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Danish Centre for Health Technology Assessment (DACEHTA)

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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 Heath 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 Børlum 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 proof-reading 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.

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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 policy-makers 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.

Guidelines for the reader

The present report is composed of 7 chapters and a number of appendices. The aim of the report is to describe the present status of organisational and patient-related assessments, and the related methodologies, in HTAs published by INAHTA members and to discuss how these assessments may be designed and undertaken in future HTAs.

- In Chapter 1 an introduction to the study is presented, including descriptions of the background and purpose of the study.

- In Chapter 2 the terminology and methodology of the present study is described.

- In Chapter 3 a description of the extent to which organisational and patient-related assessments are included in international HTAs is presented, together with a general description of the data (50 INAHTA reports) on which the study analyses are based.

- Chapters 4 and 5 present the content of the organisational and patient-related assessments of the HTAs, respectively. This is done both by describing the extent to which different organisational and patient-related issues are assessed in HTAs and by describing and discussing the way in which these issues are assessed. As an inspiration to future performers of HTAs, examples are provided of how organisational and patient-related issues can be included and assessed as part of an HTA.

- Chapter 6 reviews the methodologies used in the HTA reports for the assessment of organisational and patient-related issues. The first section reviews the methods used in regard to study design, data generation and data analysis. The second section reviews how the HTAs report on the methodology used and the extent to which the HTAs discuss the generalisability of the results. Again as inspiration to future performers of HTAs, examples are provided of different ways of reporting on methodological issues.

- Chapter 7 discusses the scope of the present study and the conclusions drawn, and presents recommendations for the design and methodology of future assessments of organisational and patient-related issues.

1 Introduction

1.1 Background

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 policy-makers with information on policy alternatives (1). The EUR-ASSESS project, which aims to improve coordination of HTA in Europe, has defined HTA 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' (2).

In recognition of the need for comprehensive HTAs that can support decision-making (3), there is a tradition in Denmark for conducting HTAs within a framework of four key elements: technological/clinical, economic, organisational and patient-related issues. The assessment of what in this study is understood as organisational and patient-related preconditions for and consequences of a technology can be a significant factor in ensuring that the HTA is useful as a policy tool (4, 5). 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 (1, 6). Similarly, patients' attitudes and experiences with a health technology can be highly relevant for the implementation and effects of a technology (7). It is important, therefore, that HTAs are comprehensive and include consideration of the organisational and patient-related issues that should be included in the assessment.

Studies of HTA practice indicate that this comprehensiveness is seldom present, with many HTAs failing to assess organisational and patient-related consequences (8, 9, 10, 11). In an attempt to rectify this situation, various projects and working groups have developed guidelines and published reports on how to achieve best practice in undertaking an HTA – see for example the report published in 2002 by the European Collaboration for Assessment of Health Interventions (ECHTA) (12).

The development of guidelines for the inclusion of organisational and patient-related issues in HTAs would be assisted by the existence of an overview of how these issues are currently assessed in HTAs (8, 13-15). The present study was thus initiated 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'.

1.2 Purpose of the study

The purpose of the study was:

- To describe the extent to which organisational and patient-related assessments are included in international HTAs
- 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

- 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.

The study was designed as a systematic literature review of HTA reports published by INAHTA members. A random selection was made of 50 HTA reports that were written in either English or a Scandinavian language and included assessment of organisational and/or patient-related issues. These reports were reviewed using a checklist developed for the purpose.

1.3 Members of the project group

The study was initiated and conducted by the Centre for Applied Health Services Research and Technology Assessment (CAST) at the University of Southern Denmark, and supported by a grant from the Danish Centre for Health Technology Assessment (DACEHTA). The report's two authors have retrieved and reviewed the selected HTA reports, developed the checklist, analysed the data and written the report. The project group has supported the progress of the study and together with a reference group has commented on and discussed drafts for the checklist and final report through participation in four meetings. No conflicts of interest are reported.

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2 Methodology of the present study

This chapter has two main sections. The first explains the various concepts used in discussing the assessment of organisational and patient-related issues. The second section describes the study design and methodology used.

2.1 Terminology used

For analytical reasons, the present study distinguishes between four key elements of an HTA (technological/clinical, economic, organisational and patient-related issues). In practice, the four elements of an HTA are interrelated and can have considerable influence on each other. An assessment of organisational issues, for example, is often a precondition for undertaking an economic analysis of a technology, and assessment of patient quality of life can be part of an economic analysis (e.g. in the form of cost-utility analysis). Furthermore, assessment of ethical issues may be undertaken as a separate and overriding element of HTAs rather than as part of an assessment of patient-related issues (ethical considerations are not restricted to the actual use of a technology but are also relevant in connection with e.g. research, recommendations and overall decisions related to assessments). For the purposes of the present study, however, a simplified approach has been chosen in which organisational and patient-related issues are considered to be distinct from each other and from technological/clinical and economic issues.

By applying a broad definition of organisational and patient-related issues, an attempt has been made to incorporate both the traditional Danish approach to HTA and the approaches used elsewhere for the assessment of organisational and patient-related issues. Despite the authors' attempts to take a broad and open-minded view in reviewing and evaluating the reports, the study's findings will inevitably be influenced by the authors' own understanding and approach to HTA. The following sections describe the approach taken and terminology used in the evaluation of organisational and patient-related issues, respectively.

2.1.1 Terminology used for organisational concepts

In the present study, organisational analysis is seen as an analytical approach that focuses on the organisational preconditions and consequences of a technology. When assessing a technology it is possible to focus on different aspects of organisation. One can focus, for example, on the policy processes involved with a technology (e.g. problem-solving, development, decision-making, diffusion, implementation and evaluation) (16), and/or one can focus on the organisational dimensions which are affected by (and which themselves affect) the implementation and use of a technology. The present study takes the latter perspective and focuses on organisational dimensions and the organisational context of a technology rather than a policy analysis of a technology and its policy processes.

The approach taken here thus comprises an analysis of the management and structural dimensions of the technology and of the social and behavioural processes related to the use of the technology, as well as the preconditions for these (17 p. 69). These various organisational dimensions are both dynamic and often interlinked. In the present study organisational issues have been reviewed under four main categories: structure, process, control/evaluation and culture/environment. These categories are inspired by recommendations in the Danish HTA Handbook (17 p. 82), with some modifications to suit the purposes of the present study. Each of these four categories has then been divided

into subcategories. The categories and subcategories (in italics) are presented below, together with a description of how each is interpreted and applied in the present study.

In the event that additional organisational issues later emerged that could not easily be placed within this framework, an extra 'other' category was available on the checklist. This category was not used, however.

Structure

Structure is used as an overall concept for the formal and informal frameworks, rules and conditions of the technology which surround, determine and are affected by social and behavioural processes (18). This overall concept encompasses different kinds of structures such as formal organisational systems and management, physical, resource, economic, legislative and regulative structures.

Formal organisational structure refers to the overall organisation of a technology in a given health system, e.g. the organisational level and sector in which a technology is placed; the level of (de)centralisation.

Physical, resource and legislative structures are the physical and legislative frameworks and resource conditions of a technology in a given health system, e.g. the requirements and conditions in regards to, for example, facilities, capacity, placement, planning, legislation, large-scale operations, equipment, devices etc.

Diffusion is the inter- and intraorganisational spreading of a technology, e.g. how the use of a technology spreads within the area of focus, the actors involved in and responsible for the diffusion.

Economic consequences at an organisational level are the positive and negative economic effects of a technology on the organisations using the technology, e.g. whether use of the technology influences payment arrangements and expenditures in the organisation.

Incentive structures are the various kinds of motivations and inducements that can affect the use of a technology, e.g. the current existence of any economic, political or career-related incentives that affect the use of a technology; whether the technology itself creates economic, political, personal or career-related incentives among personnel, patients, wards, collaborators, hospitals, counties etc.

Process

Process is used as an overall concept for more or less fixed systems of actions that relate to the use of a technology and create a given output. As such, 'process' encompasses various kinds of routines, functions and social and communicative actions and relationships, which are created and handled by different roles or actors (19, 20).

Work flow is the flow and course of actions related to the use of a technology, e.g. the work tasks, routines and procedures that are carried out in relation to the use of a technology; the way in which a technology affects organisational work tasks, routines and procedures.

Actors involved refers to the various roles and persons who carry out and create the different processes, e.g. the different types of professional groups, staff and specialists involved with the use of a technology; the way in which a technology influences the chain of responsibility and the division of labour between professional groups.

Personnel skills and resources refer to the type and number of professional workers associated with the use of a technology, e.g. what skills and staff resources are required for the implementation of a technology; whether new skills or additional personnel are required.

Interaction and communication are the communicative and social processes that occur in relation to the use of a technology, e .g. the way in which a technology affects the social relations and interactions within the area around it; whether a technology places new demands on collaboration and communication within and between different organisations.

Barriers and bottlenecks refer to different factors that may hinder the use of a technology or the work processes related to the use of a technology, e.g. the presence of attitudes, perspectives, informal habits or routines among involved actors that influence or hinder the implementation a technology; whether a lack of, for example, resources, capacity, formal structures, routines or decision-making hinders the use of a technology.

Control and evaluation

Control and evaluation issues are related to both structure (how is the control and evaluation of the use of a technology organised?) and process (who does what, and how?). For the purposes of the present study, however, control and evaluation issues are evaluated as a separate category as they have a more indirect influence on the use of a technology, in comparison to the more direct influence of structural and process issues.

Control and evaluation systems are the structures and procedures used in the monitoring and regulation of the use of a technology, e.g. the monitoring parameters that are used; the monitoring and regulatory procedures carried out by the involved actors.

Control and evaluation responsibility refers to the actors and organisations that are responsible for the development and undertaking of evaluation and control of a technology e.g. who has responsibility for the development of evaluation and control procedures; where in the organisation this responsibility should be placed.

Culture and environment

Culture and environment are used as overall concepts for the normative, social and physical working environmental context which the technology is placed in and is part of.

Culture refers to the overall habit, norm and value system in which a technology is located, e.g. whether a technology fits into the existing formal and informal traditions and values of an organisation; whether there is a need for changes in actors' perceptions or understandings of their role or function.

Psychological working environment refers to psychological effects and social conditions and context of an organisation and its employees, e.g. whether the implementation and use

of a technology affects the psychological wellbeing of the involved actors with respect to job satisfaction, level of influence, attractiveness of employment, etc.

Physical working environment refers to the physical and ergonomic conditions and context of an organisation and its employees, e.g. whether the use of a technology poses health risks to employees; the need for any ergonomic alterations.

Outer environment is the natural or geophysical environment of the surrounding society, e.g. whether the use of a technology has adverse environmental consequences or affects the 'environmental/ecological impact' of an organisation.

2.1.2 Terminology used for patient-related concepts

For the purposes of the present study the term 'patient' encompasses all potential end-users of the technology in question. This term covers a continuum that ranges from present users (e.g. an ill person receiving care and treatment in the health system or a presumably healthy person participating in a screening program) to potential future users. The term 'patient(s)' also covers a continuum from the individual patient, to a group of patients or members of society (7 p. 37).

Patient-related assessments are seen as reviews of the patients' perspectives on the use/absence of a technology. The patient's combination of experiences, perceptions, expectations and actions in relation to a technology is a bodily experience interrelated with the individual's history and life situation, and is therefore different from the professional's perspective (7).

Inspired by recommendations in the Danish HTA Handbook (17) and with some modifications to suit the purposes of the present study, the patient-related issues were chosen and divided into different categories acknowledging that these various patient-related issues are interlinked and that this division in places might seem somewhat arbitrary. The six main categories are: patient information, psychological aspects, effect of the technology (e.g. on quality of life), social issues, ethical issues and impact on the patient's financial situation. Some categories were broader than others and were thus divided into subcategories. The categories and subcategories (in italics) are presented below, together with a description of how each is interpreted and applied in the present study.

In the event that additional patient-related issues later emerged that could not easily be placed within this framework, an extra 'other' category was available on the checklist. This category was not used, however.

Patient information

Patient information can have different purposes and therefore different forms. Patient information can be seen as a linear process that includes an informer, a message and a receiver of information but is in the present study viewed as a communicative interaction that encompasses the perspectives of the persons included in the interaction as well as the message content and the context in which the communication takes place. Providing or withholding patient information has consequences for the patient perspective of the technology and might be seen as a both practical and juridical premise for the use of the technology.

Psychological issues

Psychological issues include emotional feelings and intellectual perceptions that are psychological/physical in nature and can cause or influence bodily reactions (there is in this understanding no clear distinction between body and mind) in relation to the use of a technology.

Fear and discomfort are subcategories of psychological issues that encompass patients' possible discomforts in relation to the use of a technology, e.g. feelings of fear, anxiety and restlessness and perceptions of insecurity and marginalisation. These possible discomforts may surpass the usefulness of the technology.

Satisfaction correlates with psychological wellbeing and includes satisfaction of patients (and their significant others) related to the offer of a technology and aspects of its use e.g. access, organisation and relationships with health personnel.

Patient involvement in the use of a technology and related decision-making includes patients' sense of self-reliance and control e.g. rights to information, ability to influence the decision made and opportunities to choose between alternative treatments.

Effects of the technology on quality of life

Effects of a technology are here understood as the patients' perception of possible effects of a technology which might not be reflected in more objective measures such as rates of mortality or morbidity. These perceptions are often labelled 'health-related quality of life' or simply 'quality of life' (QoL) and are here understood as the patient's perceptions of own health status.

Quality of life may also be assessed (e.g. in terms of quality-adjusted life years, QALYs) in the economic element of an HTA. In the case where quality of life measurement was included only in relation to the economic assessment of a technology, the assessment was not included in the present study.

Social issues

Social issues refer to the consequences that a technology may have for the daily life of patients and their significant others.

Patient's daily life refers to consequences that the use of a technology might have for the patient's ability to retain or resume self-reliance and to perform everyday tasks and family roles.

Patient's work life refers to consequences that the use of a technology might have for the patient's ability to retain or resume a job and for the patient's work capacity.

Implications for patients' significant others are the consequences that the use of a technology might have for the family structure, e.g. the patient's ability to support dependants and any need for increased support from relatives or others.

Ethical issues

Ethical issues are here understood as the ethical concerns and considerations that arise in relation to the actual use of a technology in relation to individual patients and a more

general acceptance among the general population. Ethical issues can be relevant not only as patient-related issues, but also to the HTA as a whole.

Patient acceptance refers to the individual patient's acceptance of a technology e.g. possible risks and discomforts in relation to the use of a technology, and to the general population's acceptance of a technology and whether a technology meets the general expectations e.g. whether its availability and its use is perceived to be relevant, equal and fair.

Fundamental and specific ethical considerations relate, for example, to whether and when it is acceptable to use a risky and/or very expensive technology and the acceptability of using technologies which might change perceptions of the threshold between life and death.

Patient's financial circumstances

The patient's financial circumstances refer here to the influence that the use of a technology might have on the patient's economic situation, e.g. direct expenses in connection with a technology (transportation, buying of drugs and appliances), the patient's ability to maintain or restore an income, as well as the patient's willingness to pay for the technology. In the case where financial issues were included only in relation to the economic assessment of a technology, the assessment was not included in the present study.

2.2 Design and methods

The study was designed as a systematic literature review of HTA reports published by INAHTA members. The following sections describe the approaches used for the literature search, the review of individual HTAs and the analysis.

2.2.1 Search strategy

The International Network of Agencies for Health Technology Assessment (INAHTA) was used as a search entrance. This network[1] was established in 1993 to support cooperation and sharing of information between organisations assessing healthcare technologies. In the summer of 2005, 41 agencies from 21 different countries were members of INAHTA. For the purposes of the present study it was decided to include HTA reports only from these 41 INAHTA members, and only reports published in the period January 2000 to July 2005.

The INAHTA website provided a list of members, including a profile of each member agency and a link to its website. Each of these websites was searched by two reviewers working independently in order to identify published HTA reports. Due to language barriers it was only possible to include agencies that had English or Scandinavian language versions for their websites and publications. On this basis 17 agencies (ASERNIP-S, MSAC, AETMIS, AHFMR, CCOHTA, DACEHTA, DSI, GR, NZHTA, SMM, CMT, SBU, CRD, NCCHTA, NHS QIS, AHRQ and VATAP) from 10 countries (Australia, Canada, Denmark, England, the Netherlands, New Zealand, Norway, Scotland, Sweden and the United States) were included in the initial list for review. The search for HTA reports was performed by two reviewers in the period from 11th May to 11th July 2005.

It was thought that a cross-check with the publications held in the Health Technology Assessment Database (22) would be useful. However, a preliminary search for HTA studies in the Database resulted in more than 4,000 hits and a brief review of these hits

1 INAHTA is an international network of organisations undertaking HTA. To become an INAHTA member an organisation must be non-profit, funded by at least 50% public resources and related to regional or national government. The HTA reports published by INAHTA members must be easily accessible and free upon request. The purpose of the network is to provide a forum for the identification and pursuit of interests common to health technology assessment agencies. Further information is available at: http://www.inahta.org.

revealed that many were not relevant to the present study (being articles, project proposals, suggestions for future work, etc.). As the Database did not appear to add any HTAs published by INAHTA members that had not already been identified from the member websites, it was decided not to search further in the Database, but to focus on the HTAs identified from INAHTA members' websites. A previous study carried out in 2005, which undertook a similar search for HTA reports, reached the same conclusion about the advantages of using the Health Technology Assessment Database for cross-checking purposes (Draborg, personal communication).

The INAHTA agencies and their websites varied considerably with regard to their purpose, structure and content. Some agencies published HTA reports only, while others also published other forms of literature. Of these latter agencies some defined and classified their literature into explicit categories, while others provided an unsorted publication list including all kinds of publications. A decision was made to include only reports that were defined as HTA reports by the agencies themselves. Where access was limited to unsorted and uncategorised publication lists, the international definition of HTA was used to scan for and identify HTA reports, i.e. 'a form of policy research that examines short- and long-term social consequences (for example societal, economic, ethical, legal) of the application of technology. The goal of technology assessment is to provide policy-makers with information on policy alternatives' (1).

After the HTA reports were identified, they were further assessed against the following inclusion criteria:

i) Language: the full report (and not just the summary) must be in English or a Scandinavian language (Danish, Norwegian or Swedish)

ii) HTA: The report should be a 'full' HTA, i.e. not an Early Warning, Rapid Assessment, technology review or a report concerning methodological HTA issues

iii) HTA content: the organisational and/or patient-related assessment must be included in the report and be identifiable in the abstract, the table of contents or the description of the purpose of the study.

The choice of language versions to be included was dependent on the reviewers' ability to read and understand the full HTA report. Reports that included organisational or patient-related assessments without being explicit about this in the abstract, table of contents or in the description of the study's purpose were excluded from the study, as their identification was considered to be too time-consuming.

All reports identified from the INAHTA member websites that met the first two inclusion criteria were put on a 'gross' list of HTA reports published in the period 2000-2005. At the end of the search this list comprised 389 reports. The reports that met the third criterion were subsequently identified and put on a 'net' list. In case of doubt about whether a report should be included or not, the two reviewers discussed the content of the report before including or excluding it from the list. At the end of the assessment, the net list comprised 153 reports. By using simple random selection in the software program SPSS, 50 of these reports were selected as the final sample for the literature review. After retrieval and review of these 50 reports, it was found that seven were Rapid Assessments; they were subsequently replaced by seven new reports chosen by a second simple random selection using SPSS. Removal of these seven reports meant that the final gross list comprised 382 reports and the net list 146 reports.

2.2.2 Review strategy

The sample of 50 reports was read and assessed by the two reviewers independently in the period 12th September 2005 to 28th July 2006. The sample is presented in Appendix 1. In order to ensure a broad and uniform assessment of the reports over time, each report was assessed using a checklist specially developed for the purpose. To avoid an overly restrictive assessment, the reviewers were able to add new issues that were not initially included in the checklist.

The checklist was developed with reference to methodological and HTA literature. It consisted of questions relating to i) the general description of the HTA and the technology in question, ii) the content of organisational issues, iii) the content of patient-related issues, and iv) the methodology of the HTA. Illustrative guidelines (e.g. lists – but not definitions – of possibly relevant categories of issues) were provided for the questions relating to content of organisational and patient-related assessment. Each question required both a quantitative answer (yes/no) and a qualitative answer in which the reviewers elaborated on the content of the issue, the data source and way in which the issue was handled.

The final version of the checklist was a result of a work process that included project group meetings, a pilot reading and assessment of two reports, and a review of the checklist's content and form by an independent reference group. The checklist is included in Appendix 2.

The two reviewers independently read each of the 50 HTA reports and reviewed it using the checklist. Apart from the common sections of a report (e.g. summary, introduction, methodology, discussion, conclusion, recommendations, synthesis and appendix), attention was paid only to sections that related to organisational and/or patient-related issues. Any findings that clearly related to technological/clinical or economic issues, apart from the sections mentioned above, were ignored. After completion of the independent assessments, the two reviewers reviewed each report together. When consensus on the assessment had been reached, an electronic checklist was filled in jointly.

The checklist was viewed as a tool to help the reviewers identify the issues included in the reports, rather than a set of definitions into which the content of the reports must fit. The checklist was thus intended to be flexible, and was in fact altered many times throughout the review process. This was due both to further development of the reviewers' understanding and interpretation of the issues, and to the wide range of issues included in the 50 reports.

2.2.3 Analytical strategy

The analyses were performed on the basis of the completed checklists. The quantitative data from the checklist were transferred to a database designed for this purpose in the software program SPSS. The qualitative data from the checklist were transferred to a database designed for this purpose in the software program Nvivo. Both a quantitative and a qualitative content analysis were conducted across the 50 reports.

2.3 Discussion

As the study aimed to assess current practice regarding organisational and patient-related assessment in HTAs, a literature review of published studies was considered to be the most appropriate study design. Alternative approaches could be a case study or a compa-

rative study based on interviews or a survey, but these approaches may have elicited information on intended or desirable practice, rather than actual practice.

The current study only includes HTAs published by INAHTA members. This group of agencies is currently the only world-wide network of organisations working with HTA, and many of the members are national or regional HTA institutions. It can thus be assumed that the HTAs under review are based on considerable knowledge about and familiarity with the concepts and methodology of HTA.

A total of 382 full HTA reports were identified, of which 146 included organisational and/or patient-related issues. Whether these two types of issues are included in an HTA depends on the technology in question as well as the purpose of the assessment and on traditions in HTA practice. It has not been within the scope of this study to look further into the connection between type of technology, HTA purpose and inclusion of organisational and patient-related issues, since this would not only be resource-intensive, but would also require a detailed knowledge of the specific technology in question and the contexts in which it would operate.

Due to resource limitations of the study and for practical reasons, HTAs not published in English or a Scandinavian language were excluded from the study. The disadvantage of this is the resulting lack of information about HTA practice outside the INAHTA network and among non-English oriented INAHTA members.

The approach used to select the 50 reports was based on the double purpose of selecting a sample that could both describe the extent to which organisational and patient-related assessments are included in HTAs and describe the different ways and best practice of carrying out these assessments. A true quantitative approach would have required a significant sample size, while in a more qualitative approach the sample might have been selected purposefully e.g. according to the type of technology assessed. In view of the scope and resources of the present study, the sample selection process was based more on convenience and pragmatic criteria than on methodological scrutiny.

Despite these limitations, it is believed that the approach chosen provides a useful insight into current practice in relation to organisational and patient-related assessment in HTA. It was decided to review the HTA reports using a specially developed checklist. The use of a checklist for reviewing very different reports or literature can ensure both a systematic approach and greater uniformity in the reading and assessment of the reports. As no previously developed checklist was found that adequately covered the issues of relevance for this study, a new checklist was developed. The study results are thus based on a checklist that has not been validated by other users or in other contexts. To compensate for this, the checklist was pilot-tested twice before the main review was undertaken. The checklist was also adjusted and improved during the review process.

Both quantitative and qualitative data were generated so as to investigate both the extent to which different organisational and patient-related issues and methodologies are included in HTAs and the depth and different ways that these issues are assessed and reported on in the HTAs.

In the light of the methodological choices made, the study was expected to generate both quantitative and qualitative information on current practice among INAHTA members in relation to the content and methodology of organisational and patient-related assessment, with focus on HTAs published in English or a Scandinavian language.

3 Results of the search and general description of the study sample

3.1 Inclusion of organisational and patient-related assessments in HTAs

In this chapter the inclusion of the organisational and patient-related assessments are discussed in relation to two questions: i) to what extent are organisational and/or patient-related issues included, and ii) how can the study sample be described and characterised. This chapter thus addresses the first purpose of the present study: 'to describe the extent to which organisational and patient-related assessments are included in international HTAs'.

Of the 382 HTA reports identified from INAHTA member websites (full HTA reports published in 2000-2005 in English or Scandinavian language), 146 (38%) included organisational and/or patient-related assessments.

