
- There should be a clear interpretation of the results. It will be helpful to include comment on their likely relevance to clinical practice and to the health care system.
- Comment on missing or uncertain information, and the reliability of the analysis (This may perhaps be brief.)
- The basis for the opinions and conclusions in the report. (Do the assessment findings follow from the data? Are additional assumptions or opinions contributing to the position taken? If so, what are they? Has the report addressed all the potential benefits and disadvantages of the intervention? Have the objectives of the assessment been met?)

The discussion should be bringing earlier components of the report together in the context of the question that has been asked.

Frequently, judgements will have to be taken in the absence of definitive data on the performance of a technology. The nature and basis of such judgements should be made explicit. As in other parts of the report, transparency should be a key feature. The reader should be given a clear account of what has been done, what has been assumed and what has not been done.

13. Are the conclusions from the assessment clearly stated?

The report should reach clear conclusions, which will make reference to the question addressed by the assessment and, where appropriate, its context. The conclusions should flow from the evidence that has been reviewed.

Some HTA reports will include recommendations. Not all agencies will have a mandate to make explicit recommendations, but the conclusions of the assessment should be clear to the reader.

14. Are there suggestions for further action?

It may be helpful for the HTA report to include discussion of current research/ information gaps, directions for future research and assessment and approaches to dissemination of findings.

It may be useful for HTA reports to address the implications of their findings for policy, where such analysis is within the mandate of the assessment organisation.

A checklist for HTA reports

This summary form is intended as an aid for those who wish to make a record of the extent to which a health technology assessment report meets the 14 questions given in the checklist.

It is NOT intended as a scorecard to rate the standard of HTA reports — reports may be valid and useful without meeting all the criteria that have been listed.

Item	**Yes**	**Partly**	**No**
Preliminary			
1. Appropriate contact details for further information?			
2. Authors identified?			
3. Statement regarding conflict of interest?			
4. Statement on whether report externally reviewed?			
5. Short summary in non-technical language?			
Why?			
6. Reference to the policy question that is addressed?			
7. Reference to the research question(s) that is/are addressed?			
8. Scope of the assessment specified?			
9. Description of the assessed health technology?			
How?			

10. Details on sources of information and literature search strategies provided?

Search strategy	Databases	Year range	Language restriction	Primary data	Other kind of information resources
O	O	O	O	O	O

Complete reference list of included studies	List of excluded studies	Inclusion criteria	Exclusion criteria
O	O	O	O

11. Information on basis for the assessment and interpretation of selected data and information?

Method of data extraction described?	Critical appraisal method (for quality assessment of the literature) described?	Method of data synthesis described?	Results of the assessment clearly presented, e.g. in the form of evidence tables?
O	O	O	O

Context? *(may or may not apply to each HTA)*

(Medico-) legal implications considered?	Economic analysis provided?	Ethical implications considered?	Social implications considered?	Other perspectives (stakeholders, patients, consumers) considered?
O	O	O	O	O

What then?	**Yes**	**Partly**	**No**
12. Findings of the assessment discussed?			
13. Conclusions from assessment clearly stated?			
14. Suggestions for further action?			