A REVIEW OF ORGANISATIONAL AND PATIENT-RELATED ASSESSMENTS IN HTAs PUBLISHED BY INAHTA MEMBERS – SUMMARY

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Foreword by DACEHTA

The report presents the results of a methodological study, comprising a literature review of a sample of national and international HTA-reports with specific focus on the analysis of organisational and patient-related issues. In the Danish HTA-model, these two aspects are significant elements, and their importance for decision-making concerning the application of health technologies is obvious. However, contrary to the evaluation of clinical and economic effectiveness, the analysis of organisational and patient-related aspects is seen more rarely in HTAs. There is clearly a need for further development in this field.

The overall purpose of the report is to provide an overview of methods used in organisational and patient-related assessments. To what extent are such analyses included in the HTA? And if they are, how is it done? How can it be done? In the report, a large number of examples is presented, analysed and discussed in order to improve methodologies in future HTAs.

The study was carried out by an interdisciplinary research team from the Centre for Applied Health Services Research and Technology Assessment (CAST) at the University of Southern Denmark, and was financially supported by funds granted by the Danish Centre for Health Technology Assessment (DACEHTA) at the National Board of Health.

The report is published in DACEHTA’s series “Danish Health Technology Assessment”. A report undergoes an editorial process and external peer-review by two relevant experts before publication in the series.

DACEHTA hopes that the report will comprise an important contribution to the development of methods applied to health technology assessment.

Danish Centre for Health Technology Assessment
June 2007
Finn Berlum Kristensen
Director
Preface by the authors

This study has been undertaken over a period of two years. It has been an enlightening process and we are grateful to have been given the opportunity to immerse ourselves in this interesting area. We are especially grateful to our colleagues Mette Birk Olsen and Rikke Juul Larsen for their part in initiating and developing the proposal for the study, as we are to our colleagues Claire Gudex and Charlotte Bruun Pedersen for their proofreading at different stages of the report. The competent and thorough comments from the members of the reference group on various drafts of the report are greatly appreciated.
Summary

Introduction

Health technology assessment (HTA) is a form of policy research that examines short- and long-term social consequences (e.g. medical, societal, economic, ethical and legal) of the application of technology. The goal of technology assessment is to provide policymakers with information on policy alternatives. HTA has been defined as ‘a multidisciplinary activity that systematically examines the technical performance, safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organisational implications, social consequences, legal and ethical considerations of the applications of a health technology’.

In recognition of the need for comprehensive HTAs that can support decision-making, there is a tradition in Denmark for conducting HTAs within a framework of four key elements: technological (clinical effects), economic, organisational and patient-related issues. Studies of HTA practice indicate that this comprehensiveness is seldom present, with many HTAs failing to include assessment of organisational and patient-related consequences. Various projects and working groups have developed guidelines and published reports on how to achieve best practice in undertaking HTAs, and an overview of how organisational and patient-related issues are currently assessed in HTAs would assist development of these guidelines.

Objectives

The purpose of the present study was threefold: i) to describe the extent to which organisational and patient-related assessments are included in international HTAs, ii) to describe and discuss the content and handling of the organisational and patient-related assessments included in international HTAs, to describe ‘best practice’ and to present recommendations for organisational and patient-related assessments in future HTAs, and iii) to describe and discuss the methodology used in HTAs for generating and analysing data in the assessment of organisational and patient-related issues, and to describe the extent to which HTAs report on the methodology used and on the generalisability of the organisational and patient-related results to other contexts.

To address this purpose a systematic literature review of HTA reports published by INAHTA members was carried out. Quantitative and qualitative analysis were performed based on a thorough review of organisational and patient-related assessments included in a random sample of 50 full HTA reports identified from INAHTA members’ websites and that included organisational and/or patient-related assessments and were published either in English or a Scandinavian language. A checklist was developed for the purpose.

