



INTRODUCTION TO MINI-HTA
– a management and decision support
tool for the hospital service

2005



The Danish Centre for Evaluation and Health Technology
Assessment

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Prepared by a project group under DACEHTA of the Danish National Board of Health with representatives from the DACEHTA, the HTA unit at Aarhus University Hospital, Odense University Hospital and Copenhagen Hospital Corporation

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Preface

In cooperation with local HTA environments, the Danish Centre for Evaluation and Health Technology Assessment (DACEHTA) has developed a flexible decision support tool, which can be used by hospital managements locally and regionally when contemplating the introduction of new health technology.

This publication introduces the decision support tool, which is based on a form and an accompanying guide. The tool is called mini-HTA as it is based on the reasoning involved in health technology assessments (HTA).

The work of developing a national mini-HTA has been carried out by a project group and is to a high degree based on results and inspiration from a survey using a questionnaire about experience of decision support tools in all Danish hospitals. DACEHTA would like to take the opportunity to thank the project group and everyone who has contributed to the final result.

Mini-HTA is intended as a flexible and dynamic tool adaptable to local conditions and the current requirements of decision-makers – which means that it can relatively easily be incorporated into local and regional budget and planning processes. Where the problem or the application extends beyond a specific local context, however, the mini-HTA cannot replace a full-size HTA.

In DACEHTA we hope that hospital managers, county health directors and heads of clinical departments around the country will be able to use this national tool as a structured assistance in making qualified decisions about the appropriate use of resources.

Danish Centre for Evaluation and Health Technology Assessment
September 2005

Finn Børlum Kristensen
Director

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What is HTA?

In the booklet “Health Technology Assessment. Why? What? When? How?” (2000) (available in Danish only – “Medicinsk teknologivurdering – Hvorfor? Hvad? Hvornår?”) the National Board of Health defines health technology assessment (HTA) as follows:

“A health technology assessment is a comprehensive, systematic assessment of the prerequisites for and consequences of using health technology.”

It is thus characteristic of the HTA reasoning that the problem is considered using a wide approach comprising four main elements:

- technology
- patient
- organisation
- economy

What is health technology?

The concept of health technology comprises drugs, devices, medical and surgical procedures used for prevention, examination, treatment, care and rehabilitation.

HTA provides a basis for decisions

An HTA is typically made prior to the introduction of new health technology in everyday clinical practice or in connection with changes in the indication for the use of existing technology. The purpose of the HTA is to establish a well-documented and comprehensive overview of the consequences of the new technology in the health service.

The objective is that information and any recommendations resulting from the HTA should then be taken into account by the decision-makers when making decisions on the proposed new technology.

The three basic principles of an HTA are:

- that it is based on evidence-based knowledge
- that it is a question of an interdisciplinary overall assessment
- that it is aimed at decision-making

More about HTA

DACEHTA’s handbook “Health Technology Assessment Handbook” offers a thorough insight into HTA and the principles of how to undertake an HTA. The handbook is also a central document in relation to the mini-HTA. The handbook is available at DACEHTA’s home page www.dacehta.dk

What is mini-HTA?

Mini-HTA is a management and decision support tool based on the reasoning involved in HTAs. The tool may be used for instance where a hospital is contemplating the introduction of new health technology.

A mini-HTA is a form or a check list with a number of questions concerning the prerequisites for and consequences of using (new) health technology, in which:

- the questions are grouped according to the four HTA perspectives: technology, patient, organisation and economy
- the answers to the questions provide a brief, written basis for decisions (2-5 pages) and takes, based on experience, 5-15 hours, excluding the time spent on information retrieval and assessment, and economic calculations
- the purpose is to provide (part of) the decision-making basis for a proposal to introduce a specific new health technology or in connection with changes in the indication for the use of existing technology
- both the preparation and the use of the decision-making basis may take place at local or regional level and be adapted to local or regional objectives, decision criteria and time schedules.

Basis for decisions on time

A mini-HTA can be made within a short timeframe and offers a contribution to the basis for decisions at the time when needed. It is therefore easily adapted to local or regional budget and planning processes.

In many hospitals typically the consultant responsible for the relevant speciality who has knowledge about the new treatment will be the person starting to fill in the form. Then for instance the staff nurse and the clinical department(s) involved, for instance the anaesthesia ward or the laboratory. Where relevant, resource persons, for instance a librarian or an economist, may be involved.

The mini-HTA should be seen as a flexible and dynamic tool. As it is prepared locally or regionally, it can be developed further and adapted to local or regional objectives and to the current requirements of the decision-makers, just as it offers the opportunity for close dialogue between health professionals and decision-makers.

Why mini-HTA?

Among health service decision-makers at local and regional level there is a growing interest in developing and using methods for decision support that may contribute to improved prioritising of resources.

In the practical reality in hospitals and in the Danish regions it is impossible to undertake a comprehensive HTA every time a decision is to be made on the introduction of new drugs, a new treatment, new medical devices etc.

Local and regional decision-makers therefore have demanded decision support tools that can work in the context of and be adapted to local and regional decision-making processes.

