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TOWARD TRANSPARENCY IN HEALTH TECHNOLOGY ASSESSMENT

A Checklist for HTA Reports

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Abstract

Objectives: As an initiative of the International Network of Agencies for Health Technology Assessment (INAHTA), a checklist for assessment reports was developed as a means of improving transparency and consistency in HTA.
Methods: Preparation of a summary of key elements in HTA reports, drawing on experience in preparation of such documents, information from guidelines for HTA, and individual assessments. Review by INAHTA agencies and modification of the summary to reflect the consensus.
Results: The resulting checklist includes 17 questions, with supporting detail. General areas covered include preliminary information, why and how the assessment has been prepared, the results of the assessment, implications of the results, and conclusions.
Conclusions: The checklist is intended to be considered by those preparing or using an HTA report. It reflects the views of INAHTA members and is seen as a mechanism to improve the standard of HTA reports, being complementary to the more detailed guidelines on how to conduct assessments.

Keywords: Health technology assessment, Technology assessment, Biomedical, Publications, Guidelines

Health technology assessment (HTA) is undertaken and applied by a very wide range of agencies and individuals. The inventory of HTA reports is now substantial. An important subset is listed in the HTA Database maintained by the NHS Centre for Reviews and Dissemination (agatha.york.ac.uk/htahp.htm). At December 2000 the database contained information on 786 ongoing projects and 1,326 completed publications, the large majority from members of the International Network of Agencies for Health Technology Assessment (INAHTA). As indicated on its website (www.inahta.org), INAHTA

Helpful comments and suggestions on drafts of the checklist were made by members of the INAHTA working group on harmonizing HTA methodology, accrediting HTA process and findings, and addressing conflict of interest issues. Suggestions on the first draft were provided by Rod Taylor (NICE, United Kingdom), and Norman Waugh and John Gabbay (NCCHTA, United Kingdom). Comments on the amended checklist were obtained from working group members Eduardo Briones (AETSA, Spain), Carlos Cano (CMS, USA), Christa Harstall (AHFMR, Canada), Jetty Hoeksema (ZonMw, the Netherlands), Jos Kleijnen (NHSCRD, United Kingdom), Menno van Leeuwen (GR, the Netherlands), Claire Packer (NHSC, United Kingdom), Miriam Siebzehner (ICTAHC, Israel), Helga Sigmund (DACEHTA, Denmark), and Bertrand Xerri (ANAES, France). The revised draft was finalized following comments by Vicki Foerster (CCOHTA, Canada) and Nathalie Jakobi Rodrigues (CEDIT, France).

has been formed to "provide a forum for the identification and pursuit of interests common to health technology assessment agencies." It furthers cooperation and exchange of information between HTA agencies and helps prevent unnecessary duplication of activities.

While this substantial and growing activity is an indication of the importance of HTA, a potential concern is the variation in quality of HTA reports and approaches taken in their preparation. Can healthcare decision makers and other researchers place reasonable reliance on an HTA report as a source of advice? In what context? Is there a possibility of developing and applying a common methodology and procedure that could be applicable across the broad range of HTA reports?

Such issues have been of considerable interest to members of INAHTA, which in 2000 set up a working group to consider the network's role in harmonizing HTA methodology, accrediting HTA process and findings, and addressing conflict of interest issues. There was a perception that INAHTA agencies were making use of the same assessment procedures but that the methodology varied to some extent. It was suggested that it might be in the interests of INAHTA members to harmonize or standardize HTA methods.

The working group first considered the issue of harmonization of HTA methodology during the 2000 Annual Meeting of INAHTA. It was agreed that while there are societal and other differences between agencies, standards or guidelines are well established for evaluation of some of the attributes of health technologies that are frequently considered in HTA reports. For example, appraisal of efficacy and effectiveness through systematic reviews is covered in guidelines such as those from the NHS Centre for Reviews and Dissemination (6). Economic analysis has been covered in guidelines such as those produced by the Canadian Coordinating Office for Health Technology Assessment (1). Approaches to health technology assessment have been outlined in detail in publications from the Agencia de Evaluación de Tecnologías Sanitarias Instituto de Salud "Carlos III" (3) and from the Danish Centre for Evaluation and Health Technology Assessment (4). Methodology issues have also been addressed in a report prepared by the EUR-ASSESS group (5).