While no previous review has in the same way examined the extent to which organisational and patient-related assessments on an overall level are included in HTAs, a few have looked at the frequency of including specific issues (that in the present study are defined as different aspects of organisational or patient-related assessment). These include issues such as technology diffusion, personnel skills and education, psychological reactions, social impact, ethics and acceptability. Results from these reviews also showed that organisational and patient-related issues were not assessed nearly as often as technological/clinical and economic issues. One study found that a significant proportion of HTAs included technological issues (in terms of effectiveness, 48%) and cost (37%), whereas ethical and social issues were less frequently assessed (17%) (10). In another study, clinical indications (as an aspect of the technological issues) were assessed in 95% and cost-effectiveness in 53% of the HTAs examined, while acceptability of the technology was assessed in 25% and personnel skills and routines in 27% (9).

It may not always be relevant to include all four assessment issues (technological/clinical, economic, organisational and patient-related issues) in an HTA, but they should at least be explicitly considered for inclusion. Of the present selected sample of 50 reports (that all included either organisational or patient-related assessment), only 2 of the 8 reports (25%) that included patient-related assessment but not organisational assessment gave a reason for this omission. Similarly, only 2 of the 7 reports (39%) that included organisational assessment but not patient-related assessment gave a reason for omitting patient-related issues.

3.2 Description of study sample

Country of origin

About half of the 50 reports included for review in the present study were undertaken by Scandinavian INAHTA members (Table 3.1). While this may reflect a greater tendency of Scandinavian HTAs to include organisational and patient-related assessments, it may also be a result of biases in generating the study sample.

Table 3.1: INAHTA member countries represented in study sample (n=50 reports)

	Frequency	%
Canada	10	20
Denmark	16	32
England	8	16
Netherlands	2	4
Norway	6	12
Scotland	3	6
Sweden	4	8
USA	1	2

These biases could be a result of:

i) Skewness in the random selection process: however, a statistical comparison of the distribution of countries in the net list of 146 reports and in the study sample of 50 reports showed no significant difference (based on a Chi goodness-of-fit-test of the sample representativity)

ii) Scandinavian INAHTA members may publish relatively more HTAs than other members: the gross list of 382 HTA reports showed, however, that only 24% were published by Scandinavian INAHTA members, with most reports coming from Australia, Canada and England.

iii) The HTA agencies may use different definitions for HTA: however, in line with INAHTA's broad definition of HTA ('Technology assessment in heath care is a multidisciplinary field of policy analysis. It studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology', www.inahta.org), most agencies include both organisational and patient-related issues in their definition of HTA.

iv) The study's inclusion criteria required reports to be written in English or a Scandinavian language, thus excluding 24 of the current 41 INATHA agencies. When disregarding INAHTA members from English-speaking countries, only one agency from the Netherlands (plus an agency from Quebec) had both an English version of their website and published their reports in English. The 17 included agencies whose websites were searched were based in 10 different countries, of which three were Scandinavian, and only two were from non-English speaking areas (the Netherlands and Quebec).

The relatively large Scandinavian representation in the sample thus appears to be partly a result of the selection process, but may also be due to differences in HTA practice and tradition in different countries.

As seen in Table 3.2, there do in fact appear to be differences between HTA agencies in the extent to which organisational and patient-related assessments are included in HTAs. While some HTA agencies (mainly from Scandinavia and Scotland) included organisational and patient-related assessments in the vast majority of their published HTAs, other HTA agencies included these issues less often.

Table 3.2 Numbers and origin of HTA reports published by the INAHTA members included in the gross list, net list (number and percentage of gross list) and in the sample (number and percentage of net list)[2]

HTA agency	Country of origin	'Gross' list (full HTA)	'Net' list (HTA including organisational and/or patient-related assessments)	Study sample
ASERNIP-S	Australia	23	0 (-%)	0 (-%)
MSAC	Australia	54	2 (4%)	0 (-%)
AETMIS	Canada	25	9 (36%)	4 (44%)
AHFMR	Canada	19	5 (26%)	4 (80%)
CCOHTA	Canada	45	9 (20%)	2 (22%)
DACEHTA	Denmark	28	24 (86%)	14 (58%)
DSI	Denmark	4	3 (75%)	2 (66%)
GR	Nederlands	11	6 (55%)	2 (33%)
NZHTA	New Zealand	11	4 (36%)	0 (-%)
SMM	Norway	35	22 (63%)	6 (63%)
CMT	Sweden	5	4 (80%)	2 (50%)
SBU	Sweden	19	11 (58%)	2 (18%)
CRD	England	0	0 (0%)	0 (-%)
NCCHTA	England	75	29 (39%)	8 (28%)
NHS QIS	Scotland	9	9 (100%)	3 (33%)
AHRQ	United States	17	7 (41%)	1 (14%)
VATAP	United States	2	1 (50%)	0 (-%)
Total		382	145 (38%)	50 (34%)

Issues included

In the selected sample, all of the 50 reports included technological issues, 84% included economic issues, 84% included organisational issues and 86% included patient-related issues (Table 3.3).

Table 3.3: Assessments included in the HTA reports (n=50)

	Frequency	%
Technologic issues	50	100
Economic issues	42	84
Organisational issues	42	84
Patient-related issues	43	86
Both organisational and patient-related issues	35	70
All four elements	31	62

This does not mean that organisational and patient-related issues are included as often as economic issues, since a precondition for reports included in this sample was that organisational and/or patient-related assessments were included. Reports only including economic and/or technology-related assessments were excluded from this study.

Purpose

In all but one report the purpose of the HTA was clearly stated. This was most often to generate knowledge and/or to support decision-making (Table 3.4). One-quarter of reports were undertaken to support implementation of a technology.

About half of the technologies assessed had a therapeutic purpose and 20-25% were preventive or diagnostic technologies. Organisational/administrative and supportive tech-

2 The 'gross' and the 'net' HTA lists can be obtained by contacting the authors.

nologies were less commonly assessed and none of the reports assessed a rehabilitative technology. About half the reports assessed a procedure and about one-third assessed a drug or a device (Table 3.4).

Target group

One-quarter of the HTA reports did not explicitly state the target group. In line with the decision-making/information gathering purpose of many HTAs, politicians and official authorities were the usual target group, but managers or administrators and health professionals were also common target groups for the report (Table 3.4).

Life cycle of the technology

All but three reports explicitly stated a time horizon for the technology. Two-thirds of the reports assessed an accepted technology, and about one-third assessed a new technology. Emerging and obsolete technologies were seldom assessed (Table 3.4)
The purpose(s) of the HTA assessment, the intended target group and the nature of the technology and its lifecycle probably influence the scope of any specific HTA. Furthermore, the time frame within which a report is developed and the multidisciplinary extent of the assessment team might influence the extent to which organisational and patient-related issues are included in an HTA. It is not within the scope of this review to elaborate further on this issue, however, as that would require an assessment of all the 382 reports included in the 'gross' list.

Table 3.4: General characteristics of the study sample (n=50 reports)

(N.B. An HTA could have several purposes, be targeted towards more than one group, and assess more than one technology. Likewise a technology could have more than one purpose and nature)

	Frequency	%
Published by a national HTA agency	33	66
Published by a regional HTA agency	11	22
Unknown publisher	6	12
Clearly stated purpose of the HTA	49	98
Generation of knowledge	43	88
Basis for decision(s)	33	67
Basis for implementation	12	24
Resource utilisation	6	12
Quality control	4	8
Clinical purpose of the technology		
Diagnostic	10	20
Preventive	14	28
Therapeutic	24	48
Organisational/administrative	5	10
Supportive	2	4
Other	2	4
Nature of the technology		
Drug	17	34
Device	14	28
Procedure	24	48
Other	6	12
Assessment against an alternative technology	33	70
Stated target group	37	74
Politicians/official authorities	33	89
Management/administration	17	46
Professionals/ medical staff	19	51
Patients	3	8
Other (e.g. general public, non-governmental organisations)	4	11
Time horizon of the technology	47	96
Emerging technology	4	9
New technology	17	36
Accepted technology	31	66
Obsolete technology	1	2

4 Organisational assessments in HTA reports

In this chapter the organisational assessments included in the HTA reports are discussed in relation to two questions: i) to what extent are different organisational issues included, and ii) how are these issues included and handled. This chapter thus addresses the second purpose of the study: *'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'.*

The aim of this chapter is to provide the reader with an overview of the types of organisational assessment that are included in the HTA reports. This should help those planning an HTA to determine which organisational issues might be relevant to include, how they can be assessed and the perceived utility of the assessment.

The number of HTA reports that assess organisational issues is first presented, together with the frequency of stating a purpose and/or research questions in relation to this assessment. The four main categories of organisational issues (structural, process, control/evaluation and cultural/environmental) are then discussed in turn with respect to the frequency of their inclusion and the manner in which they are evaluated. This includes i) an overview of the content of the issues assessed, ii) descriptions (with illustrative examples) of the included issues and the level of detail given in the HTAs and the method of presentation for each category/subcategory, iii) discussion of how the information presented in HTA reports can assist decision-makers and users of technologies, and iv) a list of issues within each organisational category that could be relevant for inclusion when undertaking an HTA.

In relation to the illustrative examples provided below it should be noted that they were first and foremost chosen for their ability to illustrate specific issues related to the content. An attempt has been made to use a range of reports for these examples rather than taking examples from a limited number of reports. Assessment of the appropriateness of the methodology and language used in the individual HTA reports was not the focus of this chapter and was not considered when choosing the examples. Different concepts (none, very few, few, quite a few, some, many, most, almost all, all) are used to describe the relative number of reports that have included or assessed specific issues in a specific way within a specific subcategory and/or issues of this subcategory. The concept 'very few' refers to a quantity that is smaller than 'few', 'few' to a quantity that is smaller than 'quite a few, 'quite a few' to a quantity that is smaller than 'some' and so on.

The lists presented under 'Issues for consideration in future HTAs' are based on the foregoing discussion of issues included in the organisational categories. In this discussion section the authors discuss the review findings in relation to their own professional insights generated through their primary and HTA education and practical experiences of conducting HTAs. The discussion section thus incorporates the authors' views, and the list of issues for consideration in future HTAs are not limited to those that were included in the 50 reports but goes beyond that to include issues that would be desirable to include in HTA assessments.

4.1 HTA reports including organisational assessments

Of the 50 HTA reports reviewed, 42 included an organisational assessment (for further details see Appendix 3). Of the eight reports that did not include an assessment of organisational issues, two stated a reason for not doing so (the technology was not expected to have any organisational consequences).
All but two of the 42 reports explained why an organisational assessment was included, and one-third of the reports included specific research questions regarding organisational issues (Table 4.1).

Table 4.1: HTA reports presenting purpose and research questions for organisational assessment (n=42)

	Yes	%
Stated purpose for including organisational issues	40	95
Formulated research questions related to organisational issues	14	33

About half of the 40 reports described the purpose of the organisational assessment in a less precise manner; it was either included in an often broad and vague description of the HTA's general purpose or was only possible to deduce from the introductory text of the HTA. The other half of the reports were more explicit and included shorter or longer statements of why an organisational assessment was included, e.g. *'… to assess the demand and need for capacity extension of pharmacy based stop-smoking courses and to assess recruitment possibilities through cooperation with GPs'* (Report no. 43, p. 13-14).

The degree of detail provided about the purpose of organisational assessment also differed between reports, ranging from a broad and more general goal (e.g. to consider organisational aspects or consequences of the technology in question) to more defined goals that focused on one or a few specific organisational aspects (e.g. to describe practice; to shed light on the technology's diffusion; to consider the implementation of the technology).

The *formulation of research questions* also differed between reports, but these questions were usually quite specific, e.g. '*In which ways may influenza vaccination be offered?'* (Report no. 17, p. xiv/11). A few reports presented more vague questions, e.g. *'How does the technology affect patient and organisational conditions?'* (Report no. 47, p. 17).

In terms of the *content of the organisational assessment,* all 42 HTA reports included process issues related to the use of the technology (e.g. work flow, interactions between actors). Issues related to organisational structure (e.g. physical and resource structures, economic consequence) and control/evaluation (e.g. methods of quality control, division of responsibility) were also often included. Cultural/environmental issues (e.g. physical and psychological working environment) were included in just over half of the reports (Table 4.2).

Table 4.2: Organisational categories assessed in HTA reports (n=42)

	Frequency	%
Structural issues	39	93
Process issues	42	100
Control/evaluation issues	34	81
Cultural/environmental issues	24	57
Other organisational issues	0	-

4.2 Structural issues

4.2.1 Content

As indicated in Table 4.2, 93% of the 42 HTA reports included an assessment of structural issues (for further details see Appendix 3). Most of these reports included assessment of issues encompassed by the subcategories of physical, resource and legislative structures and diffusion of the technology. Fewer reports assessed economic consequences and effects on incentive structures (Table 4.3).

Table 4.3: Subcategories of structural issues included in HTA reports (n=42)

	Frequency	%
Formal organisational structure	30	71
Physical, resource and legislative structures	38	90
Diffusion of the technology	31	74
Economic consequences	26	62
Effects on incentive structures	20	48

4.2.1.1 Formal organisational structure

The handling of aspects related to formal organisational structure ranged from simple, brief descriptions of where the technology is placed in an overall organisational structure (e.g. centralised or decentralised, public or private sector) to discussion and argumentation in relation to the organisational structure and placement. Some reports discussed the historical development of the technology, current placement, considerations regarding future placement, and interactions between the technology's historical development and its current placement (see example in Box 4.1). Other reports compared theory, law texts or international literature to the national context and discussed plausible organisational placements. A few reports discussed the division of responsibility between different sectors.

Box 4.1: Example of consideration of a technology's historical development and its current organisational placement

Report: no. 15

Technology assessed: Blood-saving technologies or alternatives to blood transfusion

Data used: Literature

Way of handling the issue in question: In-depth description of the overall organisation of the national transfusion service. The historical development of the service is described, and reasons for changes in the overall structure of the service are discussed along with the consequences of the current service structure (p. 15-17).

Quote: *... In the Capitals Hospital Community four blood banks were united in one head blood bank and three satellites. Centralisations of this kind enable better utilisation of donor blood, increased quality securing and reduction of resource utilisation. On the other hand, one of the most important disadvantages of this is that the blood needs to be transported between hospitals. (p. 16-17)*

4.2.1.2 Physical, resource and legislative structure

The reports varied greatly in the issues that were assessed under this subcategory, while the handling of the issues also varied from simple, brief descriptions (most reports) to detailed argumentation and discussion.

Activity level and demand/supply: Quite a few reports described the current activity level and the relationship between the demand for and supply of the technology. Some reports compared the national activity level to the international level, while others considered

the future demand for the technology. A few reports discussed the consequences of current and expected future relationships between supply and demand in regards to, for example, access to the technology and capacity requirements (see example in Box 4.2).

Box 4.2: Example of discussion of current and expected future relationships between supply and demand

Report: no. 45

Technology assessed: Perinatal intensive care

Data used: Survey and literature

Way of handling the issue in question: Discussion of the expected future demand for the technology in relation to the level of supply, and what consequences this might have for access to the technology, patient care and required capacity of intensive care cots and staff (p.45-52).

Quote: *...Provided that the conservative policy on the referral to [intensive care] of seriously premature neonates is maintained only a small additional number of infants will require [intensive care]. If the treatment-policy differences between perinatal centres widen, and this trend is considered desirable, it will be necessary to apply an average capacity utilisation ceiling of 80 per cent, since 100 per cent occupancy would mean that mothers were regularly denied access to the centre whose policy most closely coincided with the parents' views. (p. 50)*

Physical facilities: Many reports briefly described the various physical facilities required in relation to the use of the technology, e.g. equipment, devices, space. A few of these reports assessed current fulfilment of these requirements, with some making comparisons with international standards. Other reports considered future facility requirements, and a few related this to current and expected activity levels.

Physical placement: The technology's physical placement was described in different ways, ranging from simple descriptions of which ward, specialty or in- or outpatient setting the technology was placed in to a discussion of reasons for this placement and considerations of future scenarios regarding physical placement and its relation to facility requirements.

Capacity: Capacity was an issue often described in the reports. While many reports briefly mentioned capacity in relation to staff and access to machinery (see example in Box 4.3), other reports also looked at geographical differences in access to machinery, progress made towards ensuring adequate capacity and the current fulfilment of needs. A few reports included a description of access to the technology and logistics related to the use of the technology. One report discussed the relationship between logistics and the physical placement of the technology.

Box 4.3: Example of brief mentioning of staff capacity requirements

Report: no. 13

Technology assessed: Chlamydia home tests

Data used: Survey

Way of handling the issue in question: Brief mentioning of staff capacity requirements in relation to different parts of the working process regarding both implementation and use of the technology.

Quote: *... Function in relation to the coordination and sending out of screening offers and samples [headline]*

Staff capacities needed: Manager (MPH-educated etc.) – 0.5 full-years work. Secretary – 1.5 full-years work. Computer scientist – 0.2 full-years work. EDB-assistant – 0.1 full-years work (p. 87)

Legislation: Legislative issues relevant to the use of the technology were briefly handled in a few reports. Most simply described the legal foundation or the legal framework of the technology, but one report included more detailed considerations of the historical development of legislation relevant to the use of the technology and of the possible future legal developments.

4.2.1.3 Diffusion of the technology

Many different issues have been assessed under 'diffusion of technology'. Although some assessments were limited to brief descriptions, many reports discussed different aspects related to the technology's diffusion.

Diffusion procedures: Many reports described the technology's current diffusion within different organisations in relation to prescription procedures and requirements; a few reports also discussed diffusion between different health sectors. Other reports described and discussed legal aspects and the need for standards and legislation related to the technology's diffusion. A few reports looked at the historical development of the diffusion and its implications for the future diffusion process.

Actors involved in the diffusion: Most reports described the specific actors involved in the diffusion of the technology. Many reports described the various actors' responsibilities and level of decision-making in inter- and intraorganisational diffusion. Some reports discussed the advantages and disadvantages of various actors' involvement in diffusion decision-making, and others discussed reasons for the involvement of different actors in the diffusion process.

Diffusion factors: Some of the reports described the various factors that affect the diffusion process (see example in Box 4.4), and a few discussed the success of different initiatives in facilitating the diffusion of the technology. One report described health professionals' rights with respect to participation in the diffusion process, and discussed the associated moral, ethical and legal dilemmas. A few reports described health professionals' personal attitudes towards diffusion of the technology and why these attitudes existed.

Box 4.4: Example of discussion of factors that affect the diffusion process

Report: no. 43

Technology assessed: Stop Smoking Courses

Data used: Focus group interviews

Way of handling the issue in question: Discussion of factors that affect the diffusion process, and ways in which these factors could be handled.

Quote: *... Overall, the lack of information has consequences for the GP's use of the courses... A great part of the GPs remember having received information about the existence of the courses. But they cannot recall having received information about the extent and content of the courses... the GPs also call for information about the effect and quality of the courses... the consequences [of not receiving this information] are, that the GPs only to a limited extent recommend and refer the patients to the courses.* (p. 76-77)

4.2.1.4 Economic consequences at an organisational level

Most assessments within this subcategory were restricted to simple and brief descriptions.

Resource use, financing and budgeting: Most reports described the required changes in resources and level of investments; some reports did this briefly and in a less precise way, while others presented details of the resources and investments needed (see example in Box 4.5). One report discussed the possibilities for optimising current resource use. Many reports mentioned issues related to budgeting and financing of the technology; most described the budget and economic arrangements that the technology was part of, and a few reports considered budgetary consequences and the associated need for changes and legal issues. One report described import/export issues and international exchanges of resources in relation to the use of the technology.

Box 4.5: Example of detailed consideration of resources and investments needed

Report: no. 40

Technology assessed: Positron Emission Tomography (PET)

Data used: Literature

Way of handling the issue in question: Detailed description and consideration of the educational resources (time and money) that will be required by the introduction of PET technology (p. 39-40).

Quote: *... the training of the doctors, who should work with PET, will depend on the level of ambitions. Study visits for a couple of weeks can be relevant when starting to use methods well-established at foreign centers. The costs of this are unlikely to exceed 50.000 NOK per examination unit*. (p. 40)

4.2.1.5 Incentive structures

Approximately half the reports described issues related to incentive structures, and did so in a similar way.

Types of incentives: The different types of incentives (e.g. economic, political, professional and patient incentives) were described very briefly, and few reports provided more detail about these incentives and the effect they might have (see example in Box 4.6). One report considered ways of diminishing unwanted incentives, and another discussed the need for incentives.

Box 4.6: Example of considerations of economic incentives

Report: no. 1

Technology assessed: Liquid oxygen therapy at home

Data used: Literature

Way of handling the issue in question: Considerations of economic incentives affecting the use of the technology (p. 5-6)

Quote: *... due to cost pressure within the system and decreasing reimbursement for home oxygen therapy by the government, the use of liquid oxygen in the United States has declined to less than 10% of patients on home oxygen. (*p. 5)

4.2.2 Methods

The HTA assessments of structural issues were based on different types of data, but typically on secondary data. Some reports used primary data that were generated through surveys, expert assessments, interviews, observations or organisational documents; a few reports were based on debates or on data for which the source was unclear and could not be identified – most often these assessments appeared to be based on normative discussion.

Some reports combined different types of data, often secondary data combined with data from interviews, surveys or expert assessments. The reports that included discussion and argumentation in relation to structural issues typically based their assessments on a combination of different data types. An exception is the subcategory of diffusion, where only a few of the more in-depth assessments were based on a combination of data; instead they were mostly based on secondary data only.

4.2.3 Discussion

Although most of the reports (39/42) in one way or another included assessment of structural issues, they varied greatly in how they handled these issues. While many assessments were restricted to brief descriptions or simply mentioning of the issues, some reports included argumentation and discussions about various structural issues and have produced knowledge that could be relevant for future HTAs.

This is for instance so for the HTAs that presented in-depth assessments of the overall *organisational placement* of the technology and its consequences. The example in Box 1 describes a report that in-detail described the organisation of the national transfusion service; this sort of information can be used as a basis for future planning and decision-making regarding the technology's organisational placement, e.g. should it be centralised or decentralised, what traditions or special advantages would be relevant to consider before making a decision? Such in-depth knowledge about the context of the technology's organisational placement and the different aspects that are relevant to consider will also aid those who are considering the introduction of a technology into their own context, e.g. in what ways are the contexts similar to and different from each other, what are the advantages and disadvantages of different organisational structures?

HTAs that discuss consequences for the *relationship between supply and demand* (as illustrated in Box 4.2) provide a more informed basis for decision-making regarding future arrangements for the technology, e.g. the possible consequences to patients of not increasing supply, how an increase in supply would affect capacity demands. An in-depth discussion of how the activity level might affect, for example, the need for specialisation, would provide readers with valuable knowledge for future organisational planning, e.g. does the need for specialisation influence decisions about the degree of centralisation of the technology. Very few HTA reports considered different ways of meeting capacity demands. A few reports evaluated current status, but the reports seldom went further than this.

A few HTAs gave detailed descriptions or considerations of different *incentive structures* in relation to the use of the technology, e.g. how incentive structures might affect the use of the technology (illustrated in Box 4.6) or how different incentives could be strengthened or reduced. Such information is again important in planning the implementation or further diffusion of a technology.

Economic consequences were rarely discussed in the organisational assessments of the HTA reports. However, this may be due to the inclusion of a separate economic element in many of the HTAs assessed (which was not reviewed in the current study). The real extent to which a technology's economic consequences at an organisational level are considered in HTAs is thus not possible to assess on the basis of the current study. Nevertheless, this is a relevant issue especially in decision makers' choice between alternative technologies. An example of this was given in Box 4.5, which described an HTA that estimated the educational resources required, in terms of both time and money, for the introduction of a technology.

4.2.4 Structural issues for consideration in future HTAs

Depending on the given situation (e.g. the technology in question, the context and the purpose of the assessment), various structural issues can be relevant for inclusion when designing and undertaking an HTA. Based on the discussion above the following issues might be considered for inclusion in future HTA:

- Formal organisational structure of the technology, e.g. centralised or decentralised, public or private sector
- Activity level and demand/supply of the technology (and the effects these might have at an organisational level)
- Physical placement of technology
- Physical facilities required in relation to the implementation and use of the technology (and possible ways of meeting these demands)
- Capacity requirements in relation to the implementation and use of the technology (and possible ways of meeting these demands)
- Legislation relevant to the use of the technology
- Diffusion procedures
- Actors involved in the diffusion of the technology
- Factors affecting the diffusion process
- Economic consequences of the technology at an organisational level, e.g. resource use, financing and budgeting
- Types of incentives and their effects on the use of the technology

4.3 Process

4.3.1 Content

As indicated in Table 4.2, all 42 HTA reports included an assessment of process issues (for further details see Appendix 3). Of the different process subcategories, more than three-quarters of the reports mentioned issues related to work flow, actors and consequences for staff skills and resources. Interaction and communication, and potential barriers and bottlenecks were included in more than half of the reports (Table 4.4).