Background to the mini-HTA

In 2000 DACEHTA prepared a form and a guide on the acquisition of medical devices for hospitals. The purpose was to inspire to a systematic and holistic assessment before new investments are made.

Since then, the use of HTA forms has spread from medical devices to a more general use in connection with the introduction of new treatments and technologies.

Many versions of mini-HTAs

The concept of mini-HTA was framed in the Copenhagen Hospital Corporation/Copenhagen University Hospital, which was among the first to use forms as a tool for decision support in connection with approval of new treatments at clinical, administrative and political level. For more information, please see in Appendix 1: Examples of the use of mini-HTA in Denmark.

Gradually, many Danish hospitals have become inspired by the idea of the limited, but systematic, assessment based on the HTA reasoning. Therefore today there are a number of local bids for forms and for the applications of mini-HTA. Therefore today there are several local versions of forms and suggestions for applications of mini-HTA.

National tool for mini-HTA

In cooperation with some of the environments that have experience of using mini-HTA, DACEHTA has developed a common national decision support tool to be used locally and regionally. The tool is based on a form and a guide for completing the form and the name “mini-HTA” is reused.

The national mini-HTA is an offer for decision-makers and applicants proposing new technology. Mini-HTA is intended to contribute to spreading the HTA reasoning to local and regional decisions made in the hospital service in Denmark.

Mini-HTA may be used widely in connection with the introduction of health technology. Any existing, effective forms for use in connection with the acquisition of medical devices can be retained and used in parallel with the mini-HTA.

The specific tool has been developed on the basis of experience gained in Danish hospitals already using mini-HTA or similar decision support tools. The development is also inspired by the business case method used in the business sector and by surveys of how local and regional health services abroad work with health technology assessments. Finally, it is based on an analysis of the theoretical basis of decision for mini-HTA.

Finding the form and guide

In this introduction to mini-HTA DACEHTA's mini-HTA form and a guide for completing the form are available as Appendices 3 and 4.

The form and the guide can also be downloaded in Word or pdf format from DACEHTA's home page on <http://www.dacehta.dk/mini-hta>.

When to undertake a mini-HTA

It is important to define locally or regionally when a mini-HTA should be undertaken.

Is it, for instance, the case for:

- new treatments – and, if so, what is the definition of a new treatment?
- a new indication for the application of existing technology?
- new medical devices – both new technology and replacement of existing technology?
- draft budgets or activities with increasing cost pressure – at which amount is the limit?

Is a mini-HTA sufficient?

Moreover, it is important to consider when a proposal for new health technology requires undertaking a more comprehensive HTA.

For instance, if a proposal is expected to involve important issues of a fundamental nature or likely to be implemented on a large scale, a mini-HTA would not be sufficient as a basis for decisions.

The choice between making a mini-HTA or a more comprehensive HTA will often involve balancing the need for quality and thoroughness against requirements of speed and timing of the decision support tool in the situation concerned.

However, the thoroughness of a mini-HTA may vary according to requirement, just as a mini-HTA does not exclude the use of a more comprehensive HTA. On the contrary, the undertaking of a mini-HTA may in some cases accentuate a need for a more in-depth assessment and may be a forerunner for a full-size actual HTA.

Mini-HTA in relation to other HTAs

Today, DACEHTA and the regional HTA units distinguish between different types of HTA input for decision-making:

- a broad, comprehensive HTA typically aimed at an entire illness area, timeframe 1½ - 3 years
- a quick HTA, typically concerned with a specific problem and a specific technology, timeframe 3-9 months
- mini-HTA.

Quality and credibility

A mini-HTA undertaken within a short timeframe and with limited resources will not be as comprehensive and have the same quality as an HTA, but at its best it represents a systematic account of the knowledge that the organisation itself is able to deliver within a very limited timeframe.

Widespread use of mini-HTAs may therefore contribute to qualified decisions and prioritising at local and regional level. But for the decision-makers to base their decisions on recommendations from a mini-HTA it must be of a high quality implying high credibility.

Therefore a number of proposals for improving the quality of mini-HTAs are presented below.

Management backing and internal support functions

A management ensuring good conditions for the HTA work and development of internal support functions promotes quality and uniformity of mini-HTAs.

A few hospitals today have an established team of resource persons to offer advice and support to the employees who are to undertake mini-HTAs. Over time the resource persons will develop great competence and insight into the HTA principles, which will be of use to the entire organisation.

An example of an essential resource person could be a local economist with insight into business economics and preferably also health economic analysis and who is able to structure financial information so as to make it easy for the decision-makers to get an overview of the overall economic situation.

Other essential resource persons are people with competencies within literature search (for instance a librarian) and assessment of evidence (for instance a physician experienced in critical assessment of literature).

Literature search and assessment

In connection with HTAs assessment of information is essential. This also applies to a mini-HTA. Although literature search and assessment in a mini-HTA will typically be more limited, it must still be systematic so as to ensure an overview of the most qualified literature and so that it is possible to prioritise the literature in accordance with the scientific quality of the articles.