Results

A total of 382 full HTA reports published either in English or a Scandinavian language were identified. Of these reports, 146 (38%) included organisational and/or patient-related assessments. Inclusion of these two elements in HTA reports is thus generally less common than inclusion of technological/clinical and economic issues.

A review of 50 randomly chosen HTA reports showed that 42 reports included an assessment of organisational issues and 43 reports included an assessment of patient-related issues.
Of the 42 reports that assessed organisational issues, 95% stated a purpose for doing so and 33% included one or more research questions to be addressed in the assessment. A variety of organisational issues were included in the assessments. All 42 reports assessed issues related to process: these were predominantly related to the various actor group and organisations associated with the use of the technology, as well as to staff numbers and skills, and to work flow. Issues related to interaction/communication and potential barriers/bottlenecks were included in more than half of the reports. Of the 42 reports 93% assessed issues related to structure: these were mainly assessments of physical, resource and legislative structures and of diffusion of the technology. A smaller number of reports assessed economic consequences and incentive structures. Of the 42 reports 81% assessed issues related to control and evaluation of the technology: these related mainly to control and evaluation systems, with fewer reports including issues related to the responsibility for these systems. A little over half the 42 reports assessed issues related to culture and environment: these related mainly to cultural factors. Issues related to physical and psychological working environment were less often included, while assessment of impact on the outer environment was absent.

Of the 43 reports that assessed patient-related issues, 93% stated a purpose for doing so and 40% included one or more research questions to be addressed in the assessment. A variety of patient-related issues were included in the assessments. Three-quarters of the 43 reports assessed psychological issues: these related mainly to patient fear and discomfort. A smaller amount of reports included issues of patient satisfaction and patient involvement in the use of the technology. Just over 70% of the 43 reports assessed ethical issues: these were related to patient acceptance and, to a much lesser extent, general public acceptance of a technology. A small number of reports assessed specific ethical considerations. Of the 43 reports 70% assessed social issues: these related mainly to the technology’s impact on the patient’s daily life. A smaller number of reports assessed implications for the patient’s significant others and for the patient’s ability to work. Of the 43 reports 70% assessed patients’ perceptions of the technology’s effect on their health, mainly as quality of life assessment. Just under 70% of the 43 reports assessed issues related to patient information, while less than one-third assessed issues related to the patient’s financial circumstances in relation to the use of the technology.

Besides variation in the types of issues that were included in the organisational and patient-related assessments respectively, there was also considerable variation in the way these issues were handled. Most often the issues were simply described. Some reports included more comprehensive assessment of issues, however, and thereby provided knowledge that can be useful in deciding whether or not to implement a technology, and in planning the implementation strategy of a technology.

In terms of study design, most of the organisational and patient-related assessments were based on a review of existing literature, either alone or in combination with other designs (which were mainly case studies but also comparative studies).

Nearly all the assessments used literature review as a method of data generation, while just under half were based on both primary and secondary data. Primary data were generated using both quantitative and qualitative approaches. A quantitative approach was used in just over one-third of the assessments and typically comprised questionnaires. Registry data and preference instruments were more seldom used. A qualitative approach was used in nearly one-third of assessments and mainly comprised text documents and individual interviews. Focus group interviews, prospective methods, direct observation and expert/interest group involvement were more seldom used. Not all the reports expli-
citly discussed the choice of methodology, and there was a tendency for those assessments that did not discuss choice of design to use literature review as the study design. Some reports discussed the choice of method for data generation; these reports tended to include more than one data generation method.

The extent to which the HTAs reported on key methodological issues differed. Most reports simply described the methods used, while others discussed the methodological choices made thereby assisting the reader to understand the methodological steps taken, the reasons for these and their consequences for the validity and trustworthiness of the results.

Approximately half of the HTA reports discussed the generalisability of the results to other contexts. This was typically done for the report as a whole rather than for the organisational or patient-related assessments separately. It was not possible in the present study to identify issues of generalisability that were specific to organisational and patient-related elements of an HTA. This will doubtless require both systematic methodological research and comprehensive discussion among HTA researchers.