Table 4.4: Subcategories of process issues included in HTA reports (n=42)

	Frequency	%
Work flow	35	83
Actors involved	37	88
Staff competences and resources	34	81
Interaction and communications	27	64
Potential barriers and bottlenecks	24	57

4.3.1.1 *Work flow*

Many of the HTA reports included detailed descriptions of work flow issues. A few reports also presented more in-depth discussion. A variety of work flow issues were assessed; some of these were included in many reports, while other issues were more rarely included.

Patient flow: The majority of HTAs that assessed work flow issues included de facto descriptions of patient flows or work processes, in varying amount of detail. Some reports provided stepwise descriptions of patient flows and work processes (see example in Box 4.7) often combined with graphic illustrations, while other reports presented more superficial listings of patient flows. Some reports described patient flow for the full course of treatment, while others focused on the phase of treatment that were most directly related to the technology. A few reports considered different aspects of the structure and form of the patient flow, and one report compared the optimal patient flow with the typical patient flow.

Box 4.7: Example of a comprehensive description of work processes related to the use of a technology

Report: no. 13

Technology assessed: Screening for Chlamydia with home tests

Data used: Survey

Way of handling the issue in question: Comprehensive description of all the different elements of the work processes related to the use of the technology. For each element in turn, there is consideration of why the element is important, how and by whom it can be conducted and how much time/resources are needed for that part of the process (p. 85-95).

Quote: *Patients whose results show that they have been infected with Chlamydia will be asked to see a GP for treatment and partner detection. Together with the analysis results they will receive a letter, which they should give to their GP... The GP ...[also] inform the infected patient about the necessity of partner detection... the GP should have "post free" partner-packages with home tests, which they can give the patients, so that they can forward them to their partner(s) over the last 12 months... (p. 90-91*

Routines and procedures: The reports often included an assessment of the different routines and procedures related to the use of the technology. This was typically done by including a description of how the technology is or should be applied in practice and by whom. A few reports compared national routines and procedures to international routines.

Changes in routines and procedures: Some reports described needs for changes in routines and procedures. Some of these simply stated that such a need exists, others detailed the kinds of changes needed and a few reports discussed the feasibility of new routines and procedures. Some reports included descriptions or considerations of how procedural changes might affect the division of responsibility and tasks between different actors. One report made a comparison between the routines that actors think they use and the routines that they actually use.

Practice models: A few reports considered practice models of a technology. In some instances this was a description of how a technology would work its way through the organisation and lead to the expected effects, i.e. the causal link between different actions or procedures and the achievement of an effect. While a few reports viewed the full (or nearly the full) chain of causal links, most reports focused on a few specific aspects or links.

Use of time: A few reports described the time used on different tasks related to the patient flow, and some of these considered what consequences new technologies or changes of routines might have on the use of time.

4.3.1.2 Actors involved

Identifications of involved actors: Many of the reports identified the different actors and organisations involved with the use of the technology. Some simply listed all the different actors who were involved in either the whole course of treatment or in the work directly related to the use of the technology. Other reports included more detailed descriptions of the involved actors, their areas of responsibility over the course of treatment or in the procedures directly related to the use of the technology, and their physical placement in different organisations and sectors. A few reports included comprehensive considerations of why one type of actor, and not another, should be involved and given responsibility for various tasks.

Role perceptions: A few reports described different actors' perceptions of roles within the work processes. Some reports concentrated on the actors' perceptions of their own role, while others also considered actors' perceptions of other actors' roles and of division of responsibility in relation to the use of the technology.

Need for and recruitment of new types of actors: Some reports considered the need for new actors in the use of the technology. This was done by simply stating that new actors would be needed or by listing the new types and numbers of actors needed or, in a few cases, by discussing why new actors would be needed, the roles and responsibilities they should be given and the challenges that this would create. One report described, for example, expectations regarding the types of actors needed and the roles to be fulfilled in order to implement and use a new technology (see Box 4.8). A few reports also discussed possibilities for recruitment of new actors and how this might affect the technology's implementation.

Box 4.8: Example of considerations of future needs for new types of actors

Report: no. 47

Technology assessed: Dietary guidance in the primary heath sector

Data used: Interviews and documents

Way of handling the issue in question: Comprehensive consideration of the (new) actors that will be needed in the future and of the functions and roles that will need to be fulfilled in order for the implementation and use of the technology to be successful (p. 44-47).

Quote: *... It is expected that a new specialist function among dieticians will be created, since public dieticians have usually all been employed in the hospital sector. With a structure as the one described, dieticians will not be part of the resource-demanding red tape of the public hospital sector (p. 45)... there also appears to be a need for secretary assistance, since "non-dietician" work takes up 20 % of each dietician's time. (p. 46)*

4.3.1.3 Personnel skills and resources

Skills needed: Many reports described the skills and knowledge required by the involved actors in order to fulfil the tasks associated with the technology. Some did this in a detailed manner while others gave more vague descriptions. A few reports discussed why these needs exist. Some reports focused on current levels of knowledge and skills (and the reasons for these), others on the new skills and training that would be needed. One report described how skills had developed historically, and how they could be maintained in the future.

Education and training: Some reports also included considerations of the educational and training initiatives needed to develop the necessary skills. Descriptions were given of the desired content of educational initiatives, type of teaching professional, location of teaching, amount of time required and, occasionally, the professional theories on which the education and training should be based. One report, for instance, included considerations of the purpose and structure of a specific training program (see Box 4.9). Some reports described current educational and training options, and a few considered how education and training can be ensured in the future.

Box 4.9: Example of considerations of the purpose and structure of a training program

Report: no. 32

Technology assessed: Diabetic retinopathy screening

Data used: Survey, literature and expert assessments.

Way of handling the issue in question: Considerations of both the purpose and structure of a specific training program: how the program should be structured, who should participate, who should supervise the program, on what basis these decisions should be made (p. 44-45).

Quote: *...The training programme should be modular to accommodate the needs of different groups (and backgrounds) of those that might participate (e.g. nurses, photographers, optometrists, medical technical officers and medical practitioners) and the needs in different localities. It may be provided by a number of different providers under the auspices of a single national accreditation body but training should be undertaken according to national standards and quality assurance. Outcome of training should include clinical and technical skills, patient management and confidentiality, communication skills, quality assurance and audit, and IT skills. (p. 44)*

Quality and standardisation of education and competence: A few reports discussed the demands made on training and education, and the quality of current training and education. Other reports discussed the need for uniformity and standardisation of training and a minimum level of competency. A few reports considered different strategies for the achievement of these goals.

4.3.1.4 Interaction and communication

Ways of interacting and communicating: Many reports described communication, coordination and cooperation in relation to the technology's use. Some reports simply described the different participating actors, organisations and sectors and their responsibilities, while others illustrated the various interactions graphically, with varying degree of detail (see example in Box 4.10). A few reports included patients' assessments of the internal communication and coordination within the organisation of treatment. One report described actors' experiences of cooperation with other actors, and their preferences for future cooperative partners.

Box 4.10: Example of illustration of interactions within and between sectors

Report: no. 19

Technology assessed: Triple test for pregnant women.

Data used: Literature.

Way of handling the issue in question: Graphical overview and illustration of the interaction (mostly referrals) within and between sector at both local and national level. The actors at each level are identified and the links between them are illustrated (p. 25).

Quote: *See graphical illustration on pages 25.*

Changes in ways of interacting and communicating: Many reports described a need for new forms of inter- and intraorganisational communication, coordination and cooperation. Many reports simply stated such a need, while a few described the requirements in more detail and considered how they may fit into the current organisation. A few reports discussed why these new requirements had emerged. One report considered strategies for meeting these requirements in the future.

4.3.1.5 Barriers and bottlenecks

Experienced barriers: These were mostly those that hinder implementation and/or use of the technology, e.g. negative attitudes or lack of motivation on the part of actors. Many reports did not provide further detail, but simply described the required changes. One report gave a comprehensive description of different actors' perceptions as to why the technology was not used as planned (see Box 4.11).

Box 4.11: Example of comprehensive description of actors' attitudes towards technologies

Report: no. 15

Technology assessed: Blood-saving technologies or alternatives to blood transfusion

Data used: Survey

Way of handling the issue in question: Comprehensive description of different actors' and non-users' attitudes towards various medications, and their reasons for not using these. Analysis of attitudes both within and across different professional groups (p. 75-82).

Quote: *...Attitudes towards the medications: ... the statements "too expensive", "alternatives more effective" and "Not fully convinced it does work" shared the third place (p.76)... As to the future use of PAD, the society was less optimistic – among other things because a certain opposition from the blood banks is experienced ... (p. 82)*

Bottlenecks: Some reports simply mentioned that bottlenecks existed, e.g. economic and resource-related, or due to lack of the necessary knowledge or skills. Other reports went into more detail and discussed the content and consequences of these bottlenecks on, for example, the effect of the technology or access to the technology, and a few included considerations of why bottlenecks exist. The reports varied in the detail given to possible solutions for bottlenecks; a few discussed the feasibility of different solutions.

4.3.2 Methods

A little over half of the reports that assessed process issues based their assessments on one kind of data, typically secondary data. The remainder of the reports used a combination of data types, typically by combining secondary data with data generated via surveys, interviews or expert assessments.

While primary data sources were typically surveys or interviews, they also included expert assessments, observations and organisational documents; a few reports were based on debates or on data for which the source was unclear and could not be identified.

The vast majority of reports that provided comprehensive and more detailed considerations of process issues based their assessments either on primary data or a combination of primary and secondary data.

4.3.3 Discussion

All 42 HTA reports included process issues in their organisational assessment, though with varying degree of detail. Many reports gave detailed descriptions and/or discussions

of the different issues, thus providing useful knowledge for future HTAs as well as for current and future users of technologies.

Reports describing work flows, procedures and routines associated with the use of a technology typically provided a detailed overview of the processes involved (as illustrated in Box 4.7). A description of the work processes throughout the whole treatment course (rather than only those directly related to the use of the technology) is particularly useful as it highlights the importance of the context in which the technology is placed.

A few HTAs reported on the level of agreement between actors regarding their actual routines and procedures (or what they should do in the future), the manner in which these are performed and why they are performed. This would be a useful inclusion in future HTAs as it acts as a learning process for the involved actors, and offers them an opportunity to review the appropriateness of their work processes and to consider alternative approaches. New users of a technology would also benefit from a detailed description of the work flows, procedures and routines associated with the use of the technology.

HTAs that describe and discuss the type of actors and skills that are needed for the implementation of a technology, and the division of responsibility between the actors, provide information that is extremely useful to both decision-makers and the professional groups involved. Using this information, decision-makers and managers can more appropriately plan the recruitment and education of the required actors with the necessary skills and competence. Box 4.9 provided an example of an HTA that described the purpose and content of an educational course, and the resources required (e.g. time, financing, actors, physical location). For the professionals directly involved in using a technology, a detailed discussion of the actors and their roles can promote a better understanding of their own and others' roles, e.g. what do others expect of me, what can I expect from others. This may lead to a review of and perhaps changes to current staffing and divisions of responsibility. Such considerations may be particularly useful when the HTA focuses on a choice between alternative technologies, e.g. what consequences will the different technologies have on the type of actors to be involved and their roles, skills and educational needs.

In practice, uncertainties about the interactions and communication required for the successful implementation of a technology can lead to problems, and hence poorer than expected effects of the technology. More comprehensive assessment of these interactive processes in HTAs (e.g. who should contact who, about what, when and how) would help ensure that important links are not missed and that the implementation process does not come to a standstill. Assessment of current inter- and intraorganisational interactions that relate to the whole context and not only the direct use of the technology (as illustrated in Box 4.10) can provide useful input into decisions about the uptake of new technologies as well as assist in identifying problem areas in the current organisational set-up and possible solutions.

The development of comprehensive practice or programme models of the use of a technology can often assist in identifying the various issues and challenges presented by current, alternative or new technologies. Consideration of how the technology is implemented throughout the organisation and why it produces certain effects and outcomes (e.g. type and timing of work processes, actors, skills, resources, interactions, communication, division of responsibility) can help clarify where and why barriers and bottlenecks arise. It could also be relevant for HTAs to assess the current and/or likely future degree of suc-

cess in overcoming such barriers, as well as the feasibility of making the necessary changes.

4.3.4 Process issues for consideration in future HTAs

Depending on the given situation (e.g. the technology in question, the context and the purpose of the assessment), various process issues can be relevant for inclusion when designing and undertaking an HTA. Based on the discussion above the following issues might be considered for inclusion in future HTA:

- Patient flow
- Routines and procedures
- Use of time
- Changes in routines and procedures
- Practice models
- Identification of the different actors involved
- Role perceptions
- Need for and recruitment of new types of actors
- Skills needed
- Education and training
- Quality and standardisation of education and achieved skills
- Ways of interacting and communicating
- Changes in ways of interacting and communicating
- Barriers experienced and possible solutions
- Bottlenecks and possible solutions

4.4 Control and evaluation

4.4.1 Content

As indicated in Table 4.2, 81% of the 42 HTA reports included assessment of control and evaluation issues (for further details see Appendix 3). Most of these reports included issues related to the subcategory of control and evaluation systems, while fewer included issues related to control and evaluation *responsibility* (Table 4.5).

Table 4.5: Subcategories of control and evaluation issues included in HTA reports (n=42)

	Frequency	%
Control and evaluation systems	33	79
Control and evaluation responsibility	21	50

4.4.1.1 Control and evaluation systems

Many different issues were included in this subcategory. There was little variation in how these issues were assessed, however, with the majority of reports simply including brief descriptions of the issues.

Procedure and content: Most of the reports included simple descriptions of the different procedures related to quality control and evaluation and of the different parameters and indicators on which this control or evaluation was based. A few reports included more in-depth considerations of the reasons for the development of such procedures and indicators (including where and by whom) and of the purpose of the control systems (e.g. how the use of the technology is quality assured), see the example in Box 4.12. Very few reports discussed the results of quality control and evaluative processes.

Box 4.12: Example of consideration and discussion of how to monitor the use of a technology

Report: no. 13

Technology assessed: Screening for Chlamydia with home tests

Data used: Survey

Way of handling the issue in question: Discussion of how screening for Chlamydia is currently monitored (the kinds of data generated, the organisations involved), which parameters are used (with which data requirements), the purpose of screening and its future organisation (changes which should be implemented) (p. 92-94).

Quote: *Chlamydia monitoring is currently based on centralised laboratory monitoring. The counties' departments for clinical microbiology report the number of performed tests together with the number of positive tests distributed between sex and gender to the State Serum Institute... The purpose of the monitoring [is] to provide information, which constitutes the best possible basis for assessment of the effect of the screening strategy and for making decisions about changes of this [strategy]...(p. 93)*

Systems and standards for evaluation and quality control: Some reports included assessments of the future need for systems and standards in relation to control of the use of a technology. A few reports considered in detail the purpose of such systems and standards, how they should be developed and the preferred content.

Form and content of guidelines: Some reports included descriptions (form and content) of guidelines for the use of the technology, with varying degree of detail; a few reports included examples of the different guidelines used. In some cases the development, form and use of national guidelines was compared with international guidelines.

4.4.1.2 Control and evaluation responsibility

While many reports include only a brief mention of issues in this subcategory, some reports discuss them in more depth.

Placement of responsibility: Many reports included brief descriptions of the location of responsibility for evaluation and/or quality controls in the overall organisational structure

or a single organisation. A few reports detailed the central actors involved and former location of responsibility, while others discussed possible future locations and divisions of responsibility, e.g. which actors should have responsibility for which aspect of quality control (see example in Box 4.13). Some reports included an assessment of the skills needed by actors responsible for evaluation and quality control. One report discussed practice in relation to theory and included more in-depth consideration of those involved in quality control and evaluation.

Box 4.13: Example of considerations related to location of responsibility for quality control

Report: no. 28

Technology assessed: Troponin testing services

Data used: Survey and literature

Way of handling the issue in question: In-depth description and consideration of where and with whom the responsibility for quality control of the use of the technology is and could be placed (p. 7/9-7/15).

Quote: *... The Medical Devices Agency (MDA)... highlights that clear SOPs [standard operating procedures] and systems must be in place for point-of-care testing service to function effectively... To ensure this takes place it is recommended that a ´liaison group´ be set up at each center with representation from all stakeholders. The group could have responsibility for protocols that cover the whole patient pathway, and not solely laboratory aspects. (p. 7/12)*

Development of standards and guidelines: Many reports simply described the need to develop standards and guidelines for the use of the technology. A few reports discussed reasons for and content of this need. Several reports considered who should be responsible for and involved in the development of these standards and guidelines.

4.4.2 Methods

Most of the HTA assessments of control and evaluation issues were based on secondary data. A few reports used primary data that were generated through surveys, expert assessments, interviews, observations or organisational documents, and a few reports were based on debates or on data for which the source was unclear and could not be identified.

Some of the reports combined different types of data, often secondary data combined with data from surveys or expert assessments. Nearly all the reports that included more than simple descriptions of the control and evaluation related issues based their assessments on a combination of different types of data.

4.4.3 Discussion

Many of the HTA reports (33 out of 42) assessed control and evaluation issues. Although many of these simply mentioned or briefly described these issues, some reports considered different aspects in more depth.

The inclusion in HTAs of in-depth descriptions of the procedures and systems used in quality control and evaluation of a technology generates valuable information for future decision-making about methods for quality control. Box 12 presented an example where the HTA discussed both the current and the preferred monitoring processes. Such a discussion provides reasons for the current structure of the control system and highlights the factors to consider in designing future quality control systems and procedures, e.g. what are the most appropriate parameters; how should quality checks be conducted, how

can the relevant data and knowledge be generated. Although included by very few of the HTAs, it would also be relevant to review the results of current quality controls and the usefulness of the control system. Managers and technology users would benefit from this knowledge when judging whether or not the current control systems and procedures are sufficient and appropriately designed.

HTAs that discuss location of responsibility for the quality control and evaluation also generate valuable information for decision-makers and users of technology alike. Box 13 referred to a report that described in detail the options for location of responsibility for quality control of the technology. Such discussions can reveal possible consequences of choosing one option over another, for example, in terms of the kind of control needed and the resources or skills required. An even better informed basis for decision-making would be supplied if HTAs supplemented this information with a discussion of the relationship between theory and practice (e.g. differences between the ideal and the actual location of responsibility).

4.4.4 Control and evaluation issues for consideration in future HTAs

Depending on the given situation (e.g. the technology in question, the context and the purpose of the assessment), various control and evaluation issues can be relevant for inclusion when designing and undertaking an HTA. Based on the discussion above the following issues might be considered for inclusion in future HTA:

- Systems and standards for evaluation and quality control of the use of the technology
- Parameters and content of the control and evaluation systems
- Guidelines for the use and the control and evaluation of the use of the technology
- Current results of quality controls and evaluation, and usefulness of the quality control and evaluation system
- Responsibility for development of standards and guidelines for the control and evaluation of the use of the technology
- Placement of responsibility for the control and evaluation of the use of the technology
- Relationship between theory and practice, e.g. differences between the ideal, the perceived and the actual location of responsibility; differences between the ideal and actual measurement.

4.5 Culture and environment

4.5.1 Content

As indicated in Table 4.2, 57% of the 42 HTA reports included an assessment of cultural and environmental issues (for further details see Appendix 3). Issues related to the subcategory of culture were included in 40% of these reports; psychological and physical working environment issues in about one-fifth of reports, respectively, and impact on the outer environment in none of the reports (Table 4.6).

Table 4.6: Subcategories of cultural and environmental issues included in HTA reports (n=42)

	Frequency	%
Culture	17	40
Psychological working environment	7	17
Physical working environment	8	19
Outer environment	0	-

4.5.1.1 Culture

Organisational norms and values: The reports typically described the various norms and values within an organisation. Some reports described existing norms and values in relation to patient care, while others also considered norms and values related to the technology in question. One report considered, for example, the philosophy of care in relation to the patient and the technology (see Box 4.14). A few reports described the need for changes in relation to norms and values; most often, however, the report simply stated that such a need existed, without providing more detail.

Box 4.14: Example of a description of philosophy of care

Report: no. 2

Technology assessed: Portable oxygen therapy in chronic obstructive pulmonary disease (COPD)

Data used: Literature, interview and survey

Way of handling the issue in question: Consideration of the philosophy of care in relation to the patient group and the technology; the background to this philosophy (p. 30-32).

Quote: *... The philosophy of patient care also varies amongst home oxygen providers. Some clinical providers clearly focus on their role as specialists versus those that have adopted a more holistic approach. The providers of home care are known to create this kind of tension amongst providers and organisations involved in the delivery of home care – particularly for those working across traditional primary-secondary boundaries. (p. 32)*

Organisational attitudes: A few reports described patient wishes regarding professionals' attitudes towards patients and treatment. Others discussed the organisational attitude and culture that was necessary for successful use of the technology.

4.5.1.2 Psychological working environment

Technology's impact on psychological working environment: Of the few reports that included this subcategory, most focused on the way in which the technology affected different actors' psychological working environment, e.g. feelings of security and anxiety.

Job satisfaction: These reports included short descriptions or statements of how the use of the technology and different organisational factors (e.g. workload, stress, lack of resources, career options) affected different actors' job satisfaction.

4.5.1.3 Physical working environment

Health risks: Of the few reports including this subcategory, most described or stated that work related to the use of the technology may pose health risks to professional staff. One report also considered how health risks may be avoided, but most simply stated a need to further consider this (see example in Box 4.15).

Box 4.15: Illustrative statement regarding the need for further consideration of the physical environment

Report: no. 22

Technology assessed: Sugarbaker procedure

Data used: Expert assessments (unclear)

Way of handling the issue in question: A statement of the need for further consideration of the possible health risks to staff using the technology, but no further consideration of how and by whom this should be done (p. 23).

Quote: *... Exposure to low-dose intraoperative chemotherapy by health workers, by inhalation, contact, ingestion and injection, will need consideration. (p. 23)*

Ergonomics: A few reports mentioned ergonomic issues, such as physical changes made to work stations. One report briefly described the professionals' assessment of the physical working environment in general.

4.5.1.4 Outer environment

None of the reports include assessments of this subcategory.

4.5.2 Methods

Unlike the HTAs' assessment of other organisational issues, the majority of reports that assessed cultural and environmental issues based their assessments on primary data. These primary data were mostly generated through interviews, but also through surveys and in a few cases through expert assessments, observations and organisational documents. Some of the assessments of cultural and environmental issues were based on secondary data, but most often combined with primary data. About half the reports that based their assessments solely on primary data combined different kinds of primary data.

4.5.3 Discussion

Although about half of the HTA reports assessed cultural and environmental issues, the majority of these assessments comprised brief descriptions only. A few reports did include more detailed descriptions, however, and have generated useful information for future HTAs.

An organisation's norms, values and attitudes influence the manner in which a technology is used, the particular priorities that the organisation has, and the actors' understanding of why the technology is used the way it is. Knowledge about the organisational culture of those currently using the technology is valuable to both current and new users. Current users can use the information to review current values and attitudes and to consider the need for changes or improvements. New users can use the information to evaluate their own culture and to identify areas of similarity and/or divergence between the two cultures. They may be able to determine whether they will need to change their own norms, values and attitudes in order to use the technology in the same way and to produce the same effects. The HTA assessments would be even more useful if they included considerations of how these possible changes could be generated, by whom and using what resources.

Job satisfaction and the psychological working environment have consequences for the use of a technology and for the organisation in general, and thus also for the implementation of other technologies. Decision-makers and potential new users of a technology would benefit from the inclusion in HTAs of more specific consideration of how nega-

tive influences on job satisfaction and psychological working environment (and the physical working environment) could be avoided.

None of the HTAs reviewed assessed the effect that a technology might have on the outer environment. However, this may be due to HTAs including this issue under technological/clinical issues (which were not reviewed in the current study) rather than organisational issues. The real extent to which a technology's consequences for the outer environment are considered in HTAs is thus not possible to assess on the basis of the current study. Nevertheless, this is a relevant issue in the choice between alternative technologies, particularly in view of the current focus in many countries on the environment and ecological impact.

4.5.4 Cultural and environmental issues for consideration in future HTAs

Depending on the given situation (e.g. the technology in question, the context and the purpose of the assessment), various cultural and environmental issues can be relevant for inclusion when designing and undertaking an HTA. Based on the discussion above the following issues might be considered for inclusion in future HTA:

- Organisational norms and values
- Organisational attitudes towards patient care, treatment and the technology
- The technology's impact on the psychological working environment
- Impacts on job satisfaction
- Possible initiatives to avoid negative consequences on the psychological working environment
- The technology's impact on the physical working environment
- Health risks to staff
- Ergonomics
- Possible initiatives to avoid negative consequences on the physical working environment
- Environmental/ecological impact
- Possible initiatives to avoid negative consequences on the outer environment.

5 Patient-related assessments in the HTA reports

In this chapter the patient-related assessments included in the HTA reports are discussed in relation to two questions: i) to what extent are different patient-related issues included, and ii) how are these issues included and handled. The chapter thus addresses the second purpose of the study: '*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'.*

The aim of this chapter is to provide the reader with an overview of the types of patient-related assessment that are included in the HTA reports. This should help those planning an HTA to determine which patient-related issues might be relevant to include, how they can be assessed and the perceived utility of the assessment.