As stated above, it is often an advantage to involve a local librarian in the

choice of information sources and retrieval. Many hospitals have librarians on their staff that may assist in this work.

Read more about information retrieval and assessment in the schedule to Appendix 4.

For more information about databases and information sources, and about the structure of the search strategies and information search, please see “Health Technology Assessment Handbook”, which is available at DACE-HTA’s home page (<http://www.dacehta.dk/>).

Interdisciplinary work

Even in situations in which a mini-HTA is undertaken by one person to begin with, it will often be expedient to involve professionals from other occupational groups that will be affected by the new proposal. The interdisciplinary perspective ensures that significant interests and attitudes are discussed to make the assessment more comprehensive.

Independent quality check

The applicant must of course endeavour to make the mini-HTA as well documented as possible and to identify conflicting views, if any.

Today a few hospitals have an established quality assurance process in which the mini-HTA is reviewed critically by other impartial professionals within – and maybe also outside – the organisation with a view to strengthening quality and credibility.

Identifies weaknesses and uncertainties

As a mini-HTA is undertaken within a short timeframe and with limited resources, it may be difficult to have some aspects sufficiently elucidated, just as there may be weaknesses in the data basis or the assessment.

This should be reported and rendered visible in the mini-HTA so that the basis for the assessment and any recommendations is completely unambiguous. High credibility is ensured through openness and transparency.

Strengths and weaknesses

Mini-HTA is a decision support tool which has the potential to promote HTA reasoning in decision-making processes in the health service. It comprises strengths as well as weaknesses.

The strengths of mini-HTA

- Mini-HTA may be undertaken locally with local resources
- With mini-HTA the decision-making basis may be available at the right time and with local relevance, which may lead to more appropriate prioritising
- Mini-HTA, which aims to be evidence-based, may contribute to improve the quality of the decision-making basis
- The amount of work to be carried out in a mini-HTA is clear, which increases the likelihood that it will be undertaken and used
- Mini-HTA retains focus on professional standards and patient benefit in correlation with the organisation and economic considerations
- Mini-HTA is a flexible tool adaptable to local conditions
- Mini-HTA ensures that evidence and documentation for new treatments are known when it is decided to introduce them
- With mini-HTA the organisation is more geared to think in terms of HTA.

The weaknesses of mini-HTA

- The limitations of mini-HTA require awareness of when it is necessary to undertake a more comprehensive HTA.
- As a mini-HTA must often be undertaken within a short timeframe, there may be some questions that it is not possible to have sufficiently elucidated
- An effort must be made to ensure quality and credibility in mini-HTA
- There is a risk that mini-HTA is undertaken by a group of people representing one single profession, which means that it will not have the necessary interdisciplinary approach.
- There is a risk that mini-HTA may be influenced by self-interest

Appendix 1: Examples of the use of mini-HTA in Denmark

Already today mini-HTA is used for a variety of purposes, for instance when new treatments are being introduced. Likewise, there are several ways of organising the HTA work.

For inspiration some examples from the Danish health service are presented below.

Copenhagen Hospital Corporation (H:S)

In 2000 Copenhagen Hospital Corporation (H:S) developed its own mini-HTA concept. In this concept, the condition for introducing a new treatment is that the proposal is described in a mini-HTA and approved at all levels of management.

The mini-HTA concept is primarily used in connection with:

- new treatments and diagnostic initiatives for which it is possible to document a significant clinical effect
- approval of special subsidies at national and regional level implying reimbursement of the department's expenses for particularly expensive drugs or implants for a small well-defined group of patients.

Approval procedure

When a proposal for a new treatment has been described in mini-HTA format, it must be approved by the centre managements, if any, and the executive board of the hospital. It is then submitted to the management board of the Copenhagen Hospital Corporation ("H:S Direktionen"), which is comparable to a county health service. Finally the proposal is considered by the political governing body ("H:S Bestyrelsen"), to which, as something unique, the mini-HTA material is submitted for decision-making purposes. The treatments expected to be carried out on patients from other counties will also be presented to the members of the counties' health committees.

If a proposal is approved, the expenses and activities are included in the budgets of the hospital departments, distributed on the Copenhagen Hospital Corporation (H:S) and county activities. This ensures an overview

and economic cover for activities and expenses if the treatment is introduced.