Given the availability of such detailed guidelines for assessment, in principle it might be possible to specify a set of comprehensive standards for HTAs. However, it was recognized that the scope and detail of HTA reports would always vary considerably, given differences in the types of question being addressed, policy requirements, and resources available. The diversity of reports prepared by the INAHTA agencies provides an illustration, with products ranging from major assessments incorporating systematic reviews and economic analyses to short, nonrefereed briefs prepared on an urgent basis. It seemed unlikely that a comprehensive standardization of methods applicable to all types of assessment report would be realistic, but it was felt that it would be useful to develop brief guidelines that would address minimum or desirable standards for such documents. The working party noted that a key to improving the usefulness and generalizability of HTA is transparency in the assessment process. Assessments will vary considerably in terms of depth and scope of analysis, but readers of an HTA report need to be able to easily obtain information on what has been addressed, how this has been done, assumptions that have been made, limitations of the assessment, and the conclusions that have been reached. Following the advice of the working group, INAHTA agreed that a document should be developed that would provide guidelines for minimum standards that should apply to HTA reports. A general theme in this document would be the clear identification of what had been done in an assessment. Consideration would be given to available authoritative guidelines on HTA, the resource and time constraints that are frequently faced by HTA agencies, and the diversity of the questions they are asked to address.

METHODS

An initial draft of a summary of key elements in HTA reports was prepared, drawing on the experience of INAHTA in the preparation and use of such publications. This included information from HTA programs, guidelines for HTA, and material in individual assessments, particularly those prepared by INAHTA member agencies. Consideration was given to the appropriate "information trail" through an HTA report to provide the reader with some assurance of what material had been covered, in what fashion, and for what purpose. The draft checklist was discussed with three persons from INAHTA agencies and also made available to the European Collaboration for Health Technology Assessment (ECHTA) Working Group on Developing and Disseminating Best Practice in Undertaking and Reporting Assessments, which was then in the early stages of developing its guideline for HTA (2). A draft of the ECHTA guideline was made available to the INAHTA group but did not substantially influence preparation of the checklist. An update of the checklist was then discussed by the INAHTA working group at the 2001 Annual Meeting of the network. Following further changes to emphasize or clarify some points, the checklist was circulated to INAHTA members and then finalized following additional comments from two agencies. The checklist was posted on the INAHTA website (www.inahta.org) in October 2001.

RESULTS

The checklist is shown in Appendix 1. It includes 17 questions to be considered by those reviewing or preparing an HTA report, grouped under the following categories: preliminary information, why and how the assessment has been prepared, results, and implications of the results. The checklist contains only brief details of a number of important points relating to HTA reports and is intended for initial guidance of assessors and readers. It should be seen as complementary to the authoritative guidelines for assessment of health technologies that have been prepared by a number of agencies.

Two of the questions, dealing with medico-legal implications and suggestions for further action, relate to points that may not be addressed in some publications. The remaining questions deal with matters that should be considered for all HTA reports. Some of these cover provision of basic information and details of context; 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. Further points and suggestions have been added under most of the questions and are given in italics.

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 that are listed.

DISCUSSION AND POLICY IMPLICATIONS

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 organizations, the checklist gives guidance on what to look for in an HTA report and on assessing the validity of the information provided. For those undertaking HTA, the checklist gives points that should be considered when planning, conducting, and reporting an assessment. It is hoped that this guidance will help to improve the quality of HTA reports through aiding consideration of which elements have been included and which omitted. An advantage of the checklist over more comprehensive publications in this area is that it brings together advice on key attributes of an HTA report in a concise form. This short

document should serve as a useful prompt for those preparing HTA reports, while for those who use such publications, it is likely to be more accessible than the more comprehensive guidelines in this field. The checklist reflects the experience and opinion of the INAHTA agencies and is available in electronic form through the network's website.