The number of HTA reports that include patient-related assessment is first presented, together with the frequency of stating a purpose and/or research questions in relation to this assessment. Six main categories of patient-related issues (patient information, psychological aspects, effect on quality of life, social issues, ethical issues and impact on the patient's financial situation) are then discussed in turn with respect to the frequency of their inclusion and the manner in which they are evaluated. This includes i) an overview of the content of the issues assessed, ii) descriptions (with illustrative examples) of the included issues and level of detail given in the HTAs and the method of presentation for each category/subcategory, iii) discussion of how the information presented in HTA reports can assist decision-makers and users of technologies, and iv) a listing of issues within each patient-related category that could be relevant for inclusion when undertaking an HTA.

In relation to the illustrative examples provided below it should be noted that they were first and foremost chosen for their ability to illustrate specific issues related to the content. An attempt has been made to use a range of reports for these examples rather than taking examples from a limited number of reports. Assessment of the appropriateness of the methodology and language used in the individual HTA reports was not the focus of this chapter and was not considered when choosing the examples. Different concepts (none, very few, few, quite a few, some, many, most, almost all, all) are used to describe the relative number of reports that have included or assessed specific issues in a specific way within a specific subcategory and/or issues of this subcategory. The concept 'very few' refers to a quantity that is smaller than 'few', 'few' to a quantity that is smaller than 'quite a few, 'quite a few' to a quantity that is smaller than 'some' and so on.

The lists presented under 'Issues for consideration in future HTAs' are based on the foregoing discussion of issues included in the patient-related categories. In this discussion section the authors discuss the review findings in relation to their own professional insights generated through their primary and HTA education and practical experiences of conducting HTAs. The discussion section thus incorporates the authors' views, and the list of issues for consideration in future HTAs are not limited to those that were included in the 50 reports but goes beyond that to include issues that would be desirable to include in HTA assessments.

5.1 HTA reports including patient-related assessment

Of the 50 HTA reports reviewed, 43 included patient-related assessment (for further details see Appendix 3). Of the seven reports not assessing patient-related issues, two stated a reason for not doing so (in one case the scope of the HTA was reduced, and in another the patient-related issues were to be presented separately).

All but three of the 43 reports explained why patient-related assessment was included, and more than one-third of the reports had formulated specific research questions regarding patient-related issues (Table 5.1).

Table 5.1: HTA reports presenting purpose and research questions for patient-related assessment (n=43)

	Yes	%
Stated purpose for including patient-related issues	40	93
Formulated research questions related to patient-related issues	17	40

The stated purpose of the patient-related assessment ranged from a general recommendation for an HTA to include patient-related issues e.g. '*patients' experiences of the treatment is an important element of any kind of treatment strategy*' (report 2 p. 72) to more specific reasons, e.g. *'to review knowledge in relation to the psychological and social impact of the technology*' (report no 10 p. 121). Other assessments were conducted to gain insight into cultural norms or psychological, legal or ethical issues, or to estimate the demand for a technology.

The *research questions* varied in form from one general question e.g. what does the technology mean for the patient and their significant others, to one or several more specific questions e.g. the technology's impact on patient quality of life and ability to work, or *'what are the consequences of being invited to a screening test, waiting time for the test, to be risk evaluated, to receive the answer and be diagnosed with a disease*' (report 10 p. 121) and *'how do the [patients] view the [technology] and which role does payment play [for the use of the technology]'* (report 17 p. 12).

In terms of the *content of the patient-related assessment,* the most common category was psychological issues, followed by ethical, social and quality of life issues, and then patient information. Economic issues (from the patient perspective) were included in less than one-third of the reports (Table 5.2).

Table 5.2: Patient-related categories assessed in HTA reports (n=43)

	Frequency	%
Patient information	29	67
Psychological issues	33	77
Effect on quality of life	30	70
Social issues	30	70
Ethical issues	31	72
Patient's financial circumstances	12	28

5.2 Patient information

5.2.1 Content

As shown in Table 5.2, 67% of the 43 HTA reports included assessment of issues related to patient information (for further details see Appendix 3). The assessments ranged from short and more superficial descriptions (e.g. of current information available) to a

thorough description and discussion of how information is and should be provided, and the consequences of information versus no information.

Form and content: Most reports described both form and content of the patient information associated with the technology. The form of information was typically described rather than discussed (e.g. whether it should be written or oral, be given individually or in groups); in a few cases the use of language or the wording of the information was discussed. The content of patient information was often discussed in more depth, especially in terms of variation in the information currently provided and the ideal content for the technology in question. Issues such as the amount, timing and context (e.g. patient 'schools') of information were much less commonly included. A few reports discussed information requirements, e.g. materials such as booklets and videos, time use.

Provision of information: In some reports the process of exchange of information was discussed in relation to who should give the information and, less often, what skills were required e.g. the informant's role, knowledge and attitude, or level of responsibility for the information. A few reports described factors that could influence the provision of information, e.g. modes of contact, relationship between informant and recipient, different perspectives on the part of the informant and recipient, the surroundings and atmosphere in which information is provided.

Outcome and usefulness of information: A few reports described patients' experiences and satisfaction with the content, form and usefulness of the information given, as well as the impact of the information on patient knowledge, perceptions and attitudes. One report discussed patient barriers to information due to culture, language, attitude and lifestyle (see Box 5.1).

Box 5.1: Example of in-depth discussion of factors influencing outcome and usefulness of information

Report: no. 32

Technology assessed: The organisation of services for diabetic retinopathy screening

Data used: Literature

Way of handling the issue in question: Description of the patient population and the need for and goals of different kinds of information and education. Patient views and experiences were sought and discussed in relation to preferences and satisfaction with information. Proposals were given for information form, content, informant and timing. Eventual barriers to the provision and receipt of information were also discussed (p. 48-50).

Quote: *A variety of methods should be used to inform patients about the screening attendance... patients must be empowered to help manage their disease ... clear, timely information about all aspects of screening ... to be treated as an individual ... prepare specific approaches to address all groups of patients (e.g. the young, those from ethnic minorities, etc.) (selected sentences from a longer summary, p. 3)*

Who should be informed and for what purpose: A few reports considered who the recipient groups should be, and whether the patients' significant others and/or the general public should be informed. A few reports considered the role of information in relation to informed consent and to treatment agreements between patients and professionals. Very few reports included legal or ethical considerations in relation to wish for information, rights of receiving information and rights of refusing information.

5.2.2 Methods

The HTA assessments of patient information issues were based on different types of data, but typically on secondary data alone. Primary data in the form of personal interviews, focus group interviews and questionnaires were less often used. A few reports were based on both primary and secondary data e.g. information from or meetings with interest groups (mainly patient groups). In very few reports the source of information was not clearly stated.

5.2.3 Discussion

Although 67% of the 43 HTA reports assessed patient information issues, many of these assessments were limited to descriptions of current information provided. This typically comprised description of the form and content of information, while there was less frequent mention of the goal of the information, the target group and their ability to receive the information and the impact of the information given.

HTA reports that include detailed assessment of patient information issues provide knowledge that could be relevant for future HTAs. The example in Box 5.1 describes a report that considers the patient population in question, their need for information and education as well as the goal of information. This knowledge is highly relevant in decisions about which information is best suited to patients using the technology. Decisions about how to most appropriately provide this information would be aided by consideration of the purpose of information, patients' views and preferences for information and the consequences of providing information.

The purpose of patient information differs according to the nature of the technology in question and the timing of the information. This will affect the content and form of the information, as do the characteristics and needs of the patient group involved. Information might be provided in relation to the actual use of a technology ('what can be expected to happen here and now'), for educational purposes to enable the patient to use a technology independently, or to comply with a treatment. Information might also be provided for the purpose of including the patient in the decision-making process either for practical purposes as mentioned above or due to legislative provisions. Discussion of the purpose of providing patient information can also aid decisions about how best to inform different patient groups, what this information should contain and when it is best provided.

The provision or withholding of patient information about a proposed technology influences many other aspects of the patient's treatment. The provision of information affects the patient's expectations of and experiences with a technology, the use and acceptance of a technology, satisfaction with the technology and its outcome, and is also a precondition for involving the patient in the decision-making process.

5.2.4 Patient information issues for consideration in future HTAs

Depending on the given situation (e.g. the technology in question, the context and the purpose of the assessment), various patient information issues can be relevant for inclusion when designing and undertaking an HTA. Based on the discussion above the following issues might be considered for inclusion in future HTA:

- What groups should be informed, what are their preferences for information, should there be differentiation between target groups

- Purpose and timing of the information: what should the patient know/consider in relation to the technology (patient information is a precondition for patient involvement in decision-making)

- Form, content and context of information (oral, written or pictorial, length and language, provided to individuals or groups, brief summary or learning process)

- Consequences of information versus no information e.g. for the use of technology (acceptability, patient satisfaction and knowledge) and for the patients' rights to information.

5.3 Psychological issues

5.3.1 Content

As indicated in Table 5.2, 77% of the 43 HTA reports included an assessment of issues related to psychological issues (for further details see Appendix 3). Of the different subcategories, nearly two-thirds of the reports included issues related to patient fear and discomfort, while just under half reported on patient satisfaction and implications for patient involvement (Table 5.3).

Table 5.3 Subcategories of psychological subcategories included in HTA reports (n=43)

	Frequency	%
Patient fear and discomfort	27	63
Patient satisfaction	19	44
Patient involvement	18	42

5.3.1.1 Patient fear and discomfort

The reports varied considerably in terms of the issues assessed under this subcategory and the way in which the issues were discussed. While some reports simply mentioned patient concerns or sources of discomfort in relation to a technology, others discussed whether the experienced discomforts outweighed the usefulness of the technology.

Psychological and physical discomfort: Many reports discussed, often in detail, patient experiences of pain, depression and stress as well as feelings of fear, worry, anxiety, nervousness, guilt, joy, doubt, insecurity and grief. Such issues were often discussed in relation to the actual use of a technology, to the information provided about the technology and to the outcome or results from using the technology. One report included a description of patient expectations, while another discussed patient acceptance of discomfort in connection with the technology. A third report discussed the general public's fears in relation to the use of a technology (and the related disease) and the perceived impact of these concerns on society.

Reactions and self-perception: Issues such as distress, denial, peace of mind, stigmatisation, sick role, trust, hopelessness and conflict between security and alienation were less commonly mentioned in the reports.

Usefulness of the technology: A few reports discussed the advantages and disadvantages of a technology and whether the disadvantages outweighed the technology's usefulness, e.g. whether screening a large proportion of the general population in order to diagnose a few is justifiable (see example in Box 5.2). A reason for identifying so few reports including

this issue may be the inclusion of such issues in a separate technological or economic element of the HTA.

Box 5.2: Example of discussion about whether a technology's disadvantages outweigh its usefulness

Report: no. 14

Technology assessed: Strategies for diagnosing and screening for intestinal cancer

Data used: Literature

Way of handling the issue in question: Issues discussed included patient expectations, fear and worry associated with different time periods e.g. in connection with screening, GP consultations, use of the technology, waiting for a diagnosis and the time following diagnosis. The report discussed influencing factors and how to minimise these discomforts. The acceptability of making people insecure of their perceived good health was also discussed, and the technology's discomforts were compared against its usefulness. The significance of the characteristics of the patient groups were described and discussed (p. 137-142, 187-188 summary in English p. 221-242).

Quote: *The curability of cases which has arisen between screenings is not inferior to that of cases in the control group; on the contrary, mortality is somewhat lower and survival improved. This means that the false security which a negative faecal occult blood test may give does not mean that the person concerned is in a worse position than without the screening having been performed. (p. 236)*

5.3.1.2 Patient satisfaction

A few reports included issues related to patient satisfaction or patient preferences, typically limited to a simple report of the level of satisfaction with a technology.

Satisfaction: The reports referred to patient satisfaction with being offered the technology and willingness to recommend the technology, and satisfaction with the course of management e.g. structural aspects (equipment, location, access, time, coordination) and interpersonal aspects (information, skills and attitudes of professional staff, relationship with professional staff, internal communication amongst staff). The impact of the level of satisfaction on the use of the technology was less commonly discussed, as were needs for changes e.g. in order to increase patients' involvement in their own treatment. A few reports provided more detailed discussion of satisfaction in relation to different patient groups (see example in Box 5.3).

Box 5.3: Example of detailed discussion of satisfaction in relation to different patient groups

Report: no. 3

Technology assessed: Home-based chemotherapy for cancer

Data used: Literature

Way of handling the issue in question: Discussion of patient preferences and satisfaction in relation to physical, psychological and social inconveniences/discomforts and to professional services and physical facilities. The significance of the patient population and their circumstances on preference and satisfaction were also described and discussed (p. 29-36).

Quote: *Patients with cancer may discover that home is a less comforting (or comfortable) place than expected, when faced with changes brought on by the illness and the requirements of home treatment... (p. 29) Studies which examined patient preference, satisfaction and other psychosocial factors ....(p. 32)*

Preferences: Very few reports mentioned patient preferences in relation to a technology and those that did provided little detail.

5.3.1.3 Patient involvement

A few reports included issues related to patient involvement in treatment, typically limited to simple description.

Self-control: The reports referred to patients' experiences with, need for and views on coping, level of control, privacy and integrity over the course of treatment. A few reports discussed patient involvement in decision-making; some of these considered the need for and the possibilities of using informed choices and of setting priorities in relation to the use of a technology. There was also discussion of the ways in which patient knowledge, rationalising of (adverse) live events, and attitudes to risk influence patient choices (see example in Box 5.4) and how refusal to use a technology might be a valid choice.

Box 5.4: Example of detailed discussion about patient involvement in the decision process

Report: no. 45

Technology assessed: Perinatal intensive care

Data used: Literature

Way of handling the issue in question: Description and discussion of decision processes in situations involving uncertainty and value judgment differences between health professionals and patients. Discussion of how decisions can be supported, benefits of patient (in this case parents) involvement, international differences in patient involvement in decision-making. Policies and guidelines for optimising this practice are outlined (p. 43-47).

Quote: *Research into the grieving process of parents whose babies died despite more-or-less active treatment has shown that involvement in the opinion-forming and decision-making process and proper counselling are very important. It is easier for parents to cope with the loss of a child, or come to terms with a child's disability, if they believe that decisions to continue or withdraw treatment was properly thought through and made with consideration for their views (p. 46)*

Informed consent: A few reports discussed the procedures and policies for informed consent, and the associated legislative, medical and ethical concerns, as well as the rights of patients and their significant others.

5.3.2 Methods

The HTA assessments of psychological issues were based on different types of data, but mostly on secondary data alone. Primary data in the form of interviews, questionnaires and involvement of interest groups (mainly patient groups) were less often used. Just under half of the reports were based on both primary and secondary data. In a few reports the source of information was not clearly stated.

5.3.3 Discussion

A large proportion of the HTA reports included assessment of psychological issues, although there was considerable variation in the depth of this assessment, with many reports providing rather superficial descriptions or simply mentioning relevant issues.

The patient's perspective on the psychological implications of the use of a technology may differ from the health professional's perspective. Investigation into patients' satisfaction with a technology should identify factors that influence this satisfaction e.g. patient expectations, preferences and general circumstances in relation to both the tech-

nology itself and the health professionals involved. Such knowledge would be useful in planning the implementation of a technology or in changing the present use of a technology.

Some reports included detailed descriptions and discussion about patient fear and discomfort in relation to the use of a technology (as illustrated in Box 5.2). Such information can be used to inform patients of the likely discomforts they can expect from using the technology, and also to determine ways in which these discomforts may be minimised. The patient's expectations, experiences and involvement in decision-making are likely to influence satisfaction with the use of the technology; consideration of whether the usefulness of a technology outweighs its possible discomforts is important in a decision to implement the technology.

The level of patient involvement in decision-making about the use of a technology differs according to local traditions and the nature of the technology in question, but legislation in some cases requires patient consent prior to the use of the technology. Information about patients' needs and wishes with respect to involvement in decision-making (e.g. methods of gaining informed consent, attitudes to risk) is vital in determining best practice and guidelines in this area.

5.3.4 Psychological issues for consideration in future HTAs

Depending on the given situation (e.g. the technology in question, the context and the purpose of the assessment), various psychological issues can be relevant for inclusion when designing and undertaking an HTA. Based on the discussion above the following issues might be considered for inclusion in future HTA:

- Characteristics of the patients who will use the technology (e.g. age, gender, physical and psychological state, social network, illness history, prior experiences with the technology)
- Possible psychological and physical effects from the use of the technology
- Advantages and disadvantages of a technology, does the disadvantages outweighed the technology's usefulness
- Patients' reactions to the use of the technology and influence on self-perception
- Patients preferences and satisfaction in regards to the technology (e.g. in relation to equipment, location, access, time expenditure, support and information)
- Methods for involving patients in decision-making related to the use of the technology.

5.4 Effect of the technology on quality of life

5.4.1 Content

Of the 43 HTA reports, 70% included an assessment of patients' perceptions of the effect of the technology on their health or quality of life (for further details see Appendix 3). The term 'quality of life' is used here to refer to overall assessment of patient self-rated health in terms of physical, psychological, social and mental aspects, and can be equated with 'health status' or 'health-related quality of life'.

More than half the reports were limited to a description of the technology's influence on patients' quality of life, with few reports discussing the issues more fully, e.g. in regards to the purpose of assessing quality of life and the methodology used.

Quality of life: Quality of life was measured using a range of instruments and including different aspects of health status that were either common to most diseases or relevant to specific diseases, e.g. physical and psychological wellbeing (e.g. pain, stress, anxiety, depression), functional ability (e.g. ability to perform daily tasks), social functioning (e.g. contacts, isolation), overall satisfaction with health/life situation and hopes, desires and expectations for the future.

Most HTAs reported that a literature review identified very little information on the effect of the technology on patient quality of life. In the cases where such literature was available, the evidence was often handled rather superficially e.g. without discussion of the relevance or validity of the included studies, or of the relevance of assessing quality of life. A few reports did discuss such issues in more depth (see example in Box 5.5). One report noted that, despite agreement on the importance of measuring effects on patient quality of life, this measurement is still complicated by methodological problems (see example in Box 5.6).

Box 5.5: Example of in-depth assessment of patient quality of life

Report: no. 25

Technology assessed: Growth hormone therapy (GH) in adults

Data used: Literature

Way of handling the issue in question: Reasons for including quality of life assessment were given and different methodological approaches were discussed. Effects of the technology were discussed in relation to different aspects of quality of life (p. 13-21).

Quotes: *the outcome measure in this review is quality of life [QoL]. There are two reasons for the selection. Firstly, QoL is of immediate relevance to patients.....Secondly, the greatest immediate indication for GH replacement is in patients who are assessed as having impaired QoL. (p. 1)*

The term QoL has been used in this review in its widest sense to mean general health-related impact assessed from the patient's perspective and therefore may be regarded as health-related QoL. A range of instruments are used to measure QoL. (p. 5)

Trials of GH therapy in adults with GHD have not shown consistent benefit on QoL. GH may have beneficial effects on other factors.... (Summary p. iv)

Box 5.6: Example of a report discussing the methodology of measuring quality of life

Report: no. 42

Technology assessed: Treatment with chemotherapy in different forms of cancer

Data used: Literature

Way of handling the issue in question: The reason for including quality of life assessment was stated. Problems in conducting and interpreting quality of life measurement were discussed, as were historical developments in quality of life measurement, especially in relation to cancer. It was noted that despite agreement on the importance of measuring patient quality of life, remarkably few studies include such as assessment and methodological problems remain (p. 17, 105-116).

Quote: *... assessment of the patient's quality of life is nowadays seen as an important complement to the more traditional way of assessing the outcome of treatments (p. 105)*

Other effects of the use of the technology: Few reports included the technology's effect on the patients' perception of own health e.g. due to a false positive answer on a screening test, or discussed differences between the professional's and the patient's perception of the patient's health. Different understandings of test results, symptoms, treatment effects or adverse effects may cause patients to lose confidence in the technology, the medical staff or in their own ability to evaluate their own health (e.g. if they feel healthy but are informed that they have indications of disease, or in the event of a false negative test followed by a later diagnosis of disease).

An example of a report that discussed such considerations is described in Box 5.7. The report discussed possible outcomes of differing interpretations of an antenatal scan e.g. if the health professional concluded that the baby had a higher risk of disease, but the expectant mother perceived no problems, there is a possibility that the mother will consider the medical staff to be overreacting and may also face a conflict between accepting her own or the professional's interpretation of the scan results.

Box 5.7: Example of in-depth discussion of the necessity to involve the patient perspective

Report: no. 11

Technology assessed: Identification of women with high-risk pregnancy

Data used: Literature and interviews

Way of handling the issue in question: Discussion of the differences between the patient and the professional perspective; the importance of both groups being aware of the other's perspective; that patients' feelings of security and satisfaction with the technology are related to their involvement in decision-making and use of the technology. Discussions of how to achieve greater patient involvement and indication of issues that still need to be investigated (p. 28-44).

Quote: *The women experience that there is no room for their perspective… they question the results in relation to their own feelings and experiences (a lively foetus and a healthy baby after birth) … the results were varying and there were discrepancies between how the professionals used the technology and how the results were interpreted…the women are unsecured of the utility of the technology. (p. 42)*

5.4.2 Methods

The HTA assessment of quality of life issues were based predominantly on secondary data alone. A few reports included primary data (surveys) alone, and very few included both secondary data and primary data (in the form of interviews, questionnaires and involvement of patient groups).

5.4.3 Discussion

Over two-thirds of the HTA reports included an assessment of quality of life issues, typically based on data generated from the literature. In most studies no or very little relevant literature was found. The discussion in some HTA reports of the relevance and validity of the reviewed literature is helpful in understanding how to interpret the results of these studies.

The availability of quality of life data that are relevant for the patient group in question is a necessity in order to determine the effects of implementing a technology. Only a minority of reports discussed methodological approaches to measuring quality of life and the importance of identifying any divergences between the perceptions of patients and health professionals in relation to the effect of the technology.

5.4.4 Quality of life issues for consideration in future HTAs

Depending on the given situation (e.g. the technology in question, the context and the purpose of the assessment), various quality of life issues can be relevant for inclusion when designing and undertaking an HTA. Issues to consider for inclusion include the following:

- Possible effects of the technology on the patients' self-rated health/quality of life
- Aspects of self-rated quality of life that are relevant for the technology and patient group in question
- Any differences in how patients and health professionals perceive the effects of a technology on patient quality of life.

5.5 Social issues

5.5.1 Content

Of the 43 HTA reports, 70% included an assessment of social issues (for further details see Appendix 3). About half of the reports mentioned issues related to the impact of the technology on the patient's daily life, while slightly fewer assessed implications for the patients' significant others; one-third of the reports included assessment of the patient's ability to work (Table 5.4).

Table 5.4: Subcategories of social life included in HTA reports (n=43)

	Frequency	%
Impact on patient's daily life	21	49
Implications for significant others	18	42
Impact on patient's ability to work	14	33

5.5.1.1 Impact on patient's daily life

The reports varied in their approach to these issues, with about half the reports simply describing the issues and the others discussing the issues in more detail.

Changes in daily life: Some reports referred to issues such maintenance of lifestyle and a normal life despite the presence/use of a technology, changes in social relations or social role, and effects on interpersonal relationships and sexual life. A few reports described the need for care in private homes and the effects of professional caregivers' intrusion into the private sphere.

Burden on daily life: Issues mentioned included loss of concentration, insomnia, time expenditure in relation to treatment and transportation and inconveniences such as changes to usual routines, reduced ability to cope and isolation.

Restrictions in daily life: Issues mentioned included restrictions to physical activity and exercise, social activities and participation in society; loss of flexibility, restrictions in fulfilling daily tasks and dependency on others.

One of the reports that illustrated these issues clearly is described in Box 5.8.

Box 5.8: Example of in-depth discussion of effects on role and daily life of being diagnosed and living with a disease

Report: no. 10

Technology assessed: Screening, diagnosis and treatment for type 2 diabetes

Data used: Literature

Way of handling the issue in question: Discussions about changes in social roles at home and work, e.g. having others check treatment compliance, overprotection of the ill person; changes in lifestyle and daily routines as a part of treatment, e.g. meals (time and content), exercise, smoke, alcohol, handling of medical treatment (p.124, 186, 237-41, 276).

Quotes: *...For many patients this [being diagnosed with type 2 diabetes] will entail radical changes to their lifestyle.... For many patients these changes in lifestyle will be so great that they cannot implement them, and certainly not without professional support. (English summary p. 73)*

5.5.1.2 Implications for significant others

A few HTAs mentioned the technology's impact on the patient's significant others.

Changes in family relations: Issues referred to included changes in the relationship between the patient and his/her partner and/or other family members that could lead to conflicts, moral dilemmas and a greater need for understanding, accept and support from significant others. One report mentioned changes in the patient's ability to be the family's breadwinner, while another discussed how the technology might negatively influence parents' perceptions of parenthood.