Close connection with budgeting

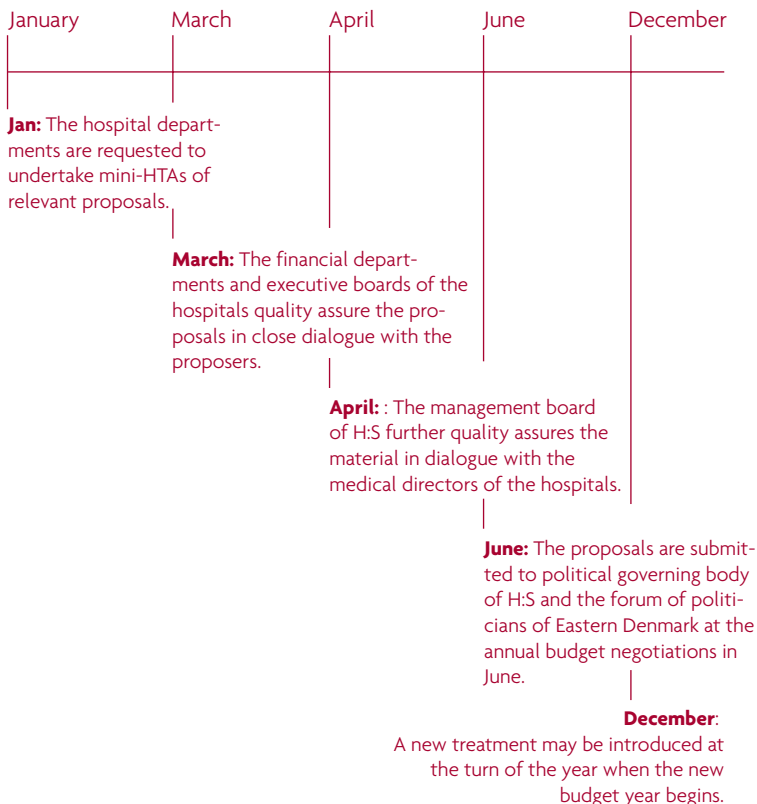
As many proposals may result in considerable additional expenditures, the mini-HTA procedure is closely connected with the annual budgeting procedure in the Copenhagen Hospital Corporation.

Unless there are strong arguments for introducing a new treatment quickly, all treatments must be approved politically in connection with the budget negotiations. Therefore a new treatment cannot be introduced until the beginning of the new budget year.

“For Copenhagen University Hospital (Rigshospitalet)/Copenhagen Hospital Corporation mini-HTA has enhanced the quality of the decision-making process in connection with the introduction of new drugs and, with the increased transparency of the decision-making process, the credibility vis-à-vis the counties that use our services.”

Helle Ulrichsen,
Managing Director, Copenhagen Hospital Corporation

Time schedule



Undertaking a mini-HTA

A mini-HTA is typically undertaken by a physician and/or the department management on the basis of a template with questions concerning patients, technology, organisation and economy. At Copenhagen University Hospital a questionnaire is also filled in, which is then used by the administration for systematic calculation of the expenses and activities related to the new treatments.

As outlined above, it takes a whole year from the decision to undertake a mini-HTA is taken and until the proposal is approved. However, the individual physician rarely spends more than one day on the work involved in the mini-HTA. But the subsequent consideration of the proposal requires more time.

What are the proposals for?

By virtue of its status as a highly specialised hospital, Copenhagen University Hospital makes by far the highest number of proposals for new treatments. For 2005 the hospital made 23 out of 29 proposals from Copenhagen Hospital Corporation. The main part of the proposals and the related expenses concern cancer treatment.

The hospitals of the Copenhagen Hospital Corporation have proved able to discard the most unsuitable proposals themselves. Therefore most of the proposals presented so far have been approved politically. When a proposal is rejected, it is most often due to insufficient documentation for the effect of the treatment.

Evaluation of the mini-HTA concept

When in 2004 the Copenhagen University Hospital and the Copenhagen Hospital Corporation's HTA unit existing at that time evaluated the concept, a very high level of satisfaction with the mini-HTA procedure was found to exist among the health care staff. This is remarkable as the physicians at Copenhagen University Hospital have previously had considerably more freedom to make arrangements independently.

The mini-HTAs which were approved four years ago are evaluated annually for the purpose of examining whether the original conditions for introducing new treatments have turned out to be relevant in practice.

“The challenge of a mini-HTA is to find documentation for the clinical effect at a time when it is not yet clear and obvious. But we have to be proactive and undertake a mini-HTA at an early stage in respect of a drug or treatment if we are to have it implemented before patients start asking for it”

Niels Borregaard,

Head of Department of Haematology, Copenhagen University Hospital, H:S

“Mini-HTA is an important decision-making basis. It gives clout upwards in the system and is a good way of securing responsiveness to new treatments.

Niels Borregaard,

Head of Department of Haematology, Copenhagen University Hospital, H:S

The County of Funen

In the County of Funen the use of mini-HTA is mandatory when clinical departments submit draft budgets concerning introduction of new treatments etc. for the hospital managements. Furthermore the County has taken organisational measures to strengthen the use of HTA.

HTA form

In the County of Funen the clinical departments were for a couple of years encouraged to fill in a form asking a number of specific HTA questions when preparing draft budgets, but experience has shown that the forms were rarely used. A working group was therefore set up consisting of representatives from the administration and managements of three clinical departments. Based on the Copenhagen University Hospital's mini-HTA the working group prepared a new form called the HTA form.

At the end of 2003 the hospital managements of Odense University Hospital and Hospital Funen decided to make the HTA form mandatory when department managements submit draft budgets for hospital managements or centre managements. The HTA form is also used when early warnings of new treatments offered at the hospitals of Funen are to be issued to the counties using their services. Most recently the HTA form has been used in 2005 in connection with the clinical departments' applications for funds from the County of Funen's cancer budget.