Conclusions

Inclusion of organisational and patient-related assessments in HTAs was less common than inclusion of technological/clinical and economic assessments. When organisational assessments were included these were mainly concerned with such issues as which actors and organisations were associated with the use of the technology, work flow, staff numbers and skills, and physical, resource and legislative structures. Issues related to organisational culture, communication and the physical and psychological working environment were less often included. When patient-related issues were included these were mainly concerned with such issues as fear and discomfort, impact on the patient’s daily life and quality of life, patient accept of the technology and patient information. Issues related to patient involvement in decision-making and impact of a technology on the patient’s personal economy and on their significant others were less often included. While some of the HTA assessments were broad, including a variety of issues, often these issues were handled in a rather restricted and superficial way. More comprehensive assessment of the included issues was less often performed. While the way of handling different issues in an HTA depends on the given technology under assessment and the given purpose and policy question of the HTA, the usefulness to decision-making of rather superficial assessments can be questioned.

There is also room for improvement in relation to the methodology applied in the assessments. Most reports simply described the methods used for generating and analysing data, while fewer reports discussed the methodological choices made. Many of the HTA reports chose a literature review as the only study design but did not explicitly discuss this choice in relation to the individual HTA assessment or to the purpose and perspective of the study. The choice of study design thus appeared to follow a generally accepted approach rather than involve consideration of the most appropriate design tailored to the individual assessment.

The absence of a description of the considerations made when determining the content and methods of the organisational and patient-related assessments limits the usefulness of an HTA. The reader is left uncertain of the relevance and validity of the organisational and patient-related assessments – was the relevant perspective chosen, were the relevant issues included and were they assessed using a relevant methodology?
Overall recommendations

For an HTA to function as a decision-making tool, it needs to be comprehensive and to take a broad perspective that is relevant to the policy question. It is important, therefore, to consider the inclusion of an assessment of the potential organisational and patient-related issues that are relevant to the specific technology under study. The types of organisational and patient-related issues to include in an HTA, and which methodology to use in their assessment, depend on the purpose of the HTA and on the research questions. It is important that the HTA reports not only the methodological steps undertaken, but also why these methodological choices were made and what consequences they had for the study findings, including the generalisability of the results. This information would enable the reader to evaluate the relevance and trustworthiness of the HTA findings.

Some areas still need to be examined and developed further. Firstly, the general quality of organisational and patient-related assessments would be enhanced considerably if systematic and relevant analytical models or frameworks were developed. Such models could be targeted at both specific types of policy questions and specific technologies. Secondly, further investigation is needed to determine useful ways of reporting on the generalisability of results from organisational and patient-related assessments.
Health technology assessment (HTA) is a form of policy research that examines short- and long-term social consequences of the application of technology. Health technologies often have an influence on, and can be influenced by, current organisational structures, daily staff routines and work practices, educational requirements and/or job satisfaction. Similarly, patients’ attitudes and experiences with a health technology can be highly relevant for the implementation and effects of a technology. It is important, therefore, that HTAs are comprehensive and considers including organisational and patient-related issues as well as technical/clinical and economic issues.

A systematic literature review of HTA reports published by INAHTA members was carried out to examine current practice for including and handling organisational and patient-related assessments in HTAs, and to review comprehensive assessments that could assist in developing guidelines for ‘best practice’.

Organisational and/or patient-related assessments were included in 38% of the identified HTA reports. While some of the assessments were broad, including a variety of organisational and patient-related issues, often these issues were handled in a rather restricted and superficial way. More comprehensive assessment of the included issues was less often performed.

While the inclusion of different issues in an HTA depends on the given technology under assessment and the given purpose and policy question of the HTA, the usefulness to decision-making of rather superficial assessments can be questioned. Also, there is room for improvement in relation to the methodology applied in the assessments. Most reports simply described the methods used for generating and analysing data, while fewer reports discussed the methodological choices made.