Burden on relatives: Reports described the burden of being an informal caregiver and the impact on relatives' health, quality of life, social relations and time expenditure. A few reports discussed the relationships of informal carers to health professionals and the need for information and support (see example in Box 5.9).

Box 5.9: Example of in-depth discussion of the technology's impact on significant others

Report: no. 28

Technology assessed: Troponin testing services

Data used: Literature and focus group interview

Way of handling the issue in question: Discussion of relatives' experiences of adverse effects (e.g. distressing emotions, mood changes) in relation to the patient's disease and treatment; conflicts due to role changes (e.g. the relative as a monitor or enforcer of treatment or as a buffer) and in managing daily tasks; the relatives' interaction with health professionals, their need for information, and avenues of communication and support, as well as suggestions for how this communication could be improved (Part 6 p.1-17).

Quote: *Relatives reported a number of adverse effects after the patient's cardiac event. They experienced a variety of distressing emotions including guilt...anguish, frustration, resentment, powerlessness and fear ... problems trying to combine their normal roles with the new responsibilities of caring for the patient ...some had difficulties eating, sleeping and concentrating. Others worried about household finances (p. 10-11).*

5.5.1.3 Implications for patient's ability to work

Few of the HTA reports included issues related to the patient's ability to work, with most reports simply presenting the relevant issues.

Employment and career: Issues included consequences of the use of the technology on the patient's ability to continue educational activities, and discrimination in relation to possibilities for work and career.

Work capacities: The patient's ability to a resume job and to return to work after treatment was included in a few reports.

Absence form work: Patients' absence form work due to the use of a technology was mentioned in some reports.

One of the reports that illustrated these issues clearly is described in Box 5.10.

Box 5.10: Example of discussion of a technology's impact on patient educational and work activities

Report: no. 49

Technology assessed: Internet-based services for people with different handicaps

Data used: Interview

Way of handling the issue in question: The Internet services allow users to follow courses from home, thereby possibly increasing their educational chances. For other patients, the technology provides new ways of participating in education and possibly of managing a job (p. 36, 46, 73).

Quote: *The participants' experiences were that it was fantastic to be able to receive education in their mother tongue, something of vital meaning for the deaf person's (especially those born deaf) possibilities for communicating and participating in e.g. courses on as equal terms as possible with hearing participants ….this meant new possibilities for education (p. 36)*

5.5.2 Methods

The HTA assessments of social issues were based predominantly on secondary data, with far fewer reports using primary data sources (interviews and questionnaires). A few reports used both primary and secondary data sources, while in a few other reports the source of information was not clearly stated.

5.5.3 Discussion

Over two-thirds of the HTA reports included an assessment of social issues, with assessments typically limited to a presentation of the relevant issues but also the occasional deeper discussion about social implications for patients and (less often) for their significant others.

The use of a technology can have social implications for both the patient and their significant others. These effects might be changes in daily life, which could either be intentional and welcome or unintentional and possibly problematic. Reports that discuss these issues (as illustrated in Box 5.8) provide useful knowledge for the implementation of a technology, especially if they indicate how unwelcome social changes can be minimised and welcome changes enhanced.

Patients' significant others can be affected directly and indirectly by a technology. They may become concerned and anxious about the patient's reduced ability to perform daily duties or maintain a family role, or the patient's greater dependence on others. As illustrated in Box 5.9, discussion of such issues allows consideration of how to reduce or avoid adverse effects of the technology on patients' relatives, how to improve the situation for them, and how to support them in their role as informal caregivers. It is also important to determine which significant others (and of which patient groups) are most

affected by the technology, so that strategies can be targeted to the relevant group.
Few reports assessed the technology's impact on the patient's ability to work. The use of some technologies may cause the patient to have a lengthy absence from work or prevent work totally, or may even enhance the patient's ability to work. Again such information is important in deciding whether or not to implement the technology and in determining how to minimise work-related problems due to the use of a technology.

5.5.4 Social issues for consideration in future HTAs

Depending on the given situation (e.g. the technology in question, the context and the purpose of the assessment), various social issues can be relevant for inclusion when designing and undertaking an HTA. Based on the discussion above the following issues might be considered for inclusion in future HTA:

- Implications for the patient's daily life (e.g. maintenance of daily tasks and responsibilities)
- Implications for the patient's ability to work (e.g. absence from work, influence on educational activities, work capacity, employment possibilities and career)
- Implications for the patient's significant others (e.g. changes in family/friend roles and family activities, perceptions of being a family)
- Which significant others are affected by the technology, what are their needs for information and support (e.g. in relation to the patient's treatment, daily tasks and functions, impact on their quality of life).

5.6 Ethical issues

5.6.1 Content

Of the 43 HTA reports, 72% included an assessment of ethical issues (for further details see Appendix 3). Of the different ethical subcategories, most reports mentioned issues related to patient acceptance of a technology, while fewer reports included other specific ethical considerations (Table 5.5).

Table 5.5: Subcategories of ethical issues included in HTA reports (n=43)

	Frequency	%
Patient acceptance of the technology	32	74
Fundamental and specific ethical considerations	17	40

5.6.1.1 Patient acceptance of the technology

There was some variation in the way that issues were assessed in the reports. Some HTA reports included a short statement about the technology being acceptable for the individual patient, others described patients' general attitudes towards the technology, while others discussed in more depth the factors that influence the acceptance of the technology and how these might be handled. Quite a few reports assessed general public acceptance of a technology. The assessments varied from descriptions of possible barriers to the use of the technology to more in-depth discussion of public confidence in the technology and proposals of how this might be achieved.

Factors influencing the individual patient's acceptance: Many reports described and quite often discussed factors that could influence the individual patients' view on being offered the technology and patients' attitudes and acceptance of the use of the technology.

Such factors included patient expectations, the ability to maintain privacy, social and cultural factors. Factors related to the technology included the content of the technology, how it was offered and its accessibility, financing, eventual side effects and outcome. A few reports presented a model showing the factors associated with the individual patient's acceptance of the technology, while others discussed the relative importance of different factors and the possibility of influencing them (see example in Box 5.11).

Box 5.11: Example of discussion of factors that can influence patient acceptance of a technology

Report: no. 43

Technology assessed: Organisation and use of a specific smoking cessation course

Data used: Literature and survey

Way of handling the issue in question: Analysis of the influence of different factors on the current and future use of the technology; characteristics of smokers who are interested in the technology and what influences this interest (age, gender, opportunities for smoking in the home and at work etc., advice from the general practitioner, cost and financing of the technology, expected outcomes). The factors' relative importance were analysed as odds ratios and willingness-to-pay estimates, and it is discussed how the factors might be influenced and possibly altered (p. 44-59).

Quote: *There is among every day smokers a willingness to pay for participating in a smoking cessation course, but the payment does at the same time reduce the number of every day smokers who wishes to participate in a smoking cessation course offered by the general practitioner. (p. 59)*

Other reports described, and to some extent discussed, issues related to the wider public such as political factors (e.g. principles of equal access), cultural norms, religious beliefs, views of human nature, public trust in the technology and accept of the possible consequences (see example in Box 5.12).

Box 5.12: Example of discussion of factors that influence general public acceptance of a technology

Report: no. 13

Technology assessed: Self/home test to screen for Chlamydia infection among young people

Data used: Literature and survey

Way of handling the issue in question: Ethical preconditions for general acceptance of the technology were discussed: the technology must be relevant to the disease, the test results must be trustworthy and useable, and that it is generally accepted as a relevant object for financing. Ethical concerns in relation to effects on cultural norms, and possible approaches to reduce religious barriers to the use of the technology were also discussed (p. 67-69 and 73-78).

Quote: *The first premise for [the use of the technology] is that the strategy includes a disease that in a greater number of cases are without symptoms or with weak symptoms ... the second premise is that the diagnostic results are or near to unequivocal ... the third premise is that the long term consequence of the disease are serious ...the fourth that there is a cure. (p. 68)*

5.6.1.2 Fundamental and specific ethical considerations

A number of more fundamental ethical issues were either mentioned or discussed more fully in the reports.

Equality and equity: Issues here included ethical dilemmas in relation to setting criteria for which patients should be offered the technology (e.g. age limitations) and discrimination in relation to access to the technology e.g. due to geographical distance, waiting

time, poor contact with the health care system (marginalised patients); commercialisation, financing and ownership of the technology.

Safety: Ethical concerns in relation to use of a technology with possible, but still unknown, adverse effects.

Utility: Does the usefulness of the technology relate to the burden of the disease, is it acceptable to use a large amount of (scarce) resources on a few patients.

Patient involvement: Ethical concerns in relation to the general involvement of patient in treatment, patient self-reliance and the right to know/not to know (e.g. informing a person about a positive test result or about being a disease carrier without the possibility of treatment/cure).

Healthy or ill: Ethical considerations of how technology might influence the distinction between life and death, of being healthy or ill, possible impact on eugenic social policies.

One of the reports that illustrated these issues clearly is described in Box 5.13.

Box 5.13: Example of discussion of ethical issues surrounding the use of a technology

Report: no. 7

Technology assessed: Tests to facilitate assessment of an individual genetic substitution

Data used: Literature

Way of handling the issue in question: Presentation and discussion of issues such as who should be offered/not offered the technology (children, adults with limited intellectual capacity); potential discrimination due to racial origin, changes in insurance options following testing, insurance demand for testing; ethical and legal concerns in relation to disclosure of non-paternity, conflicts between patient confidentiality vs. obligation to inform others at risk; potential outcome of inconclusive test results and in relation to diseases with no known cure; prenatal testing, concerns about genetic perfectionism and eugenic social policies; concerns related to informed consent, privacy and self-determination; concerns about ownership of technology, e.g. patents on genes (p. 29-36).

Quote: *The ethical issues related to genetic testing for cancer susceptibility are many, and often overlap many of the legal issues ...Two themes dominated the discussions related to these two principles; the ethics of providing information about potential cancer risks in the absence of established options for reducing risk and the ethics of providing genetic susceptibility testing when many of the psychological and social consequences of testing and long-term risks and benefits of available medical management strategies remain unknown (p. 33) ... specific discrimination against communities in which a high prevalence of susceptible mutations has been identifies ... fear of discrimination could impede equal assess (p. 34)*

5.6.2 Methods

The HTA assessments of ethical issues were mainly based on secondary data alone, with less use of primary data (interviews, questionnaires and involvement of interest (mainly patient) groups). Under half the reports included both primary and secondary data sources, while in some reports the source of information was not clearly stated.

5.6.3 Discussion

Over two-thirds of the HTA reports included an assessment of ethical issues. The assessments varied in depth and were sometimes based on a more general debate about ethical concerns in relation to the use of a technology.

Both the individual patient's acceptance and a more general public acceptance of a technology is influenced by patient or societal factors (expectations, personal habits, political and cultural norms) as well as by characteristics of the technology itself. Discussion of such factors and how they can be altered (as illustrated in Boxes 5.11 and 5.12) provide knowledge that is useful in determining the use and diffusion of a technology.

Some technologies have implications for more fundamental ethical issues, such as a technology's influence on society's ideas of equity and equality e.g. who should have access to the technology, are resources better used on treating a few seriously ill patients or on treating many patients suffering from a widespread but not serious disease, does the use of a technology alter the general understanding of health versus disease, and of life versus Death. Box 5.13 described one of the few reports that included in-depth assessments of such issues; information like this is highly relevant in decisions about whether to implement a technology and how it might best be implemented.

5.6.4 Ethical issues for consideration in future HTAs

Depending on the given situation (e.g. the technology in question, the context and the purpose of the assessment), various ethical issues can be relevant for inclusion when designing and undertaking an HTA. Based on the discussion above the following issues might be considered for inclusion in future HTA:

- Factors related to individual patients' acceptance of the technology (both patient factors and factors related to the technology itself)
- Factors related to society's acceptance of the technology (both societal factors and factors related to the technology itself)
- Implications in relation to the society's norms for equality and equity
- Safety and utility of the technology
- The relevance, norms for and possibility of involving individual patients in the use of the technology and its results
- Possible effects on the understanding of health vs. disease, life vs. death.

5.7 The patient's financial circumstances

5.7.1 Content

Of the 43 HTA reports, 28% included an assessment of issues related to the patient's financial circumstances (for further details see Appendix 3). Most reports described patient expenses in relation to use of the technology, while some discussed patients' willingness to pay and the possibilities for public funding of expenses.

Patient expenses: Most often the reports described direct and indirect expenses for patients in relation to use of the technology, e.g. payment for extra facilities or electricity, time expenditure by patients and their significant others.

Coverage of patient expenses: Some reports included descriptions and sometimes discussion of differences in and possibilities for public payment and/or compensation of patient expenses. One report described the technology's influence on the patients' possibilities of receiving public aid.

Willingness of payment: Few reports included patients' willingness to pay for a technology (see example in Box 5.14).

Box 5.14: Example of discussion of patient willingness-to-pay for a technology

Report: no. 43

Technology assessed: Organisation and use of a specific smoking cessation course

Data used: Literature and survey

Way of handling the issue in question: A telephone survey of 5,000 randomly selected participants; approximately 1,000 of the respondents were was daily smokers. Participants were asked is they would be willing to participate in a free course recommended by the GP, if they would be willing to pay for the course and what the maximum acceptable payment would be. Presentation of different scenarios of hypothetic willingness-to-pay among daily smokers and discussion of the relationship between payment size and willingness to participate in the course (p. 54-57).

Quote: *From an interventional perspective it may be argued that since the smokers are willing to pay an amount of money equal to the cost of the direct expenses there a some arguments for intervening and thereby gain the health profit for population (p. 57)*

5.7.2 Methods

The HTA assessments of impact on patients' financial circumstances were based either on secondary data alone or on primary data (interviews, questionnaires and, in one report, consultations within clinical institutes and societies) alone.

5.7.3 Discussion

Relatively few HTA reports assessed impact on patients' financial situation and in most cases this was limited to a description of patients' direct and indirect expenses (money and time expenditure) in relation to use of the technology. However, this may be due to such issues being included in the economic element of the HTA.

Very few reports gave a detailed discussion of a technology's impact on the patient's financial circumstances. This would be valuable information in determining the extent to which a technology may be taken up and how to influence this uptake.

5.7.4 Patients financial circumstances and issues for consideration in future HTAs

Depending on the given situation (e.g. the technology in question, the context and the purpose of the assessment), various issues related to the patient's financial circumstances can be relevant for inclusion when designing and undertaking an HTA. Based on the discussion above the following issues might be considered for inclusion in future HTA:

- Direct and indirect expenses for patients and significant others (e.g. payment for receiving the technology, financial and time expenditure associated with use of the technology), needs and possibilities for compensation
- Patient willingness-to-pay for the technology and the influence of this on the use of the technology
- Impact on patients' possibilities for earning a living or of receiving public or other financial aid.

6 Methodologies of the HTAs

This chapter reviews the methodology used in the HTA reports for the assessment of organisational and patient-related issues. 'Methodology' refers here to study design and methods of data generation and data analysis, as well as methods of reporting the results and the generalisability of results to other contexts.

The chapter has two main sections. The first reviews the methods used in the HTAs in regard to study design, data generation and data analysis. The second reviews the way in which the HTAs report on the methodology used and the extent to which the HTAs discuss the generalisability of the results of the organisational and patient-related assessments.

This chapter thus addresses the third purpose of the study: *'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'.*

6.1 Methodological choices in HTA

Methodological choice is here understood as the methods used in relation to study design, data generation and data analysis, and the reasons and perceived consequences of these choices.

With reference to both the organisational and the patient-related assessments, the three issues of study design, data generation and data analysis are discussed in turn, under i) the reported use of different methods and whether these choices have been explained, and ii) a discussion of the possible consequences of considering and explaining choice of method.

6.1.1 Study design

Study design was reported for all the HTA assessments. Review of existing literature, either alone or in combination with other designs, was the by far most common approach used for both organisational and patient-related issues (Table 6.1). Next most common were case studies and comparative studies. Intervention studies and longitudinal studies were seldom used. 'Other' study designs were modelling (of organisational issues) and cross-sectional design (of patient-related issues). Almost half of the HTA reports that assessed organisational issues used more than one study design, while this was the case for less than one-third of the reports that assessed patient-related issues.

About two-thirds of the HTA reports explicitly discussed the choice of study design, for example in relation to the purpose of the assessment and/or the research questions.

Table 6.1: Designs used in assessment of organisational and patient-related issues

(N.B. An HTA could assess both organisational and patient-related issues, and could use more than one study design)

	HTAs including organisational issues (n=42)	%	HTAs including. patient -related issues (n=43)	%
Review	33	78	35	81
Intervention studies	3	7	3	7
Comparative studies	10	24	7	16
Longitudinal studies	0	-	2	5
Case studies	15	36	7	16
Other	1	2	1	2
Explicit discussion of study design	26	62	29	67

Discussion

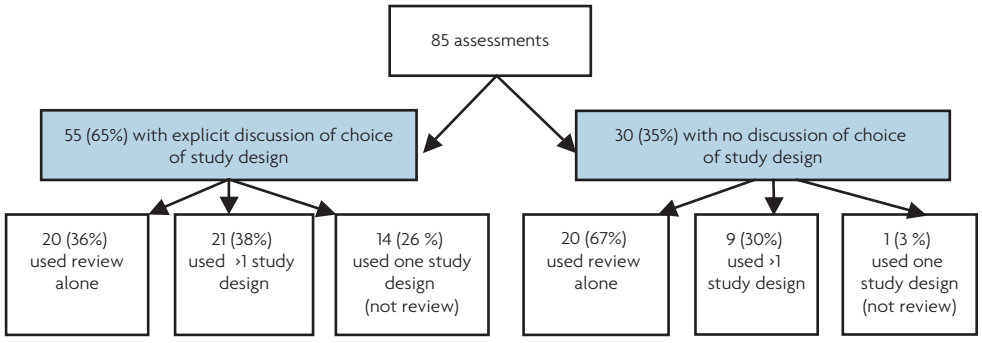
It is possible that there is a connection between the choice of design and an explicit discussion of this choice. One hypothesis is that if an HTA is perceived to be a review of existing knowledge, then discussion of choice of study design may not be considered necessary, since it is implicit in the methodology of the HTA. Another assumption is that if the choice of design is not discussed, then the study design is more likely to be a review, in the assumption that such a design has been used in previous studies and choice of study design has not been explicitly considered.

These assumptions were tested by examining the designs used in the 50 HTA reports. With 42 assessments of organisational issues and 43 of patient-related issues, a total of 85 assessments were included. Of these, the choice of design was explicitly discussed in 55 reports, while in 30 reports there was no discussion of the choice of study design for the assessment (Figure 6.1). The 55 assessments varied in the extent to which choice of study design was discussed; in most cases the design was described and briefly discussed as part of the overall purpose or remit of the HTA (and not in relation to the organisational and/or patient-related assessment), while in fewer cases there were specific arguments for the choice of study design.

Of the 55 assessments that explicitly discussed choice of study design, 36% used review only, 26% used another design alone and 38% used more than one study design.

Of the 30 assessments that did not discuss choice of study design, 67% used review alone, 3% used another design alone and 30% used more than one study design.

Figure 6.1: Type of study design used according to whether or not choice of study design was discussed



It would thus appear that HTAs that include explicit discussion of choice of study design tend to use more than one study design or, when limited to one study design, to use a design other than a review. In contrast, HTAs that do not explicitly discuss choice of study design tend to use review alone. This confirms the hypothesis of a connection between discussion of choice of study design and actual choice of design, although the direction of this association is not known. The perspective of the assessment (e.g. is the perspective used in the HTA the perspective of individual/groups of patients, the perspective of specific groups of professionals/of health providers or of organisations/systems or a societal perspective) is also of influence for the choice of design, but only 8 of the 42 HTA reports including organisational assessment and 13 of the 43 HTA reports including patient-related assessment reported explicit on perspective of the assessment. The perspective was thus implicit in most of the HTA reports.

6.1.2 Methods of data generation

Nearly all of the organisational and patient-related assessments were based on secondary data (literature). Primary data was used in approximately 60% of the organisational assessments and 40% of the patient-related assessments (Table 6.2). Approximately two-thirds of the reports explicitly discussed the choice of data generation method, for example in relation to the purpose of the assessment and/or research questions.

Table 6.2: Type of data on which organisational and patient-related assessments were based

(N.B. An HTA could assess both organisational and patient-related issues, and could use more than one data type)

	HTAs including organisational issues (n=42)	%	HTAs including patient-) related issues (n=43	%
Primary data	26	62	18	42
Secondary data	41	98	40	93
Explicit discussion of data generation	29	69	28	65

Primary data

As shown in Table 6.2, 26 of the HTA reports generated primary data for assessment of *organisational issues.* Of these, 18 generated quantitative data and 18 generated qualitative data. Of the 18 HTA reports that generated primary data for assessment of *patient-related issues,* 11 generated quantitative data and 13 generated qualitative data.

Regarding the generation of *quantitative data,* all the reports explicitly described the method of data generation. Questionnaires were used in approximately 80% of organisational assessments and all of the patient-related assessments (Table 6.3). Registry data (i.e. data collected routinely at different levels of the health system) were used in nearly 40% of organisational assessments and three reports used other methods (e.g. registrations, enquiries). Only two of the patient-related assessments used methods additional to questionnaires (registry data, preference measurement).

Table 6.3: Generation of quantitative data in HTA assessment of organisational and patient-related issues

	HTAs including organisationalissues (n=18)	%	HTAs including patient-related issues (n=11)	%
Questionnaire	15	83	11	100
Registry data	7	39	1	9
Preference measurement	0	-	1	9
Other data	3	17	0	-

Regarding the generation of *qualitative data,* all but three of the reports including organisational assessment and all but two of the reports including patient-related assessment explicitly described the method of data generation. After exclusion of reports without description of data source, approximately half of the organisational assessments used text documents and 40% used individual interviews (Table 6.4). Focus group interviews and prospective methods were used less often, and direct observation in very few assessments. Of the four reports that used 'other' methods (involvement of experts and interest groups), three used these approaches in addition to other methods, and one report used this approach alone.

After exclusion of reports without description of data source, approximately 65% of the patient-related assessments used individual interviews, while focus group interviews were used in 45% and text documents in 27% (Table 6.4). Two reports used additional data generation methods (involvement of different interest groups, including patients).

Table 6.4: Generation of qualitative data in HTA assessment of organisational and patient-related issues

	HTAs including organisational issues (n=15)	%	HTAs including patient-related issues (n=11)	%
Observation	2	13	0	-
Individual interviews	6	40	7	64
Focus group interviews	4	27	5	45
Text documents	8	53	3	27
Prospective methods	3	20	0	-
Other	4	27	2	18

Secondary data

As shown in Table 6.2, secondary data were generated by 41 of the HTA reports assessing organisational issues and 40 of the HTA reports assessing patient-related issues. Five of the reports including organisational assessment and eight of the reports including patient-related assessment did not describe the method of data collection. After exclusion of these reports, systematic data generation was the main method of generating secondary data for both types of assessment (Table 6.5).

Table 6.5: Generation of secondary data in HTA assessments of organisational and patient-related issues

	HTAs including organisational issues (n=36)	%	HTAs including. patient-related issues (n=32)	%
Systematic	33	92	31	97
Unsystematic	6	17	3	9

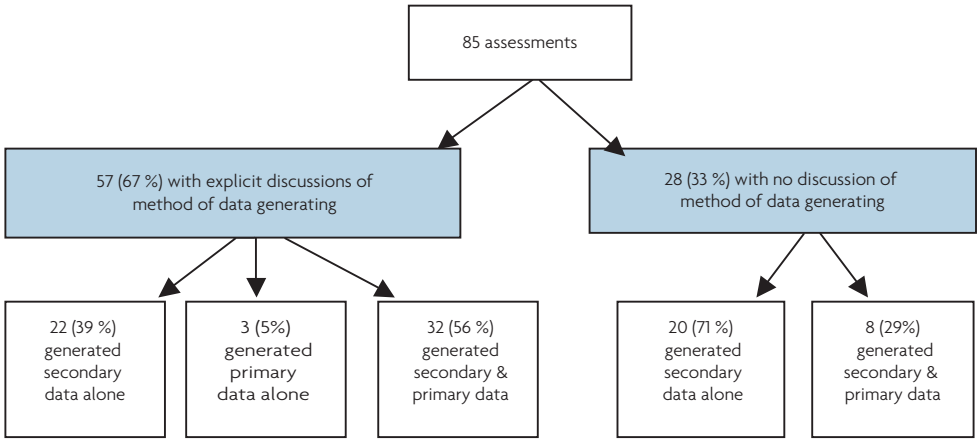
Discussion

It would again appear that there is a connection between explicit discussion of the methodological choice (here regarding data generation) and the type of method used in the assessment. Of the 85 assessments of organisational and patient-related issues, 67% explicitly discussed the choice of method for data generation (for example in relation to the purpose of the assessment and/or research questions), while 33% did not (Figure 6.2).