HTA department

The requirement of using mini-HTAs is part of the Danish counties' commitment to enhance the use of HTA as a basis for decisions at both department and hospital management level. In this connection a special research and HTA department has been set up at Odense University Hospital with the purpose among other things to assist clinical departments in their HTA work.

Support for mini-HTA work

The requirement of mandatory use of mini-HTA was presented to the department managements of the county's hospitals at a HTA project day in February 2003. Moreover, several types of support for the HTA work were presented, including mini-HTA.

"Anyone with insight into the health service must recognise that HTA is an important assessment and decision tool. But introducing HTA in the decision-making processes is not as simple as that. As the chairman of the County of Funen's HTA committee, in which HTA and Early Warning have been on the agenda since 1997, it is my experience that the greatest obstacle is the time it takes to undertake and complete an HTA. To disseminate the HTA reasoning as much as possible we have since 2004 been aiming at a development towards mini-HTA."

Jens-Otto S. Jeppesen,
Director, Odense University
Hospital

Types of support available:

- **Support for literature studies**

A special “HTA librarian” has been employed to assist the departments in carrying out literature studies in connection with HTA and projects relating to evidence-based practice.

- **Courses in HTA and literature studies**

A number of courses in undertaking HTA and literature studies are available.

- **HTA portal**

An HTA portal accessible from for instance the home page of Odense University Hospital (www.ouh.dk) has been created providing information on HTA, databases and guidelines in carrying out literature studies.

- **Guidelines**

The research and HTA department has offered assistance to the clinical departments in connection with the questions in the HTA form.

Experience

Mandatory use of mini-HTA has entailed increased use of the HTA form as the basis for decisions on the introduction of new treatments in hospitals in Funen. On several occasions, representatives from the clinical department managements have supported the use of the form but also indicated that the form is comprehensive and makes heavy demands on the description of especially the economic consequences of the new treatments. This may be a contributory cause to the fact that the use of the form has not been as consistent as expected. A proper assessment of the use of the form has not yet been carried out in 2005.

“The advantage of mini-HTAs is that you force everybody to think in terms of HTA, that you make sure that the literature has been read, that there is a clinical effect etc. It is a good tool that ensures that all aspects are taken into consideration, also in respect of organisation and procedures.

There is a big need for training, however, and that applies not only to the physicians, but also other health care groups, such as nurses and physiotherapists, who will be able to use the tool.”

Hans Ri Jørgensen,

Chief Consultant, Department of Orthopaedics Surgery, Middelfart, Odense University Hospital

Appendix 2: Local and regional use of HTA in health services abroad

In a few places abroad (for instance in Sweden, Australia and Canada) decision support tools are used which are comparable to the mini-HTA as they are aimed at local or regional decisions. Two systems are introduced as inspiration, as they may be instructive for Danish conditions.

The County Council in Östergötland, Sweden

Östergötland is a Swedish county with three large hospitals, including the University Hospital in Linköping. At the beginning of 2004, the county council that politically and administratively manages Östergötland established a so-called methods board to give advice regarding introduction of new technology and methods within the health services.

The methods board comprises seven persons with extensive experience and research background; including experts from the regional HTA unit that forms part of the University of Linköping.

No other Swedish counties have such methods boards but work is currently carried out in order to extend the scope of the methods board to a regional Methods Board.

Objective of the methods board

The methods board is to be a sparring partner for the management of hospitals and a resource in political questions and questions of priority.

The task is to:

- identify and evaluate diagnostic, treatment and rehabilitation technologies that are expected to be of great importance to the hospital service
- contribute with a complete basis for decisions for the introduction of new procedures and technologies that are of

“We have a broad competence on the Methods Board and the intention is for us to assess health technologies more objectively and in a broader perspective”

Gösta Berlin,
hospital medical director responsible for research in the county council, Östergötland, Sweden

- principal interest and that involve the political decision level
- the methods boards may also assess technologies already implemented but with a questionable effect.

The Medicines Committee of the county council assesses new drugs whereas the methods boards deals with all other new technologies.

HTA of the methods board

Primarily, the methods board should assess technologies at the request of the hospital management and the county council but the board may also take the initiative for an HTA.

An HTA comprises the following aspects:

- technology
- the expected target group
- actual knowledge of the clinical effect and consequences for the patients, for instance complications and adverse effects
- ethical aspects
- cost effectiveness and the economic consequences for the health and hospital services
- consequences for the hospital structure and organisation.

The methods board is advisory

The methods board assesses new technologies on an ongoing basis. Typically, the assessment takes approximately six months and results in a 3-5-page report with summary and recommendation and facts of the individual aspects.

Based on the assessment, the methods board gives its recommendation on the new technology. The recommendation forms the basis for the decision and economic priorities of the county council

More information:

See article on the work of the methods board and the recommendations of the newly established board on the website of the county council in Östergötland. (www.lio.se)

“The role of the methods board is to carry out an objective assessment of technologies that will be of use but that are for instance hazardous or very expensive”

Lena Lundgren,

Health Care Director in the country council, Östergötland, Sweden

“It is a challenge to choose the right point in time to assess a technology. If the assessment starts too early there isn't enough knowledge, to evaluate the patient benefit and the costs. If it is done too late the technology may already be in use on a routine basis in some hospital services and it may be difficult to change procedures even if the results suggest that the technology should not be used”.