Application of the checklist would be strengthened if reference to it were made in HTA reports. One option would be to include the checklist as an addendum to the HTA report, so that the points covered are immediately available to the reader. However, that might not be realistic for brief HTA reports, though for short documents, inclusion of the one-page summary included on the INAHTA website at the end of the checklist would be a possibility. A further option, though of less immediate benefit to the reader, would be to state that in the preparation of the HTA report, the INAHTA checklist had been used, with a reference to the published version of the guidelines.

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 report. Both the checklist and comprehensive HTA guidelines give descriptions of appropriate procedures, but there will always be a need for judgment on how they should be applied in a particular case. Judgments on an HTA report should consider issues such as whether the client for the assessment and the international HTA community were appropriately informed and the level of analysis that is sufficient to provide adequate advice.

Influence on the policy process might come both from changes to assessments and to the understanding of decision makers who read them and make use of their findings. Decision makers should have a clearer idea of what has been done, the relevance to questions they have raised, and limitations to consider. Higher quality and more transparent HTA reports should contribute to better decisions on the appropriate place of technologies in health care.

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APPENDIX 1
INAHTA Checklist for HTA Reports

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 should be noted that conflict of interest may arise in relation to non-financial matters. 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.
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 question that is addressed and the context of the assessment?
The context of an HTA report is an important aspect in considering its contribution to knowledge about a technology. Reports should specify why an assessment has been undertaken and, where appropriate, who has requested this work. It will also be important to outline the relationship of the HTA question to the health care system, with reference to related health services and technologies, and the population for whom the technology is intended.
7. 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.
8. 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 textbook approach is not needed. Brief reference to alternative or competing technologies may also be helpful.

How the Assessment Has Been Undertaken

9. What sources of information have been used?

- Details of the literature search should be provided. These should include data bases used, years covered, any language restrictions, and key search terms. Details of 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.
- Information on the source of any other administrative data should be provided, with comment on their scope and accuracy.
- A list of references/bibliography should be included.

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.

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.

10. Is there information on the process for selecting material for assessment?

- Process used by assessors (The report should indicate who has undertaken selection and extraction of data and how this processing has been done.)
- 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?)
- Economic impact (May include cost or economic studies of similar applications; the basis for selection should be given.)
- Equity (Material relevant to the local health care system and community, possibly also to the disease or condition for which the technology is to be used. Details of the basis for selection should be given.)
- Societal and ethical issues (Any specific issues relevant to the technology and its use should be included.)
- Organisational issues (Any issues specific to the local health care system that are related to the acquisition and operation of the technology.)

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.

If the sources of information have been identified, are there details to indicate how material has been selected for inclusion or exclusion in the report? Use of a CONSORT type diagram to summarise what has been included and excluded in the literature selection process would be a helpful feature. Some attributes (for example, safety of the technology) may not be covered in some reports.

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

- Technical issues (If technical issues related to the technology have been assessed, they should be addressed clearly and appropriately.)
- Safety (The relevance to the specific application and the local healthcare system should be made clear.)
- Efficacy/effectiveness (The report should describe results of relevant studies and consider their quality and limitations. There should be an indication of how these results have been synthesised; the approach taken to any non-quantitative synthesis should be outlined.)
- Economic impact (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.)
- Equity (There should be a description of what has been done in the analysis, including the arguments and approaches used.)
- Societal and ethical issues (The basis for discussion should be clearly outlined.)
- Organisational issues (Sources of information should be clear and analysis transparent.)

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.

The Results of the Assessment

12. Are the results of the assessment clearly presented?

There will be a synthesis from the analysis of the material selected for assessment—quantitative or non-quantitative. Absolute values should be presented, not just relative values. Estimates or indications of uncertainty should be included.

13. Is there interpretation of the assessment results?

There should be some indication of how the results have been interpreted. It will be helpful to include comment on their likely relevance to clinical practice and to the health care system.

Tabular presentation of material is a commonly used and helpful approach.

Implications of the Assessment Results and Conclusions

14. 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.)
- 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.

15. If relevant to the assessment, are medico-legal implications considered?

16. 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.

17. 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.