Of those 57 assessments that explicitly discussed choice of data generation method, 39% generated secondary data alone, 5% generated primary data alone and 56% generated both secondary and primary data.

Of the 28 assessments that did not discuss choice of data generation method, 71% generated secondary data only and 29% generated both secondary and primary data. None generated primary data alone.

Figure 6.2: Type of data generated according to whether or not choice of data generation method was discussed



It would thus appear that HTAs that include explicit discussion of choice of data generation methods tend to use more than one method of data generation. In contrast, HTAs that do *not* explicitly discuss choice of data generation methods tend to generate secondary data only. This confirms the assumption of a connection between discussion of choice of data generation method and actual choice of method, although the direction of this association is not known.

6.1.3 Methods of data analysis

A description of how data were analysed was included in more than one-half of the reports, while fewer reports explicitly discussed the choice of analytical method (e.g. in relation to the purpose of the assessment and/or research questions) (Table 6.6).

Table 6.6: Analytical methods performed in HTA assessments of organisational and patient-related issues

	HTAs including organisational issues (n=42)	%	HTAs including patient-related issues (n=43)	%
Description of analytical method	26	62	24	56
Discussion of choice of analytical method	18	43	17	40

6.1.4 Discussion of the methodological choices in the HTAs

HTAs based on literature reviews appear to have a tendency not to explicitly discuss this choice of study design. On the other hand, HTAs that use other designs or multiple study designs do tend to include some discussion or argumentation for doing so.

This trend could be due to an assumption that HTA is an assessment of existing knowledge, an assumption that might be upheld by the fact that literature review is common practice in HTA. This is not a problem if the literature can provide adequate, relevant and valid knowledge in relation to the technology, context and patient group in question. If existing knowledge is inadequate, however, it is necessary to consider how this should be addressed.

In the methodological HTA literature there appears to be a growing awareness of the need to consider study design more explicitly, and a consequent broadening of design concepts (21). It is not certain, however, whether this awareness is transferred to practice, as a review of 433 HTA reports published in 1989-2002 showed that literature review was by far the most common study design used (9) – a tendency that has not changed over the years (23).

While most of the HTA reports reviewed in the present study described the method used for data generation, approximately one-third of them did not discuss the choice of data generation method. It would appear that HTAs that include explicit discussion of choice of data generation methods tend to use more than one method of data generation, while HTAs that do *not* explicitly discuss choice of data generation methods tend to generate secondary data only. While more than one-half of the HTA reports described the analytical method used, approximately only 40% explicitly discussed how this choice of analytical method was made.

Presentation of the reasons for choosing the study design, data generation method and analytical method of an HTA is necessary to explain the methodological choices made. Absence of such a discussion may not be a direct threat to the internal validity of an HTA, but makes it extremely difficult for the reader to judge the appropriateness and trustworthiness of the methodology used.

6.2 Methodological reporting and validity

This section reviews the reporting methodology used in the HTA reports. The level of transparency of reporting and the extent to which the reader can follow the methodological steps taken and the reasons and consequences of these steps, is referred to here as 'methodological validity'.

Below the extent to which the HTAs have reported on methodological issues and generalisability of organisational and patient-related result will be described, and the way of handling this reporting will be described, illustrated with different examples, and discussed. The aim of this is to provide the reader with different examples of how the different issues have been reported and to inspire future reporting on methodological issues and generalisability of organisational and patient-related result.

6.2.1 Reporting on methodological issues

Various methodological issues can be relevant for discussion in an HTA report. Tables 6.7 and 6.8 indicate the extent to which HTA reports have reported on methodological issues, in relation to whether the report generated secondary or primary data.

Table 6.7: Inclusion of methodological issues in HTA assessments based on primary data

	Qualitative data				Quantitative data			
	Organisational (n=15)		Patient-related (n=11)		Organisational (n=18)		Patient-related (n=11)	
	N	%	N	%	N	%	N	%
Concept definition	14	93	10	91	15	83	11	100
Data generation method	14	93	10	91	17	94	11	100
Sampling	10	67	9	82	15	83	10	91
Methodological context	11	73	9	82	13	72	9	82
Analytical method & strategy	11	73	7	64	10	56	6	55
Critical discussion of data interpretation	5	33	5	46	10	56	7	64
Critical discussion of data quality	4	27	5	46	8	44	7	64
Critical discussion of researcher's role	1	7	2	18	3	17	0	-
Other topics	0	-	0	-	0	-	0	-

Table 6.8: Inclusion of methodological issues in HTA assessments based on secondary data

	Secondary data Organisational assessment (n=36)		Secondary data Patient-related assessment (n=32)	
	Frequency	Percent	Frequency	Percent
Concept definition	12	33	13	41
Search protocol	34	94	31	97
Analysis methods and strategy	17	47	17	53
Critical discussion of validity of included data	23	64	23	72
Critical discussion of relevance of included data	28	78	28	88
Critical discussion of researcher's role	8	22	10	31
Other topics	0	-	0	-

6.2.1.1 Concept definition

Concept definition is reported on in nearly all of the reports generating primary data and in 30-40% of those generating secondary data. This was mostly done by including a glossary of the central concepts used in the assessment. Some reports included thorough description and sometimes discussion of the technology assessed and the central concepts used (see example in Box 6.1). A few reports presented the theoretical base of the assessment (e.g. in relation to anthropology or sociology).

Box 6.1: Example of description and discussion of central concepts used in an HTA assessment

Report: no. 39

Technology assessed: Relationship between hospital/physician volume and quality of care

Data used: Primary and secondary data

Way of handling the issue in question: Thorough description and discussion of different ways of interpreting and using a central concept (volume), followed by clear description of how the concept was used in the assessment (p. 10).

Quote: *By reviewing the literature, the concept of volume pose two different problems. Volume can by understood as the number of procedures necessary to learn a certain skill, simply the learning curve in relation to the implementation of a new procedure. This issue will not be included in this report. Volume can also be understood as the number of procedures necessary to maintain a certain skill. The literature distinguishes between physician volume, which is related to a single physician's necessary experience with a technique or procedure to be able to offer an adequate quality of care, and hospital volume, which reflects the hospital's total experience with a procedure to be able to maintain a good quality of care... (p. 10)*

6.2.1.2 Data generation method

Nearly all the reports generating primary data described the method used for data generation, but the level of detail varied considerably. Some reports briefly described the method, and sometimes how it was used. A few reports discussed the reason for choosing a particular method (see Box 6.2), sometimes with advantages and disadvantages of different data generation methods, and arguments for and consequences of the final choice made.

Box 6.2: Example of reporting on choice of data generation method

Report: no. 9

Technology assessed: Dietary guidance

Data used: Primary and secondary data

Way of handling the issue in question: Explicit reporting of why individual interviews were used for one group of actors, but focus group interviews for another (p. 11).

Quote: *Individual interviews are chosen for the patients since the topic is expected to be sensitive, especially for very obese patients. In the individual interview it is possible to create an atmosphere of confidence between the interviewer and the patient, so the patient can come forward with his/her point of view. Focus group interviews are chosen for GPs in the hope that the GPs can inspire and challenge each other in a dynamic conversation. (p. 11)*

6.2.1.3 Sampling

Sampling issues were reported in 80-90% of the reports generating primary data, but the level of reporting varied from a brief mention to a thorough description. Many reports simply reported the total number of respondents or interview persons, or their distribution in relation to different criteria. Some reports, however, did also discuss different sampling criteria and general sampling issues, e.g. problems and possible biases in connection with sampling and selection of interview persons (see example in Box 6.3). Other reports presented analyses of drop-outs and sample representativeness, while a few reports discussed possible reasons for drop-outs.

Box 6.3: Example of discussion of possible biases related to participation in research project

Report: no. 48

Technology assessed: Mobile video communication for deaf persons

Data used: Primary data

Way of handling the issue in question: General discussion of possible biases and problems in relation to the study design and inclusion of participants; assessment of the relevance and effect of these possible biases in the present study (p. 9).

Quote: *The fact that the service is tested and assessed within a more or less delimited research project can mean that it can be difficult to remain completely objective. The feeling of being part of a research project...maybe 'specially chosen', can make the participants more positively minded. In addition, considerations of, for instance, the project manager can in some cases lead to the omission of negative criticism... This research project has been undertaken in a very casual form without any clear-cut compounded project group, and we judge that no clear project effects have affected the assessment. (p. 9)*

6.2.1.4 Methodological context of data generation

Roughly three-quarters of the HTAs that generated primary data reported on the methodological context for the data generation. This was often done by describing the procedures followed and their settings, e.g. the undertaking of interviews, surveys, conference sessions, observations or document readings. Most of these reports simply described or stated what was done, e.g. how respondents or interview persons were contacted, location of the interview, how many participated in each interview? Very few reports mentioned all the different elements of data generation. One report both described the choice of location (for interviews) and discussed why this was chosen.

In relation to data generation, many of the reports that generated primary data reported on the specific instruments used, e.g. interview guide or questionnaire. Almost all of the reports did so by simply including the instrument in an appendix or by briefly describing the topics included, the total number of questions asked and the answer categories used. A few reports described the development of the instrument, e.g. how a questionnaire was developed and pilot-tested (see example in Box 6.4). Some of these reports also discussed how the content of the instrument was determined and the reasons for the developmental approach used.

Some reports also briefly described the technical equipment and materials used for data generation, as well as the timing of data generation and the associated time expenditure. None of these reports gave reasons for these choices.

Box 6.4: Example of description of questionnaire development

Report: no. 16

Technology assessed: Standard IVF (S-IVF) compared with "friendly IVF" (CC-IVF)

Data used: Primary and secondary data

Way of handling the issue in question: Thorough description of the process of developing a questionnaire.

Quote: *The literature was reviewed to identify areas and topics known to be of special relevance for patient satisfaction and liability in relation to IVF treatment. An interim questionnaire with 23 questions was constructed by three persons in the clinic (physician, laboratory technician and a nurse). In a pilot test 10 couples were interviewed after having filled in the questionnaire. Here it was confirmed that the chosen topics were of importance and that the questionnaire was understandable and clear. (p. 46)*

6.2.1.5 Search protocol

Nearly all of the reports that used secondary data included a search protocol, but there was considerable variation in the level of detail provided. Some HTAs reported on all or a few methodological issues in relation to the search, while others included a very comprehensive search protocol with description and consideration of many different methodological issues.

Most of the HTAs described the databases and websites, search terms and keywords, and in- and exclusion criteria used for the search. Some reports described the results of the search, e.g. total number of hits and number of included studies. Some of these reports also included a list of these studies in an appendix. One report discussed the search results, with reasons for these results. A few reports described the whole search and selection process, e.g. who did what, and in what time period. Some of these reports discussed the development of the search protocol and others discussed particular elements, e.g. arguments for the chosen databases, in- and exclusion criteria and selection process (see example in Box 6.5).

Box 6.5: Example of detailed description of selection of relevant literature

Report: no. 20

Technology assessed: Interventions to promote breastfeeding

Data used: Secondary data

Way of handling the issue in question: Thorough description of the data handling process, including the selection of relevant literature from the identified studies (p. 8-10).

Quote: *Titles and abstracts of identified studies were independently assessed for relevance by two reviewers. Where no clear decision could be made on the basis of the title or abstract, studies were considered relevant. This process identified over 1100 potentially relevant studies, for which full reports were retrieved for more detailed consideration. One reviewer used a pre-screen form to systematically assess retrieved papers against the inclusion criteria. Pre-screening decisions were independently assessed by a second reviewer, and disagreements were resolved through discussion or, if necessary, by recourse to a third reviewer. (p. 8-9)*

6.2.1.6 Analytical methods and strategy

Over half of the HTAs that generated primary data and approximately half of the HTAs that generated secondary data reported on the analytical method and strategy used. This was mostly done by very briefly mentioning the analytical method used. Some reports simply stated that statistical methods were used, with no further detail provided, while others mentioned the specific qualitative or quantitative approach used. In some cases it was possible to deduce the analytical method from the figures or tables presented in the

report. A few reports also considered why a particular analytical strategy was chosen (see example in Box 6.6).

Box 6.6: Example of reporting of chosen method of analysis

Report: no. 11

Technology assessed: Doppler test

Data used: Primary and secondary data

Way of handling the issue in question: Description of the data handling process, including theoretical considerations behind the choice of analytical method; detailed description of the analytical process (p. 14).

Quote: *... The analysis is carried out on the basis of critical 'common-sense understanding'. Here the starting point is the self-perception of the pregnant woman, but one remains critical to this self-perception and focuses on the content of the statement...(p. 14)*

Some HTAs reported the analytical strategy and process more explicitly, e.g. step-by-step descriptions of the process and how analytical models had been developed. Sometimes the whole analytical process was presented, while in some cases only the data handling process was described, e.g. transcription of data. One HTA described the theories on which the analytical models rested. A few reports described the analytical methods and models, how these were used, and why these and not other methods were used. Some reports described the analytical equipment, e.g. the software programs used to handle and analyse the data.

6.2.1.7 Critical discussion of central methodological issues

Many of the HTAs reflected on various central methodological issues. Reports that generated primary data often discussed the quality and interpretation of the gathered data, e.g. possible problems due to biases, data ambiguity and response rates. Reports that used secondary data often discussed the validity and/or relevance of the included studies, either by discussing the methodological problems and possible solutions for each study in turn, or by appraising the overall validity of the included studies. Many of these reports described the instruments used for the validity appraisal, e.g. checklist, hierarchy or scale of evidence. Some reports simply included these instruments in an appendix, while others discussed how they were used and what problems were encountered. A few reports described the development of their own instruments.

Some reports discussed the overall validity of the HTA, and a few of these discussed the consequences that this might have for the interpretation and generalisability of the HTA results.

A few reports reflected on the role of the researcher and how this might have affected the data gathered, and hence the results of the study. One report described how the researchers themselves had experienced the data generation process and their own affect on it. Other reports simply included declarations of capacity or a brief description of the source of financial support for the study or report.

The reports often discussed various aspects of interpretation of data and limitations to the data gathered. Some did this by discussing the ways in which the methods chosen for data generation and analysis could affect and limit the interpretation of the data (see example in Box 6.7). Others discussed alternative ways of interpreting and understanding the data and analytical results, with a few reports reporting on differences of opinions

between the authors of the report and relevant experts in relation to the interpretation of the data and results. Some of these reports also compared the study findings with the results from other studies, and a few stated the need for further studies to confirm the results generated.

Box 6.7: Example of consideration of interpretation possibilities and possible sources of error

Report: no. 48

Technology assessed: Mobile video communication for deaf persons

Data used: Primary data

Way of handling the issue in question: Thorough and explicit consideration of methodological problems and possible sources of error in the assessment (p. 9-10), and their relevance for the study.

Quote: *... [It] should be noted that it was difficult to recruit 'clean' new users [of the technology] for the study, meaning that most of the users already before the research project had some experience with 3G-telephony. This fact makes it difficult to compare the 'new' technology to the ones that existed before... (p. 10)*

When HTAs were based on secondary data, some reports discussed the relevance of the included studies. Some did so by discussing which research questions could be answered by the included studies, and where and in relation to which questions further evidence still were required. A few reports included considerations of why the included studies could not answer all research questions, e.g. general methodological and ethical problems related to study designs. One report discussed how the lack of evidence affects the usefulness of the HTA to different decision makers.

6.2.2 Discussion

Many different methodological issues can be relevant in the reporting of an HTA, and the method of reporting can vary considerably. Most of the HTA reports reviewed for the present study simply described the methodology used, although sometimes in a very detailed manner, while others included rather inadequate descriptions that did not help to clarify how the results of the HTA had been generated. The few reports that did discuss how the various methodological choices had been made and why, were considerably more enlightening with respect to the methodological steps taken, the reasons for these and their consequences for the validity and trustworthiness of the results.

A single concept can often be defined and interpreted in several ways, depending on the context and reason for its use. HTAs that provide concept definition, by explaining how the central concepts (e.g. the technology, key evaluative parameters) have been interpreted and used in the study allow readers to understand the terminology used and to define the context and perspective in which the technology has been assessed.

Adequate reporting of the *methodological context for data generation* should enable readers to identify the steps taken in the data generation process and to allow replication of the methodology used. This can help to test the validity of the data generation process and the results. HTAs that are based on secondary data appear to have a tradition for comprehensive reporting of the *search protocol,* including detailed reporting of search terms and keywords, in- and exclusion criteria, databases and selection procedures used, time period, search history and search results. HTAs that in addition discuss why certain methodological choices were made enable readers to understand the reasoning behind the data generation and, more importantly, the possibilities and limitations of the data

generation process. Thus it is useful to explain how inclusion criteria were selected, why seemingly relevant databases or websites were not searched, why a less than optimal interview procedure was used, or why it was not possible to include all relevant questions in the questionnaire. The lack of answers to such questions can cause readers to doubt the intentions and methodological capabilities of those performing the HTAs – especially if the HTA concludes that insufficient data exist and that further data need to be generated. As factors such as the resources available to undertake the HTA can set limits on the data generation process, it is important to be explicit about the choices made and why they are considered to be the best possible design and data generation process in the given situation.

HTAs that generate primary data should explicitly state *sampling* methodology and the reasons for the sampling choices made, e.g. which patient or professional groups have been included, whose perspective the HTA is based on. Explicit discussion of such issues and their implications for the data gathered (and hence for the results and usefulness of the HTA) help to avoid suspicion of a hidden agenda or lack of knowledge or attention shown to relevant actors and aspects of the problem in question.

While many HTAs reported in one way or another on the methodology used for data generation, they seldom reported on the methodology used for *data handling and analysis.* Some HTAs, that mostly generated primary data, mentioned which analytical method had been used but they seldom described why. More detailed explanation of the analytical strategy and methods allow readers to understand how the raw data have been interpreted and systematised. Discussion of why one analytical method was chosen over another contributes to the reader's understanding of various problems or limitations in the data set, and also helps to define the focus of the study.

A *critical discussion of the methodology* used in an HTA is a key element of the reporting process. Some reports discussed both internal and external validity of the study results, for example by indicating that some of the gathered data were considered to be unreliable or unrepresentative, possible sources of bias, what was done or could have been done to avoid problems encountered, how the methodological or data limitations affect the usefulness of the results, the extent to which the study results can be transferred to other contexts and with what reservations or limitations. HTAs that include discussions of these issues go a long way towards demonstrating the reliability of the HTA and its conclusions.

Quite a few of the HTAs concluded that new data or further research was needed to adequately answer the research questions posed and to achieve the goal of the HTA. This seldom went beyond a simple statement of need, but a few HTAs did suggest requirements for future studies, and why these had not been possible to achieve in the current study. Information of this sort can help to indicate what skills, resources and time expenditure would be required for further or more adequate assessment of a technology, and may increase the likelihood that further study will be carried out.

6.2.3 Considerations for future HTAs

Depending on the given situation (e.g. the technology in question, the context and the purpose of the assessment), various methodological issues can be relevant for inclusion when reporting an HTA. Based on the discussion above the following issues might be considered reporting on in future HTAs:

- Concept definition: clear terminology, explicit description of the use and interpretation of central concepts used in the HTA

- Data generation methodology: the methodological approaches used, their relevance and the appropriateness of the choices made

- Methodological context for data generation: the process used (e.g. procedures followed, researchers involved, location of data generation, timing and length of data collection, materials and audiovisual aids used) and reasons for this methodology (advantages and disadvantages).

- Search protocol: comprehensive consideration and description of all elements of the search process; development of the search protocol (who, how, why), final search protocol (what and why in relation to search terms, key words, inclusion and exclusion criteria, databases, websites, hand searching), search history, selection process and the results of the search.

- Sampling: number and characteristics of participating respondents or interview persons, why and how they were selected, reasons for the sampling strategy used (advantages and disadvantages)

- Analytical strategy: how the data were handled, the analytical methods and models used, reasons for the analytical strategy used (advantages and disadvantages)

- Critical discussion of the methodology used: limitations and problems encountered during the research process, internal and external validity of the study, data quality and the interpretations made, limitations of the results, whether the goal of the HTA was achieved and the research questions adequately answered, reasons for the study's failure to meet expectations and how these can be addressed in future studies.

6.3 Generalisability of the HTAs' organisational and patient-related assessment

6.3.1 Reporting of generalisability

Of the 50 HTA reports, 27 (54%) explicitly discussed the extent to which the HTA results could be generalised to other contexts. In close to all cases, this was done for the report as a whole, rather than separate consideration of the generalisability of the organisational or patient-related assessments alone.

Most reports considered how contextual differences might limit the transference of the study results to other settings. Sometimes specific contextual aspects were discussed, e.g. cultural or geographical differences, or differences in population characteristics. Some reports briefly discussed how the results could be used in a national or international setting, while others focused on the transference of results from a local to a national context. Common to most of these discussions were that they were very diffuse and insubstantial and mostly made on a somewhat theoretical level. However, a few reports were more concrete regarding implementation of the study results (see example in Box 6.8). One report discussed differences between the research setting and the real world, and how these might affect the generalisability of the research results.

Box 6.8: Example of consideration of the applicability of study results to another setting

Report: no. 32

Technology assessed: Organisation of services for diabetic retinopathy screening

Data used: Primary and secondary data

Way of handling the issue in question: Consideration of the challenges related to local implementation of a national screening program, supplemented by specific practical recommendations for addressing these challenges (p. 85-88).

Quote: *Each local NHS Board system will have specific challenges to address in order to introduce the nationally recommended programme. HTBS recommends that this is done by planned incremental building upon existing services: namely 'evolution' rather 'revolution'. The key components cover organisational issues, people issues, IT system issues, equipment issues and provision of relevant resources... (p. 85)* [recommendations for handling these issues are thereafter described and discussed over several pages]

A few reports considered how different methodological choices and the data quality might affect the generalisability of the study results, while others noted that the lack of relevant and solid data limited the extent to which the study results could be transferred to other contexts.

6.3.2 Discussion

Practically all the HTAs assessed generalisability of the study results as a whole, rather than for the organisational or patient-related assessment alone. This made it difficult to identify generalisability issues that were specific to these elements of an HTA. However, many of the generalisability issues mentioned in the reports could be assumed to be valid across the different elements of an HTA. Considerations of how differences between contexts might affect the possibilities of transferring the results of a report to another context can be of relevance independent of which aspects of a technology have been assessed. Similarly, issues of methodological validity are common to all elements of an HTA, whether they deal with clinical/technological, economic, organisational or patient-related aspects.

Despite many of the HTAs treating issues related to the generalisability of results rather superficially, such issues are highly relevant to report. It may be that issues of generalisability are lacking in HTA reports because comprehensive and practical guidelines or principles of how to deal with these issues are not yet available. This is likely to be a challenging task, however, as identification of appropriate contextual aspects for examination would depend on the characteristics of both the technology and the contexts in question.

A few reports considered how the methodology used and the comprehensiveness of the reporting affected the generalisability of the study results to other contexts. Of course, a reader's assessment of the usefulness of an HTA report will also depend on his/her own general assessment of the methodological approaches used. This can be difficult for readers with less experience in performing or interpreting HTAs, as there is little consensus as to what 'acceptable' or 'good' validity is. For example, does 'good' validity refer only to choosing the most appropriate design and methods for data generation and analysis, or does it also include good reporting of the HTA methodology? And how should 'good' reporting be defined: is it only a description of the methodological steps taken or does it also require a discussion of why these steps were taken? And with what level of detail should this description and discussion be presented? Who should be the judge in deciding whether the study design and methods were the most appropriate ones to use, and on the basis of which criteria? Does there even exist a 'correct' study design or a 'correct'

methodology for data generation and analysis, or does the judgement of 'the right design' depend on professional beliefs and traditions?

Such questions need to be answered in order to better equip the performers and users of HTAs in assessing the generalisability of study results to other contexts. This is especially the case regarding organisational and patient-related assessment in HTAs, and will doubtless require both systematic methodological research and comprehensive discussion among HTA researchers.

6.3.3 Considerations for future HTAs

Depending on the given situation (e.g. the technology in question, the context and the purpose of the assessment), various issues related to the generalisability of the study results can be relevant for inclusion when reporting an HTA. Based on the discussion above the following issues might be considered reporting on in future HTAs:

- Context for the technology's current and/or future use, e.g. how contextual differences might affect the applicability of the results to another context
- Specific contextual aspects of relevance, e.g. differences in population characteristics, cultural or geographical differences
- Validity and reliability of the HTA, e.g. how the methodology used and the comprehensiveness of the reporting affects the generalisability of the study results to other contexts.

7 Conclusions and recommendations

The purpose of the study was 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. A search of INAHTA members' websites in July 2005 identified a total of 382 full HTA reports published either in English or a Scandinavian language. Of these reports, 146 (38%) included organisational and/or patient-related assessments. Inclusion of these two elements in HTA reports is in general less common than inclusion of technological/clinical and economic issues.

A review of 50 HTA reports, randomly chosen from the 146 reports including organisational and/or patient-related assessments, 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 90% 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 80% 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 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 patients' 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 impact of the technology on the *patient's financial circumstance*s.