Åke Rosandher,

County Council Director and Lena Lundgren, Health Care Director in the County Council, Östergötland, Sverige

Southern Health, Melbourne, Australia

Southern Health, Melbourne comprises four large hospitals and three health care centres. Southern Health has used HTA for a couple of years as part of decision-making basis when introducing new technology. New technology is approved by “New Clinical Procedures Committee” (NCPC). This applies to for instance all clinical (including dental) technologies, care technologies as well as technologies used by acupuncturists, audiologists, dieticians, physiotherapists, chiropractors and other health care professionals.

The objective of NCPC is to ensure that:

- the development and the introduction of new clinical procedures, treatments and technology is assessed at all levels and in all departments
- the staff receive the relevant training in order for new procedures and new equipment to be used correctly
- all patients are treated safely and according to the highest standards

Application on new procedures/technology

The applicants are typically physicians or a departmental management requesting to introduce a new procedure/technology. The application is prepared locally but only submitted to the NCPC after acceptance by the senior management.

The application must comprise:

- a description of the technology
- an HTA comprising the safety of the technology, clinical efficiency and costs, including literature review
- a statement from the clinical director to the effect that the department has staff qualified to use the technology
- a description of the target group (the patients)
- written patient information
- a description of whether the technology has been used and evaluated somewhere else and whether these results are registered in a database

The application form is a check list with 19 questions with the possibility of clarifying arguments in the attached appendix.

The role of NCPC

The members of NCPC are appointed by Southern Health and the NCPC is chaired by a physician. NCPC has representatives from for instance Southern Health’s centre of clinical efficiency, patient organisations and in each individual case a representative from the department contemplating to use the new technology.

NCPC assesses the written applications based on three criteria:

- effect – is the medical effect based on evidence?
- safety – what are the risks and gains for patient and physician?
- economy – does the benefit measure up to the costs?

The applicant is invited to a short meeting with the NCPC with the opportunity to comment and answer questions from the committee. The aim is for NCPC's assessment to be as well-informed as possible.

Recommendations from the NCPC then form the basis for the decisions by the hospital management.

Follow-up

At first, approval of a new procedure/technology is only valid for 12 months. Then NCPC takes the initiative to a follow-up. The applicants are obliged to continuously inform the NCPC of consequences of introducing the new procedure/technology and they must report experience and benefit after one year.

“The perspective is cooperation with other university hospitals ensuring that assessment of new technologies is shared across the country in order to save doing the job twice and save resources.”

Richard King,

Clinical Director, Monash Medical Centre, Melbourne, Australia

Appendix 3: Mini-HTA (form)

For guidelines regarding completion of the form please refer to appendix 4.

The form may be downloaded from the DACEHTA home page www.dacehta.dk and it can then be completed in the electronic form.

Questions 1 - 3: Introduction

1: Who is the proposer (hospital, department, person)?

2: What is the name/designation of the health technology?

3: Which parties are involved in the proposal?

Questions 4 -12: Technology

4: On which indication will the proposal be used?

5: In which way is the proposal new compared to usual practice?

6: Has an assessment of literature been carried out (by the department or by others)?

7: State the most important references and assess the strength of the evidence.

8: What is the effect of the proposal for the patients in terms of diagnosis, treatment, care, rehabilitation and prevention?

9: Does the proposal imply any risks, adverse effects or other adverse events?

10: Are there any other ongoing studies in other hospitals in Denmark or abroad of the effect of the proposal?

11: Has the proposal been recommended by the National Board of Health, medical associations etc.? If YES, please state institution.

12: Has the department previously or on any other occasions, applied for introduction of the proposal?

Questions 13 -14: Patient

13: Does the proposal entail any special ethical or psychological considerations?

14: Is the proposal expected to influence the patients' quality of life, social or employment situation?

Questions 15 -20: Organisation

15: What are the effects of the proposal on the staff in terms of information, training or working environment?

16: Can the proposal be accommodated within the present physical setting?

17: Will the proposal affect other departments or service functions in the hospital?

18: How does the proposal affect the cooperation with other hospitals, regions, the primary sector etc. (for instance in connection with changes of the requested care pathway)?

19: When can the proposal be implemented?

20: Has the proposal been implemented in other hospitals in Denmark or internationally?

Questions 21 - 26: Economy

21: Are there any start-up costs of equipment, rebuilding, training etc.?

22: What are the consequences in terms of activities for the next couple of years?

23: What is the additional or saved annual cost per patient for the hospital?

24: What is the total additional or saved cost for the hospital in the next couple of years?

25: Which additional or saved cost can be expected for other hospitals, sectors etc.?

26: Which uncertainties apply to these calculations?

Other comments

Appendix 4: Guide to mini-HTA

Introduction

Information is collected and organised in the mini-HTA prior to decisions on introduction of new health technology.

The mini-HTA should contribute to ensuring a comprehensive and systematic basis for decisions for the introduction of new health technology and in general it is recommended that replies to the individual questions in the mini-HTA follow the principles of health technology assessment, cf. Health Technology Assessment Handbook at <http://www.dacehta.dk/>

The form comprises a short introduction and questions on:

- Technology
- Patient conditions
- Organisational consequences
- Economic consequences

This guides offers a short explanation and practical advice on the individual questions in the mini-HTA.

A basis for decisions in the form of a mini-HTA is less comprehensive than the conventional HTA descriptions of new technologies. Thus, the persons answering the mini-HTA questions have a special obligation to visualise the uncertainty and any weaknesses in the description of the consequences of the proposal.

All mini-HTA questions should be answered in a clear and comprehensible language and a yes or no is not sufficient.

Questions 1 - 3: Introduction

1: Who is the proposer (hospital, department, person)?

Please state which hospital(s), department(s) and/or person(s) make the proposal(s).

2: What is the name/designation of the health technology?

Please state the specific subject of the application - for instance new drug for a specific patient group.

3: Which parties are involved in the proposal?

Often it is beneficial to be able to discuss a proposal with a local drug committee, a device committee, other affected departments or any other relevant cooperation forum. Please state with whom the proposal has been discussed, if any, and the conclusion.

Questions 4 -12: Technology

4: On which indication will the proposal be used?

Please state the indication on which the proposal should be applied (for instance diagnosis or procedure).

5: In which way is the proposal new compared to usual practice?

A proposal often replaces another technology. Thus, please state in which way this proposal is new compared to usual practice in the department. Apart from the fact that a proposal often replaces other existing technology there also may be other alternatives to the new proposal. Consequently the mini-HTA should comprise an assessment of benefits and drawback compared to usual practice and any other alternatives.

- 6: Has an assessment of literature been carried out (by the department or by others)?

A health technology assessment should primarily be based on documented knowledge. An assessment of the present evidence can benefit from the principles of literature search, cf. the supplement.

- 7: State the most important references and assess the strength of the evidence.

The documentation for the effect of the proposal should be stated giving the most important references at the highest possible level. For the benefit of the reader the evidence level should be stated for each reference. An evidence form can be used for this, please see the supplement.

- 8: What is the effect of the proposal for the patients in terms of diagnosis, treatment, care, rehabilitation and prevention?

Please provide a short summary of the most important conclusions of above references (for instance the effect of the proposal on the mortality, morbidity, functional capacity, quality of life etc. of the patients).

- 9: Does the proposal imply any risks, adverse effects or other adverse events?

The risks, adverse effects and other adverse events should be assessed in relation to the benefit. These drawbacks should be compared to the drawbacks of the actual practice and any alternatives.

- 10: Are there any known ongoing studies in other hospitals in Denmark or abroad of the effect of the proposal?

Please state any ongoing studies of the effect of the proposal.

- 11: Has the proposal been recommended by the National Board of Health, medical associations etc.? If YES, please state institution.

Please state any recommendations.

12: Has the department previously or on any other occasions, applied for introduction of the proposal?

Please state if the use of the proposal has previously been applied for (to whom, when) and any reason for the rejection.

Questions 13 -14: Patient

13: Does the proposal entail any special ethical or psychological considerations?

Please state ethical and psychological aspects of the proposal. It should be stated if the proposal could affect the patient's experience of insecurity, discomfort or anxiety. The considerations should be related to actual practice and any alternatives.

14: Is the proposal expected to influence the patients' quality of life, social or employment situation?

Please state if – and if so how – the patient's quality of life, social or employment situation is expected to be affected by the proposal. The considerations should be related to actual practice and any alternatives.

Questions 15 -20: Organisation

15: What are the effects of the proposal on the staff in terms of information, training or working environment?

Please state the derived staff-related aspects of the proposal, including which staff groups will be affected by the implementation of the proposal. Possible consequences should be stated in relation to need for information and training and influence of working environment.

16: Can the proposal be accommodated within the present physical setting?

For the purpose of planning please state if the proposal can be accommodated within the present setting. If not, please state how this could be solved.

17: Will the proposal affect other departments or service functions in the hospital?

Often a proposal will entail changes in the cooperation between the department of the proposer and other departments. If this is the case, please state in which way it is expected to affect them. It may be a question of changed collaboration pattern, work load etc.

18: How does the proposal affect the cooperation with other hospitals, regions, the primary sector etc. (for instance in connection with changes of the requested care pathway)?

A proposal can often change the cooperation with other sectors - for instance that the referral criteria are changed. If this or something else is the case please state changes of the requested care pathway, including the location of the preliminary examination, treatment and post treatment course.

19: When can the proposal be implemented?

For the purpose of planning please state when the proposal can be implemented.

20: Has the proposal been implemented in other hospitals in Denmark or internationally?

Please state if the proposal has been implemented – or planned to be implemented – somewhere else. Depending on the nature of the proposal it may be relevant to explain why increased decentralisation is considered necessary.

Questions 21 -26: Economy

21: Are there any start-up costs of equipment, rebuilding, training etc.?