Not only was there 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 that these issues were handled. Most often the issues were described only. Some reports included more comprehensive and in-depth assessment of issues and thereby provided knowledge that can be useful, for instance, 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 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 the 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 explicitly 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 and how 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.

Half 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.

As shown above, inclusion of organisational and patient-related assessments in HTAs was less common than inclusion of technological/clinical and economic assessments. When organisational and patient-related assessments were included, they covered a variety of issues and these issues were handled in very different ways. For an HTA to function as a decision-making tool, it needs to be comprehensive. It is important, therefore, to consider assessment of organisational and patient-related issues in relation to the overall policy questions of the HTA and to the specific purpose and research questions. A technology cannot be implemented in an organisation and used in relation to patients without some implications for the organisation, the patients and the technology itself.
While some of the HTA assessments were broad and included a variety of issues, these issues were often handled in a rather superficial way. More comprehensive and in-depth

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 lack 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 (and is the chosen perspective relevant for me as a reader), were the relevant issues included (and are they relevant to the technology and context in which the reader is considering to implement the technology), were the issues assessed using relevant and valid methodology and, finally, which policy questions does this HTA answer, how representative are the results and what are the limits of this HTA?

7.1 The scope of the review

While the review was designed to meet its specified purposes, there are some limitations to the study. The study is descriptive in nature and no comparative analyses have been conducted. The review only includes HTAs published by INAHTA members and in Scandinavian or English languages. A disadvantage of these choices is the resulting lack of information about HTA practice outside the INAHTA network and among non-English oriented INAHTA members.

The focus of the study was on organisational and patient-related assessments included in full HTA reports. A sample of 50 reports was assessed, this sample size being based on convenience and pragmatic selection criteria and on the dual purpose of both describing the extent to which organisational and patient-related assessments are included in HTAs and the different ways and best practice of doing this. A disadvantage of these choices is a resulting lack of information about HTA practice outside the scope of the 50 reports.

Despite these limitations, it is believed that the approach chosen gives a useful insight into current practice in relation to organisational and patient-related assessment in HTA and provides a potential learning tool based on examples of good practice and suggestions for issues to be considered in future HTAs.

7.2 Recommendations

The present study offers those undertaking HTAs an insight into how a broad interpretation of 'health technology assessment', which includes assessment of organisational and patient-related issues, increases the usefulness of an HTA. The study shows that many different issues related to organisational and patient-related elements might be of relevance to include in an HTA, depending on the purpose of the assessment and the rese-

arch questions under investigation. These aspects of the study are central in determining not only which issues should be addressed in the HTA, but also what approach should be used in relation to study design, data generation and analytical method. If the methodology and findings of the HTA are reported in a way that includes not only the methodological steps undertaken but also the reasons for choosing these particular steps and their consequences for the HTA findings, then readers of the HTA are more easily able to evaluate the relevance and trustworthiness of the HTA results.

The findings from the present study give rise to a number of recommendations in relation to the inclusion, assessment and reporting of organisational and patient-related issues in HTAs. These recommendations are primarily related to which organisational and patient-related issues might be included, and how the methodological choices and their implications for the generalisability of the results should be reported.

The choice of which *organisational and patient-related issues* should be included in an HTA depends on the policy question of the HTA and on the particular technology under investigation. The decisions should thus always be taken on an individual basis for each HTA. Having said that, many HTAs are undertaken with the purpose of addressing policy questions that focus on assessment of general organisational or patient-related consequences of a technology, e.g. what are the organisational and patient-related consequences of implementing and using a technology, or how to implement a technology with its associated organisational and patient-related consequences? In the investigation of policy questions like these there are a number of organisational and patient-related issues that should be considered for inclusion in the HTA.

There are several different categories of organisational issues that should be considered for an HTA. If, for instance, the purpose of an HTA is to assess how to implement a technology in a setting with no prior experience with technologies of that kind, it could be relevant to include and assess a range of *structural issues*. For instance, where could the technology be placed in the overall organisational *structure*, what are the technology's likely consequences in relation to capacity, staff and the physical environment and how could these consequences be dealt with, what issues are relevant for the wider diffusion of the technology, which incentive structures are at work and how do they affect the implementation and use of the technology, what are the economic consequences at the organisational level of the implementation and use of the technology?

If, on the other hand, the purpose of the HTA is to assess and compare the organisational consequences of the implementation and use of a new/alternative technology with those of an already established technology, many of the same structural issues could be relevant to consider but from a somewhat different perspective. For example, it might be relevant to consider the consequences for the current organisational placement, staff, capacity, the physical environment, diffusion, incentive structures and the economic consequences at an organisational level. (For a full list of structural issues to consider for inclusion in future HTAs, see section 4.2.4.)

When faced with a policy question that focuses on both the organisational consequences of the use of a new technology and on how best to implement the technology, a comprehensive assessment of *process-related issues* is important. It is these issues that deal more closely with the practical and daily use of a technology. Assessment of process-related issues can provide a concrete product (e.g. a work manual) for new users of the technology (who might be new organisations or new colleagues), but are also essential to the practical use of the technology – and hence also to beneficial results in terms of the

effects and outcome of a technology. It is important that all involved parties are aware of who does what in relation to the technology, when it is done, how and why it is done and, not least, what the individual's role and responsibility is in relation to the roles and responsibilities of other actors.

With the introduction of a new technology or a change to a current technology, it is inevitable that a variety of questions will arise such as: How is everybody supposed to work together and interact? What can I expect from others and what can they expect from me? What does this new technology and way of working require in relation to staff skills and resources? These questions need to be addressed by decision-makers, whether they are planning and preparing budgets for a future, or whether they are deciding about the continued use of a technology. Currently, these questions and their answers often remain unspoken, and different actors involved in the use of the technology simply assume that everybody else has the same understanding and opinion of what is going on and why. But this is not always the case. Not infrequently, actors and organisations unknowingly work in different ways and directions; this can have serious consequences for the effects of a technology. In other cases actors may perform actions that are unnecessary or could be undertaken more easily and effectively by others. Many of these problems might be avoided by the inclusion and assessment of relevant process-related issues in an HTA. This would support a more explicit discussion of actors' roles and responsibilities, staff needs and lines of communication, and potential problems could be identified and prepared for. (For a full list of process-related issues to consider for inclusion in future HTAs, see section 4.3.4.)

Quality control and evaluation is an integral part of the working processes associated with the use of a technology. HTAs that assess either new or already established technologies could include a range of issues related to quality control and evaluation. For instance, how should quality control of the use of the technology be undertaken, what parameters should be measured and for what reason, how can these parameters be measured, which kind of data should be gathered, who should collect the necessary data? Furthermore, who should develop the systems and procedures for quality control and evaluation, and who should actually perform the practical quality control and evaluation? If the purpose of the HTA is to assess a technology already in use, it could also be relevant to consider whether the current system and procedures for quality control and evaluation are effective and whether they measure the desired parameters. (For a full list of control and evaluation issues to consider for inclusion in future HTAs, see section 4.4.4.)

In line with these questions, different issues and questions related to organisational *culture and environment* should also be considered for inclusion in HTAs that are undertaken with the purpose of assessing the general organisational consequences of the use of a technology or how to implement a technology. The following questions could, for instance, be relevant to consider for both new and experienced users of a technology: how does the technology fit into the organisational culture and philosophy of care, hence what constitutes the organisational culture and philosophy of care? Do there need to be changes in the organisational culture and how can these be made? How does the use of the technology affect the psychological and physical working environment and the outer environment, and how can possible negative effects be avoided? (For a full list of culture and environment issues to consider for inclusion in future HTAs, see section 4.5.4.)
As with organisational issues, there are several different categories of patient-related issues that should be considered for an HTA. If the purpose of the HTA is to assess how to implement a technology in a setting with no prior experience with technologies of that kind, it could be relevant to include and assess issues related to *patient information*. It

would be useful to know, for instance, which patient groups would be using the technology, what sort of information they would need, and when and how this information should be provided. It could be relevant to include and assess *psychological issues*. Aspects of importance for patients could include, for example, expected psychological effects and reactions due to the use of the technology and how these effects might be handled, and how patients might be involved in decisions related to the use of the technology. After a technology is implemented it might be relevant to investigate the patients' preferences and level of satisfaction in regard to the use of technology. It could also be relevant to assess *quality of life issues*, e.g. how might the use of the technology affect the self-rated health or quality of life of the patients or their significant others. The inclusion of social issues would allow, for example, an assessment of the implications of the technology on the patient's (and their significant others') daily lives and ability to work and of their needs for information and support. It could also be relevant to consider *ethical issues* such as factors related to individual patients' acceptance of the technology and how this might be enhanced e.g. the relevance and possibility of involving individual patients in the use of the technology and its results. Finally, it could be relevant to consider patient economic issues in relation to the direct and indirect expenses that could be expected to arise for patients and their significant others.

If, on the other hand, the purpose of the HTA is to is to assess and compare the patient-related consequences of the implementation and use of a new/alternative technology with those of an already established technology, many of the same issues could be relevant to consider but from a somewhat different perspective. While again, in relation to *patient information*, it would be relevant to consider which patient group would be using the technology, it could also be important to consider the patients' rights to information and the consequences of information versus no information for the use of technology and for the patients' experiences with the technology. In relation to *effects on quality of life* it would be useful to consider which aspects of self-rated quality of life might be affected by the technology as well as possible differences in how patients and health professionals perceive the effects of a technology on patient health-related quality of life. In relation to *psychological, social and quality of life issues* it could also be relevant to consider whether the eventual disadvantages of the technology outweigh the technology's usefulness. In relation to *ethical issues* it might be important to also consider the safety of the technology as well as factors related to society's acceptance of the technology, possible implications for the society's norms for equality and equity and perhaps also effects of the technology on the general understanding of health vs. disease and life vs. death. In relation to *patient economic issues* it could be relevant to assess patient willingness-to-pay for the technology and investigate any influence of this on the use of the technology, as well as the technology's impact on patients' possibilities for earning a living. (For a full list of patient-related issues to consider for inclusion in future HTAs, see Chapter 5.)

The choice of which *study design and approaches for data generation and analysis* to use when undertaking a HTA should be based on a consideration of the policy questions to be investigated, the technology in question, the context of the technology and the available research time and resources (and access to the study area). However, although the application of different designs and methods will vary from HTA to HTA, there should always be the same comprehensive *reporting of the methodological choices made and of the generalisability of the results of the organisational and patient-related assessment*. A number of recommendations are provided in the present study that should help to enhance both the usefulness and the trustworthiness of HTA findings. The reporting of an HTA should always make clear to the reader what methodological steps have been undertaken and, just as importantly, why these steps were undertaken and with what consequences.

This holds for all aspects of the HTA methodology including concept definitions, data generation methods, context for data generation, search protocol, sampling and analytical strategy. In line with this, the authors should also provide a critical discussion of the applied methodology and the generalisability of the study results, with explicit reference to the context for the technology's current and/or future use, specific contextual aspects of relevance, the validity and reliability of the HTA findings. (For a full list of recommendations regarding reporting of methodological issues in future HTAs, see sections 6.2.3 and 6.3.3.)

It is hoped that the present study will make a significant contribution to current knowledge about organisational and patient-related assessment in HTAs and the methodology applied in these assessments. Some areas still need to be examined and developed further, however. 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, the results of the present study show that few HTAs adequately report on the generalisability of the results of organisational and patient-related assessments. Further investigation is needed to determine ways of reporting on generalisability of results that will be useful not only for those undertaking HTAs but also for those wishing to assess the relevance of the findings of an HTA for their own setting. The assessment of a study's internal and external validity in relation to generalisability of the study results would be made easier by more comprehensive reporting of the context for the individual HTA and more knowledge about how users can evaluate the context and relevance of the HTA in relation to transferring the results to another setting. It is likely that these developments will require both systematic methodological research and comprehensive discussion among HTA researchers.

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Appendix 1: The 50 HTA reports included in the assessment

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Appendix 2: Checklist used for the assessment

Selection of literature

1. Which language is the report written in?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	a. Scandinavian		
	b. English		
	c. Other		

If criteria a) and/ or b) are met, move on to question no. 2.

2. Which elements are included in the report? (Mark more than one if necessary)			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	a. Technology		
	b. Economy		
E.g. structure, process, (implementation), evaluation/control and/or culture	b. Organisation		
E.g. effects, psychological, information, economic, social and/or ethical aspects	c. Patient		

If criteria c) and/or d) are met, move on to question no. 3.

3. Which kind of HTA has been produced?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
Which term has in the report been used about the study/investigation that has been undertaken?	a. (Full) HTA		
	b. Early warning		
	c. Rapid assessment		
	d. Other		

If criterion a) is met, the report will be included.

1. Overall description of the HTA

1.1 Reference of the report?	
	Comments
Title:	
Author(s):	
Publisher and year of publication:	
Reference number in Ref. Man.:	

1.2 In what country has the study been undertaken?	
	Comments
Country:	

1.3 Who has published the report?			
Hints	Options of answers	Assessment(mark most relevant)	Comments/descriptions/ references to the report
	a. A national HTA institute		
	b. A regional HTA institute		
	c. Other		

1.4 Is the purpose(s) of the study clearly stated?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, which type of purpose? (mark more than one if necessary)			
E.g. creating more knowledge about consequences of possible choices, solutions or priorities.	a. Generation of knowledge		
E.g. creating improved basis for decision(s) by illumination of different assumptions, interests and consequences	b. Basis for decision(s)		
E.g. creating improved basis for planning, including implementation and utilisation of the technology.	c. Basis for implementation		
E.g. creating basis for more appropriate resource utilisation.	d. Resource utilisation		
E.g. creating basis for quality development in connection to examination, treatment, nursing and care of, for instance, certain groups of patients.	e. Quality control		
Write which ones in the comment box	f. Other		

1.5 Which kind of technology is being studied?			
1.5.1 What is the medical purpose(s) of the technology? (mark more than one of necessary)			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. a technology that helps determine what disease processes occur in a patient	a. Diagnostic technology		
E.g. a technology that protects an individual from disease or prevents its progression.	b. Preventive technology		
E.g. a technology that provides treatment for a disease that is sometimes curative, but more often gives symptomatic or functional relief but does not address the underlying problem.	c. Therapeutic technology		
E.g. a technology with the purpose of compensating for a functional (or psychological) problem or assisting a person with a disability to rise to a higher level of functioning.	d. Rehabilitative technology		
E.g. a technology that is used in management and administration to ensure that health care is delivered as effectively as possible.	e. Organisational or administrative technology		
E.g. a technology that is used to provide patients, especially those in hospital, with needed services, such as hospital beds and food.	f. Supportive technology		
Write which ones in the comment box	g. Other		

1.5.2 What is the physical nature of the technology? (mark more than one if necessary)	
E.g. any chemical or biological substance that may be applied to, ingested by, or injected into humans in order to prevent, treat, or diagnose disease or other health conditions.	a. Drug
E.g. any physical item, excluding drugs, used in health care, and may range from a machine requiring a large capital investment to a small simple instrument or implement.	b. Device
E.g. a combination, often quite complex, of provider skills or abilities (technique) with drugs, devices, or both.	c. Procedure
Write which ones in the comment box	d. Other

1.6 Is the technology compared with alternative technology – is a comparator used?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. two different ways of organising the technology, a previous technology compared to a new, or a new placement (hospital vs. home) etc.			
	Yes		
	No		

1.7 Is the target group of the HTA report described?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, which one(s)? (mark more than one if necessary)			
E.g. the government (of a county), decision makers on a central/political level	a. Politicians/officials		
E.g. on a hospital or a ward, decision makers on a decentralised/practical level	b. Management/ administration		
E.g. physicians, nurses, laboratory technicians, home care assistants etc.	c. Professionals/ medical staff		
E.g. patients under treatment, potential patients (carers, relatives)	d. Patients		
Write which ones in the comment box	e. Others		

1.8 Is the time for caring out the study specified in connection to the life cycle of the technology?			
Hints	Options of answers	Assessment(mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, when?			
Technology not yet developed	a. Future technology		
Technology prior to adoption	b. Emerging technology		
Technology in the phase of adoption	c. New technology		
Technology in general use	d. Accepted technology		
Technology that (maybe) should be taken out of use	e. Obsolete technology		

2. Description of organisational elements in the included HTAs.

2.1 General issues

2.1.1 Is the purpose of including the organisational element in the study clearly stated?			
Hints	Options of answers	Assessment(mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, write the purpose(s):			

2.1.2 Is the reason for not including organisational related issues in the study clearly stated?			
Hints	Options of answers	Assessment(mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, write why (in short)			

2.1.3 Have research questions related to the organisational element been formulated?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, what questions:			

2.1.4 Which theme(s) is/are included in the organisational element?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	a. Structure		
	b. Process		
	c. Control/evaluation		
	d. Culture/environment		
Write what theme in the comment box	e. Other		

2.2 Structure

2.2.1 Is the formal organisational structure of the technology described?			
Hints	Options of answers	Assessment(mark most relevant)	Comments/descriptions/ references to the report (If yes, describe: 1. data source, 2. Issues included, 3. Way of handling the subject (description or discussion).
E.g. organisational level – centralised/decentralised.	Yes		1. 2. 3.
	No		

2.2.2 Is the physical, resource and legislative structures of the technology described?			
Hints	Options of answers	Assessment(mark most relevant)	Comments/descriptions/ references to the report
E.g. demands in regard to the capacities of for example facilities, planning, large-scale operations, equipment, devices etc.	Yes		1. 2. 3.
	No		

2.2.3 Is there a description of considerations for diffusion of the technology?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. has an assessment of how the technology is spread within the focus areas of the health technology assessment been carried out? Is there a description of who is responsible for the diffusion?	Yes		1. 2. 3.
	No		

2.2.4 Is it described whether or not the technology has economic consequences on an organisational level?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. has an assessment of the ways in which the technology may cause changes in accordance to payment arrangements, rates/tariffs, additional expenditure etc. been carried out?	Yes		1. 2. 3.
	No		

2.2.5 Is it described whether or not the technology has an effect on the given incentive structures?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. has an assessment of which kind of economical, political, career related, working process related or treatment related incentives the technology creates among personnel, patients, wards, collaborators, hospitals, counties etc. been carried out?	Yes		1. 2. 3.
	No		

2.3 Process

2.3.1 Is the working flow related to the use of the technology described?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. has an overview of tasks, working processes and social processes in regard to the use of the technology been constructed, e.g. existing routines can be changed or replaced by new tasks and routines or the number of patients and/or the arrangement of the course of treatment can be changed.	Yes		1. 2. 3.
	No		

2.3.2 Is there a description of what kind of actors (personnel) should be involved in the use of the technology?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. has an assessment of the personnel or the personnel groups who are going to use the technology been carried out, e.g. an assessment of changes in responsibilities and division of labour between the different professions, if, for example, a technology can only be applied by a specialised group of personnel.	Yes		1. 2. 3.
	No		

2.3.3 Is there a description of whether or not the technology has consequences for the personnel competences and personnel resources?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. has an assessment of the needs for more information and education, and/or an assessment of existing resources and future resource needs (recruitments etc.) been carried out?	Yes		1. 2. 3.
	No		

2.3.4 Is there a description of changes in interaction and communication with the surroundings/outside world?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. has an assessment of changes in the relations between the unit of treatment and its surroundings (e.g. other units of treatment, cross functions, patients, relatives, outside actors etc.) and here under an assessment of new demands on collaboration and communication been carried out?	Yes		1. 2. 3.
	No		

2.3.5 Are potential barriers and bottlenecks identified and described?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
Has an assessment of whether or not there is identified barriers reg. the use of the technology. Has an assessment of weather or not the technology will lead to bottlenecks been carried out, e.g. in regard to increased capacity needs in the short run caused by more treatments or an increased need for certain groups of personnel. (The needs can for example be both in regard to personnel, economy and facilities and in regard to knowledge and information on a certain issue).	Yes		1. 2. 3.
	No		

2.4 Control and evaluation

2.4.1 Is there a description of who is responsible for the control with and evaluation of the use of the technology?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. has an assessment of where in the organisation the unit of control/evaluation is/should be placed been carried out, e.g. who is in charge of securing the quality/control/evaluation?	Yes		1. 2. 3.
	No		

2.4.2 Is there a description of the systems used for the control and evaluation of the use of technology?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. has an assessment of how the ongoing control with and the quality control of the use of the technology takes place and is organised been carried out.	Yes		1. 2. 3.
	No		

2.5 Culture/environment

2.5.1 Has an assessment of whether or not the technology has consequences for the organisational culture been carried out?			
Hints	Options of answers	Assessment(mark most relevant)	Comments/descriptions/ references to the report
E.g. has an assessment of whether or not the technology will meet resistance or accept among the personnel been carried out, e.g. whether or not the technology matches existing formal/informal structures, routines, traditions, norms and values in the organisation, whether or not there is a need for changed perceptions and understanding etc.	Yes		1. 2. 3.
	No		

2.5.2 Is the impact of the technology on the psychological working environment described?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. has an assessment of the impact of the technology on job satisfaction, influence of employees, attraction of employees etc. been carried out?	Yes		1. 2. 3.
	No		

2.5.3 Is the impact of the technology on the physical working environment described?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. has an assessment of the impact of the technology on the ergonomics been carried out, e.g. working place arrangement, handling of health injurious substances etc.	Yes		1. 2. 3.
	No		

2.5.4 Is the impact of the technology on the outer environment described?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. has an assessment of the advantages and disadvantages of the technology on the environment been carried out, e.g. green balances/accounts.	Yes		1. 2. 3.
	No		

2.6 Other

2.6.1 Have other assessments related to the organisational element been carried out?			
Hints	Options of answers	Assessment(mark most relevant)	Comments/descriptions/ references to the report
	Yes		1. 2. 3.
	No		
If yes, write which ones here:			

2.7 Study design/strategy

2.7.1 Is the perspective(s) of the organisational issues explicitly described?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E. g. individual, group, society perspective			
	Yes		
	No		

2.7.2 Is the design of the study described?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, which design? (mark more than one if necessary)			
Hints	Options of answers	Assessment(mark most relevant)	Comments/descriptions/ references to the report
E.g. studies based on existing literature reporting one, or more, original studies, retrieved from databases etc.	a. Reviews		
E.g. experimental studies with intervention- and control groups (RCT, case-control studies, cross-over studies) - controlled environment and efficacy	b. Intervention studies		
E.g. comparing two or more cases regarding differences in use of the technology e.g. ways of organisation, pricing etc. (The purpose of studying more cases is to compare the different cases use of the same technology)	c. Comparative studies		
E.g. studying changes over time, prospective or retro prospective (cohort and other epidemiological studies, register studies and before-after studies)	d. Longitudinal studies		
E.g. an in-depth study of a single or multiple cases (including its context) comprising one or more individuals/organisations. (The purpose of studying more cases is to identify and study more and different aspects of the technology – broaden the perspective on the technology)	f. Case studies		
Describe the design in the comment box	g. Others		

2.8 Data generation and data analysis

If No) move on to question no. 2.8.5.

2.8.1 Is there a description of how data is generated?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, how/which kind of data? (mark more than one if necessary)			
Elaborate on this in question no. 2.8.2 and/or 2.8.3	a. Primary data		
Elaborate on this in question no. 2.8.4	b. Secondary data		

If no) move on to question no. 2.8.5

2.8.2 Is there an explicit description of how qualitative data has been generated?			
Hints	Options of answers	Assessment(mark most relevant)	Comments/descriptions/ references to the report
	Yes		
Qualitative data has been generated, but there is no explicit description of how it has been generated	No		
	Qualitative data has not been generated		
If yes, how is it generated? (mark more than one if necessary)			
E.g. field study, participative observation, experiments	a. Observations		
E.g. structured or unstructured interviews with key informants, experts, witnesses and/or representatives with personal experiences	b. Individual interviews		
E.g. group interview with informants and/or representatives	c. Focus group interviews		
E.g. laws, written guidance, patient information's etc.	d. Text documents		
E.g. delphi-method, workshops on future sceneries etc.	e. Prospective methods		
Describe the method in the comment box	f. Other		

2.8.3 Is there an explicit description of how quantitative data has been generated?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
Quantitative data has been generated, but there is no explicit description of how it has been generated	No		
	Quantitative data has not been generated		
If yes, how is it generated? (mark more than one if necessary)			
E.g. questionnaires in writing or oral using open or fixed categories for answers. Used for a selected sample of a population. E.g. Patients self-rated health condition	a. Questionnaires		
E.g. willingness-to-pay, conjoint analysis	b. Preference measurement		
E.g. national, local or private registers on use of healthcare services, output etc.	c. Registers		
Describe the method in the comment box	d. Others		

2.8.4 Is there an explicit description of how secondary data has been generated?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
Secondary data has been generated, but there is no explicit description of how it has been generated	No		
	Secondary has not been generated		
If yes, how is it generated? (mark more than one if necessary)			
E.g. systematic searches in relevant databases, and explicit criteria for inclusion	a. Systematic		
E.g. convenient or already known/ easily available sample of literature	b. Unsystematic		

2.8.5 Is the method of analysis described?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, which method(s)? (mark more than one if necessary)			
E.g. descriptive, critical common sense, theoretical analysing etc.	a. Qualitative		
E.g. frequencies, use of statistics, meta-analyses etc.	b. Quantitative		

2.9 Validity of the HTA

2.9.1 Is the chosen study design explicitly discussed with regard to purpose, relevance and research questions and issues?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		

2.9.2 Is the chosen method of data generation explicitly discussed with regard to purpose, relevance and research questions and issues?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		

2.9.3 Is the chosen method of analysing explicitly discussed with regard to purpose, relevance and research questions and issues?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the repor
	Yes		
	No		

Field in the questionnaires according to the types of studies that have been carried out in the HTA (question no. 2.8.2, 2.8.3 and/or 2.8.4)

2.9.4 Is a sufficient basis established for the reader to assess the validity of the qualitatively interpreted studies? Are the following topics explicitly described and/or discussed?

Hints	Options of answers	Assessment (mark most relevant)		Comments/descriptions/ references to the report
		Yes	No	
E.g. definition and explained use of central concepts	a. Concept validity			
E.g. description of theoretical frame, methodologies, models etc.	b. Theoretical point of departure and applied theories			
E.g. description of the method(s) used (interview, observation, texts, workshops etc.)	c. Qualitative methods used			
E.g. identification of, and contact to, areas of observation and participants. Handling of drop-outs etc.	d. Sampling			
E.g. description of the context for observation, interviewing, relations, ethics, interview guides, length of interview/observation, use of audiovisual and/or electronic equipment.	e. Methodological context			
E.g. description of how the generated data is handled and interpreted (transcribing, condensing, coding, writing up etc., use of audiovisual and/or electronic equipment).	f. Analysis			
E.g. discussion of the complexity and heterogeneity of data, methods of interpretation, possible misinterpretations, concordance to other studies	g. Critical reflection – alternative interpretations			
E.g. discussion of the quality of selecting data sources, data generation and data handling	h. Critical reflection – quality of data			
E.g. discussion of personal biases, role etc.	i. Critical reflection – the role of the researcher			
	j. Other topics			

2.9.5 Is a sufficient basis established for the reader to assess the validity of the quantitatively interpreted studies? Are the following topics explicitly described and /or discussed?				
Hints	Options of answers	Assessment(mark most relevant)		Comments/descriptions/ references to the report
		Yes	No	
E.g. definition and explained use of central concepts	a. Concept validity			
E.g. description of theoretical frame, methodologies, models etc.	b. Theoretical point of departure and applied theories			
E.g. description of the method(s) used (questionnaire, register withdrawal, etc.)	c. Quantitative methods used			
E.g. description of identification, size of and contact to sample. Handling of drop-outs etc.	d. Sampling			
E.g. description of context (register, questionnaire, number of questions/requests, possible answers, form (written/oral), distribution etc.)	e. Methodological context			
E.g. description of methods used for interpretation, hypothesis, representativity, size of sample, confidence interval, analysis of drop-outs etc.	f. Analysis			
E.g. discussion of complexity and heterogeneity of data, possible misinterpretations, statistical uncertainty, concordance to other studies	g. Critical reflection – alternative interpretations			
E.g. discussion of quality in selecting data sources, data generation and data handling, confounders, bias (validity and reliability)	h. Critical reflection – quality of data			
E.g. discussion of personnel biases, role etc.	i. Critical reflection – the role of the researcher			
	j. Other topics			

2.9.6 Is a sufficient basis established for the reader to assess the validity of the secondary data? Are the following topics explicitly described and /or discussed?				
Hints	Options of answers	Assessment (mark most relevant)		Comments/descriptions/ references to the report
		Yes	No	
E.g. description of search strategy, databases, thesaurus/indexes	a. Search protocol			
E.g. description of method used for interpretation	b. Analysis			
E.g. discussion of the quality of the included secondary data	c. Critical reflection - validity of the included studies			
E.g. discussion of relevance with regard to purpose, and research questions	d. Critical reflection – relevance of the includ-ed studies			
E.g. discussion of prejudice, role etc.	e. Critical reflection – the role of the researcher			
	f. Other issues			

3. Description of the patient related issues in the included HTA's

3.1 In general

3.1.1 Is the purpose of including patient related issues in the study clearly stated?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, copy the stated purpose:			

3.1.2 Is the reason for not including patient related issues in the study clearly stated?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, state why (in short):			

3.1.3 Are research questions stated in relation to patient related issues			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, state (copy) which one(s):			

3.1.4 Which patient related issues are included in the study? (mark more than one if necessary)			
Hints	Options of answers	Assessment	Comments/descriptions/ references to the report
	a. Patient information		
	b. Psychological issues		
	c. Effect/quality of life		
	d. Social issues		
	e. Ethical issues		
	f. Patient economy		
	g. Other issues		

3.2 Patient information

3.2.1 Is it described how patients are informed about the technology?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report (If yes, describe: 1. data source, 2. Issues included, 3. Way of handling the subject (description or discussion).
E.g. patient information can be in writing or oral, include various information about the technology; when, why and how it is used, limitations to its use and usefulness etc. The aim could be to give the patient (next of kin) knowledge/support/realistic expectations to the technology suggested/offered, and may possibly make the patient (next of kin) capable of choosing between alternatives or to express preferences. Is the right information available at the right time and form is it understood and what the consequences of information versus no information are.	Yes		1. 2. 3.
	No		

3.3 Psychological issues

3.3.1 Is there a description of involvement of the patients in the implications of the technology, and in decisions in relation to the technology?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. are the technology's implication for the patient's sense of control and self-reliance considered. Are the patients opportunities for having a say in decision-making and the patient's rights as an individual considered (e.g. will the patient be apple to choose between alternatives considering pros and cons)	Yes		1. 2. 3.
	No		

3.3.2 Is there a description of the technology's implication for the patient's sense of fear and discomfort?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. assessment of the consequences of the technology on, for instance psychological or physical discomfort, fear, insecurity, worrying, guilt etc. Assessment of weather these consequences surpass the usefulness of the technology (for the patient and for the next of kin)	Yes		1. 2. 3.
	No		

3.3.3 Is there a description of the patient's satisfaction with the use of technology?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. assessment of the patient's satisfaction (and maybe their next of kin) with the use of the technology e.g. information, accessibility, organisation, relation to the health/medical staff using the technology etc.	Yes		1. 2. 3.
	No		

3.4 Effects on quality of life

3.4.1 Is it described how patients experience the effects of the technology?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. are the patient's experience of effects considered (e.g. measurements of quality of life), and do they divert from the medical health/medical staff's expectations or assessments.	Yes		1. 2. 3.
	No		

3.5 Social issues

3.5.1 Is there a description of the technology's impact on the patient's daily life?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. does the technology have implications for retaining or resuming self-control/reliance and for handling everyday life and its tasks?	Yes		1. 2. 3.
	No		

3.5.2 Is there a description of the technology's implication for the patient's work capacities?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. does the technology have implications for retaining or resuming a job, for work capacity etc.	Yes		1. 2. 3.
	No		

3.5.3 Is there a description of the technology's implication for the relatives?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. does the technology have implications for the patient's need of physical/psychological/social etc. support from relatives and/or friends? For the family structure, or for the patient's capability of supporting dependants?	Yes		1. 2. 3.
	No		

3.6 Ethical aspects

3.6.1 Is there a description of the patient's acceptance of the technology?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. does the patient accept the use of the technology for examination, treating, caring etc? Considering practical issues, in daily living and work life, and considering ethical issues and expectations to the health services.	Yes		1. 2. 3.
	No		

3.6.2 Is there a description of the population's acceptance of the technology?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. does the population accept the use of the technology? Considering ethical issues, expectations to health services, possible changes in cultural values, demographic changes, implications for the environment, legal system etc.	Yes		1. 2. 3.
	No		

3.6.3 Is there a description of specific ethical issues regarding the technology and its use?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. is it ethically reasonable to use a (maybe) risky/ painful/very expensive etc. technology (e.g. gene-therapy, screening of healthy individuals, in vitro insemination etc.)? Are there considerations of access to the health services, of equality and equity.	Yes		1. 2. 3.
	No		

3.7 Patient economy

3.7.1 Is there a description of the technology's implication for the patient's economy?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. do the patients have direct or indirect expenses in connection with the use of the technology (e.g. transport, medicine, aids and appliances for handicapped etc.?) Is the use of the technology influenced by the patient's willingness and ability to pay?	Yes		1. 2. 3.
	No		

3.8 Other issues

3.8.1 Are there descriptions of patient related issues other than the previous mentioned?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		1. 2. 3.
	No		
If yes, state which issues			

3.9 Study design/strategy

3.9.1 Is the perspective(s) of the patient related issues explicitly described?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E. g. individual, group, society perspective	Yes		
	No		

3.9.2 Is the design of the study described?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, which design? (mark more than one if necessary)			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. studies based on existing literature reporting one, or more, original studies, retrieved from databases etc.	a. Reviews		
E.g. experimental studies with intervention- and control groups (RCT, case-control studies, cross-over studies) - controlled environment and efficacy	b. Intervention studies		
E.g. comparing two or more cases regarding differences in use of the technology e.g. ways of organisation, pricing etc. (The purpose of studying more cases is to compare the different cases use of the same technology)	c. Comparative studies		
E.g. studying changes over time, prospective or retro prospective (cohort and other epidemiological studies, register studies and before-after studies)	d. Longitudinal studies		
E.g. an in-depth study of a single or multiple cases (including its context) comprising one or more individuals/organisations. (The purpose of studying more cases is to identify and study more and different aspects of the technology – broaden the perspective on the technology)	f. Case studies		
Describe the design in the comment box	g. Other		

3.10 Data generation and data analysis

3.10.1 Is there a description of how data is generated?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, how/which kind of data? (mark more than one if necessary)			
Elaborate on this in question no. 3.10.2 and/or 3.10.3	a. Primary data		
Elaborate on this in question no. 3.10.4	b. Secondary data		

If No) move on to question no. 3.10.5.

3.10.2 Is there an explicit description of how qualitative data has been generated?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
Qualitative data has been generated, but there is no explicit description of how it has been generated	No		
	Qualitative data has not been generated		
If yes, how is it generated? (mark more than one if necessary)			
E.g. field study, participative observation, experiments	a. Observations		
E.g. structured or unstructured interviews with key informants, experts, witnesses and/or representatives with personal experiences	b. Individual interviews		
E.g. group interview with informants and/or representatives	c. Focus group interviews		
E.g. laws, written guidance, patient information's etc	d. Text documents		
E.g. delphi-method, workshops on future sceneries etc.	e. Prospective methods		
Describe the method in the comment box	f. Other		

3.10.3 Is there an explicit description of how quantitative data has been generated?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
Quantitative data has been generated, but there is no explicit description of how it has been generated	No		
	Qualitative data has not been generated		
If yes, how is it generated? (mark more than one if necessary)			
E.g. questionnaires in writing or oral using open or fixed categories for answers. Used for a selected sample of a population. E.g. Patients self-rated health condition	a. Questionnaires		
E.g. willingness-to-pay, conjoint analysis	b. Preference measurement		
E.g. national, local or private registers on use of healthcare services, output etc.	c. Registers		
Describe the method in the comment box	d. Others		

3.10.4 Is there an explicit description of how secondary data has been generated?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
Secondary data has been generated, but there is no explicit description of how it has been generated	No		
	Secondary has not been generated		
If yes, how is it generated? (mark more than one if necessary)			
E.g. systematic searches in relevant databases, and explicit criteria for inclusion	a. Systematic		
E.g. convenient or already known/ easily available sample of literature	b. Unsystematic		

3.10.5 Is the method of analysis described?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, which method(s)? (mark more than one if necessary)			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
E.g. descriptive, critical common sense, theoretical analysing etc.	a. Qualitative		
E.g. frequencies, use of statistics, meta-analyses etc.	b. Quantitative		

3.11 Validity of the HTA

3.11.1 Is the chosen study design explicitly discussed with regard to purpose, relevance and research questions and issues?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		

3.11.2 Is the chosen method of data generation explicitly discussed with regard to purpose, relevance and research questions and issues?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		

3.11.3 Is the chosen method of analysing explicitly discussed with regard to purpose, relevance and research questions and issues?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		

Field in the questionnaires according to the types of studies that have been carried out in the HTA (question no. 3.10.2, 3.10.3 and/or 3.10.4)

3.11.4 Is a sufficient basis established for the reader to assess the validity of the qualitatively interpreted studies? Are the following topics explicitly described and /or discussed?				
Hints	Options of answers	Assessment (mark most relevant)		Comments/descriptions/ references to the report
		Yes	No	
E.g. definition and explained use of central concepts	a. Concept validity			
E.g. description of theoretical frame, methodologies, models etc.	b. Theoretical point of departure and applied theories			
E.g. description of the method(s) used (interview, observation, texts, workshops etc.)	c. Qualitative methods used			
E.g. identification of, and contact to, areas of observation and participants. Handling of drop-outs etc.	d. Sampling			
E.g. description of the context for observation, interviewing, relations, ethics, interview guides, length of interview/observation, use of audiovisual and/or electronic equipment.	e. Methodological context			
E.g. description of how the generated data is handled and interpreted (transcribing, condensing, coding, writing up etc., use of audiovisual and/or electronic equipment).	f. Analysis			
E.g. discussion of the complexity and heterogeneity of data, methods of interpretation, possible misinterpretations, concordance to other studies	g. Critical reflection – alternative interpretations			
E.g. discussion of the quality of selecting data sources, data generation and data handling	h. Critical reflection – quality of data			
E.g. discussion of personal biases, role etc.	i. Critical reflection – the role of the researcher			
	j. Other topics			

3.11.5 Is a sufficient basis established for the reader to assess the validity of the quantitatively interpreted studies? Are the following topics explicitly described and /or discussed?				
Hints	Options of answers	Assessment (mark most relevant)		Comments/descriptions/ references to the report
		Yes	No	
E.g. definition and explained use of central concepts	a. Concept validity			
E.g. description of theoretical frame, methodologies, models etc	b. Theoretical point of departure and applied theories			
E.g. description of the method(s) used (questionnaire, register withdrawal, etc.)	c. Quantitative methods used			
E.g. description of identification, size of and contact to sample. Handling of drop-outs etc.	d. Sampling			
E.g. description of context (register, questionnaire, number of questions/requests, possible answers, form (written/oral), distribution etc.)	e. Methodological context			
E.g. description of methods used for interpretation, hypothesis, representativity, size of sample, confidence interval, analysis of drop-outs etc	f. Analysis			
E.g. discussion of complexity and heterogeneity of data, possible misinterpretations, statistical uncertainty, concordance to other studies	g. Critical reflection – alternative interpretations			
E.g. discussion of quality in selecting data sources, data generation and data handling, confounders, bias (validity and reliability)	h. Critical reflection – quality of data			
E.g. discussion of personnel biases, role etc	i. Critical reflection – the role of the researcher			
	j. Other topics			

3.11.6 Is a sufficient basis established for the reader to assess the validity of the secondary data? Are the following topics explicitly described and /or discussed?				
Hints	Options of answers	Assessment (mark most relevant)		Comments/descriptions/ references to the report
		Yes	No	
E.g. description of search strategy, databases, thesaurus/indexes	a. Search protocol			
E.g. description of method used for interpretation	b. Analysis			
E.g. discussion of the quality of the included secondary data	c. Critical reflection - validity of the included studies			
E.g. discussion of relevance with regard to purpose, and research questions	d. Critical reflection – relevance of the included studies			
E.g. discussion of prejudice, role etc.	e. Critical reflection – the role of the researcher			
	f. Other issues			

4. Assessment of possible generalisation of the HTA's results

4.1 Are the possibilities of generalising and using the study's results in a different context explicitly considered?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, describe how it is considered			

4.2. Is it possible for the reader to assess, with regard to the organisational issues, if the results of the study can be generalised or used in a different context? Is sufficient information established within the following areas?				
Hints	Options of answers	Assessment (mark most relevant)		Comments/descriptions/ references to the report
		Yes	No	
E.g. description of applied methodology – design, data generation and analysis (reliability)	Intern validity			
E.g. description of the study's context and form of generalisation (natural, statistical or theoretical)	Extern validityb. Analysis			

4.3 Is it possible for the reader to assess, with regard to the patient related issues, if the results of the study can be generalised or used in a different context? Is sufficient information established within the following areas?				
Hints	Options of answers	Assessment (mark most relevant)		Comments/descriptions/ references to the report
		Yes	No	
E.g. description of applied methodology – design, data generation and analysis (reliability)	Intern validity			
E.g. description of the study's context and form of generalisation (natural, statistical or theoretical	Extern validity			

5. Description of the HTA's conclusion and synthesis

5.1 Are the organisational issues included in the conclusion and synthesis of the HTA?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No	2	
If yes, describe in which way:			

5.2 Are the purpose of the organisational issues met and are the organisational research questions answered?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, describe in which way:			

5.3 Are the patient related issues included in the conclusion and synthesis of the HTA?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, describe in which way:			

5.4 Are the purpose of the patient related issues met and are the patient related research questions answered?			
Hints	Options of answers	Assessment (mark most relevant)	Comments/descriptions/ references to the report
	Yes		
	No		
If yes, describe in which way:			

6. Overall assessment of the organisational- and patient related issues in the HTA

6.1 Describe the overall assessment of the organisational- and patient related issues in the HTA
6.1.1 Strengths concerning the organisational issues
6.1.2 Weaknesses concerning the organisational issues
6.1.3 Strengths concerning the patient related issues
6.1.4 Weaknesses concerning the patient related issues
6.1.5 Overall assessment

Appendix 3: Which reports include which categories and subcategories?

The reports that include organisational assessment (no.): 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 28, 30, 32, 33, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 50.
The reports that include structural issues (no.): 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 13, 14, 15, 17, 19, 20, 21, 22, 23, 24, 25, 26, 28, 30, 32, 33, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47.
The reports that include the subcategory 'formal organisational structure' (no.): 2, 3, 4, 8, 9, 10, 11, 13, 14, 15, 17, 19, 20, 21, 24, 28, 30, 32, 33, 35, 36, 37, 39, 40, 41, 42, 43, 45, 46, 47.
The reports that include the subcategory 'physical, resource and legislative structure' (no.): 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 13, 14, 15, 17, 19, 20, 21, 22, 23, 24, 25, 26, 28, 30, 32, 33, 35, 36, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47.
The reports that include the subcategory 'diffusion of the technology' (no.): 1, 2, 3, 4, 7, 10, 11, 13, 14, 15, 17, 19, 20, 21, 23, 24, 25, 28, 30, 32, 33, 36, 37, 40, 41, 42, 43, 44, 45, 46, 47.
The reports that include the subcategory 'economic consequences at an organisational level' (no.): 2, 3, 4, 8, 9, 10, 11, 13, 14, 15, 17, 22, 24, 26, 28, 30, 32, 33, 38, 40, 41, 42, 43, 45, 46, 47.
The reports that include the subcategory 'incentive structures' (no.): 1, 2, 3, 4, 7, 8, 9, 10, 11, 13, 14, 15, 17, 20, 24, 30, 33, 41, 43, 46.
The reports that include the process issues (no.): 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 28, 30, 32, 33, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 50.
The reports that include the subcategory 'work flow' (no.): 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 17, 18, 19, 20, 21, 22, 24, 26, 28, 30, 32, 33, 36, 37, 38, 41, 42, 43, 44, 45, 46, 47.
The reports that include the subcategory 'actors involved' (no.): 1, 2, 3, 5, 7, 8, 9, 10, 11, 13, 14, 15, 17, 18, 19, 20, 21, 22, 23, 24, 26, 28, 30, 32, 33, 35, 36, 37, 38, 40, 41, 42, 43, 45, 46, 47, 50.
The reports that include the subcategory 'personnel skills and resources' (no.): 2, 3, 4, 5, 7, 9, 10, 11, 13, 14, 15, 17, 18, 19, 20, 21, 22, 23, 24, 26, 28, 30, 32, 33, 36, 39, 40, 41, 42, 43, 45, 46, 47, 50.
The reports that include the subcategory 'interaction and communication' (no.): 2, 3, 4, 6, 8, 9, 10, 11, 13, 14, 15, 17, 19, 20, 28, 30, 32, 33, 36, 39, 41, 42, 43, 44, 45, 46, 47.
The reports that include the subcategory 'barriers and bottlenecks' (no.): 2, 3, 4, 5, 7, 8, 9, 10, 14, 15, 20, 22, 25, 28, 30, 32, 33, 35, 36, 41, 43, 45, 46, 47.
The reports that include control and evaluation issues (no.): 1, 2, 3, 4, 5, 7, 10, 11, 13, 14, 15, 17, 19, 20, 21, 23, 24, 25, 26, 28, 30, 32, 33, 36, 37, 38, 39, 41, 42, 43, 45, 46, 47, 50.
The reports that include the subcategory 'control and evaluation responsibility' (no.): 2, 7, 10, 11, 13, 14, 15, 17, 19, 20, 21, 28, 30, 32, 33, 36, 38, 41, 42, 45, 50.
The reports that include the subcategory 'control and evaluation systems' (no.): 1, 2, 3, 4, 5, 7, 10, 11, 13, 14, 15, 19, 20, 21, 23, 24, 25, 26, 28, 30, 32, 33, 36, 37, 38, 39, 41, 42, 43, 45, 46, 47, 50.
The reports that include cultural and environmental issues (no.): 2, 3, 4, 7, 9, 10, 11, 15, 19, 20, 21, 22, 26, 28, 30, 32, 35, 36, 38, 41, 43, 45, 46, 47.
The reports that include the subcategory 'culture' (no.): 2, 3, 9, 10, 15, 19, 20, 21, 26, 28, 30, 32, 36, 43, 45, 46, 47.
The reports that include the subcategory 'psychological working environment' (no.): 3, 9, 11, 35, 43, 45, 46.
The reports that include the subcategory 'physical working environment' (no.): 3, 22, 26, 28, 36, 38, 41, 45.
The reports that include the subcategory 'outer environment' (no.): None of the reports include assessments of this subcategory.

The reports that include patient-related assessment (no.): 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 34, 35, 36, 37, 41, 42, 43, 44, 45, 47, 48, 49.

The reports that include patient information issues (no.): 2, 3, 7, 9, 10, 11, 12, 13, 14, 16, 17, 19, 20, 21, 24, 26, 27, 28, 30, 31, 32, 35, 37, 43, 44, 45, 47, 48, 49.

The reports that include psychological issues (no.): 1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 21, 22, 24, 26, 27, 28, 30, 31, 32, 36, 37, 43, 44, 45, 47, 49.

The reports that include the subcategory 'Patient fear and discomfort' (no.): 1, 2, 3, 4, 5, 7, 9, 10, 11, 12, 13, 14, 16, 17, 19, 22, 24, 26, 27, 28, 30, 31, 32, 36, 43, 44, 47.

The reports that include the subcategory 'Patient satisfaction' (no.): 1, 3, 4, 6, 9, 10, 11, 12, 14, 16, 17, 18, 21, 28, 32, 36, 47, 48, 49.

The reports that include the subcategory 'Patient involvement' (no.): 3, 7, 10, 11, 16, 17, 19, 21, 24, 26, 27, 28, 31, 32, 37, 43, 45, 47.

The reports that include effects on quality of life issues (no.): 1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 14, 19, 22, 23, 24, 25, 27, 28, 29, 30, 32, 34, 37, 41, 42, 45, 47, 48, 49.

The reports that include the social issues (no.): 2, 3, 4, 5, 7, 9, 10, 11, 12, 13, 17, 19, 22, 23, 24, 25, 26, 27, 28, 29, 30, 32, 35, 36, 37, 44, 45, 47, 48, 49.

The reports that include the subcategory 'Impact on patient's daily life' (no.): 2, 3, 4, 5, 7, 9, 10, 13, 17, 22, 24, 27, 28, 29, 30, 36, 44, 45, 47, 48, 49.

The reports that include the subcategory 'Implications for significant others' (no.): 3, 7, 10, 11, 12, 13, 19, 22, 23, 24, 25, 26, 27, 28, 29, 35, 36, 45.

The reports that include the subcategory 'Implications for patient's ability to work' (no.): 3, 4, 9, 10, 11, 23, 24, 25, 28, 32, 37, 45, 48, 49.

The reports that include ethical issues (no.): 2, 3, 4, 7, 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 24, 25, 26, 29, 30, 31, 32, 37, 42, 43, 45, 47, 48, 49.

The reports that include the subcategory 'Patient acceptance of the technology' (no.): 2, 3, 7, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 24, 28, 29, 30, 32, 43, 47, 48, 49.

The reports that include the subcategory 'Specific ethical considerations' (no.): 2, 3, 4, 7, 8, 9, 13, 19, 20, 24, 25, 26, 31, 32, 37, 42, 45.

The reports that include patients' financial circumstances (no.): 1, 2, 3, 10, 11, 14, 17, 26, 27, 43, 47, 48.

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.

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