Please state the expected start-up costs. The costs may cover rebuilding, new equipment, training, preparation of guidelines or patient information etc.

22: What are the consequences in terms of activities for the next couple of years?

Please state the consequences in terms of activities per year, for instance how many patients the proposal is expected to involve within the next couple of years. (The number of patients is often lower the first year due to a start-up phase). Depending on circumstances, consequences in terms of activity may be assessed based on number of patients, number of discharges, number of outpatient clinic visits, number of bed days, casemix etc.

23: What is the additional or saved annual cost per patient for the hospital?

Please state the direct additional or less expenditure per patient per year for the hospital if the proposal is carried out.

24: What is the total additional or saved cost for the hospital in the next couple of years?

Please multiply the number of patients with the additional/less expenditure per patient, resulting in the total additional/less expenditure.

25: Which additional or saved cost can be expected for other hospitals, sectors etc.?

If the proposal results in expenditure or a saving for other hospitals, regions, the primary sector or the patients etc. please state this.

26: Which uncertainties apply to these calculations?

Please state if above calculations are uncertain.

Supplement: Literature search and assessment for mini-HTAs

Literature assessment is fundamental to the health technology assessment. This also applies to mini-HTA. The first part is thus to retrieve information. This is followed by a summary of literature that translates into conclusions on technology, organisation, patient perspective and economic consequences.

Literature search

For details about databases and information sources within 1) to 6) and about the structure of the search strategies and search, please see Health Technology Assessment Handbook at <http://www.dacehta.dk/>.

A short literature search in mini-HTA may comprise the following steps:

- 1) Search for completed or ongoing HTA projects locally, nationally and internationally:

The national project database for HTA <http://www.dacehta.dk/>; The HTA database www.york.ac.uk/inst/crd/htahp.htm; INAHTA www.inahta.org; HTAi Vortal www.htai.org/vortal/

- 2) Search on systematic review articles prepared by for instance Cochrane: www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME

It is possible to stop the literature search following the first two steps in the cases where existing literature reviews are identified. The following steps are carried out, if necessary, dependent of the technology in question and the application.

- 3) Search on recent randomised controlled studies within the last few years:

Medline for instance via www.ncbi.nlm.nih.gov/entrez/query.fcgi;
Access to Embase via: hospital libraries, the Danish State and University Library (Statsbiblioteket), the Danish National Library of Science and Medicine (Danmarks Natur- og Lægevidenskabelige Bibliotek), University Library of Southern Denmark (Syddansk Universitetsbibliotek) or another institution

- 4) Search for health economic analyses:

NHS EED (National Health Service Economic Evaluation Database) www.york.ac.uk/inst/crd/nhsdhp.htm;

Proquest (ABI), access via licensed locations, for instance hospital libraries, Copenhagen Business School www.cbs.dk/library; DSI-Bib www.dsi.dk/frz_bibliotek.htm

- 5) Search in specific technical databases for, for instance, the patient aspect: For instance Cinahl and PsycInfo, access via licensed locations, for instance hospital libraries, the Danish State and University Library, the Danish National Library of Science and Medicine, University Library of Southern Denmark or another institution
- 6) Supplementary search for grey literature, for instance conference abstracts, reviews of home pages of relevant institutions etc.

It is recommended to involve a local librarian in the choice of information sources and searches.

Libraries

- Local health libraries, for instance hospital libraries or the Danish National Library of Science and Medicine www.dnlb.dk
- The State and University Library www.statsbiblioteket.dk/emneguide/sundhedsvidenskab/
- University Library of Southern Denmark www.bib.sdu.dk/,
- Videncentret (the knowledge centre), Odense University Hospital www.sdu.dk/Videncentret/
- Psychiatric research library in Aarhus (Psykiatrisk Forskningsbibliotek i Aarhus) www.aaa.dk/aaa/index/serviceomraader/psykiatri/psyk-viden.htm
- Danish Institute for Health Services Research (the library), DSI-Institut for Sundhedsvæsen (biblioteket) www.dsi.dk/frz_bibliotek.htm

Selection and assessment of the retrieved literature

1. Review and selection (by title and abstract) of the identified studies based on inclusion and exclusion criteria
2. Assessment of remaining studies. First the relevance then the validity is assessed. It may be advantageous to use checklists
3. Level of evidence is stated

Below evidence diagram makes it possible to prioritise the retrieved literature in accordance with the scientific quality of the articles.

Please refer to <http://www.dachehta.dk/> for other information on principles of evidence assessment, checklists and levels of evidence.

Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDRT validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDRT with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval)	Individual inception cohort study with ≥ 80% follow-up; CDRT validated in a single population	Validating** cohort study with good††† reference standards; or CDRT tested within one clinical centre	Prospective cohort study with good follow-up***	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts††	All or none case-series	Absolute better-value or worse-value analyses††††
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level 2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level 2 economic studies
2b	Individual cohort study (including low quality RCT; e.g. <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDRT or validated on split-samples§§§ only	Exploratory** cohort study with good††† reference standards; CDRT after derivation, or validated only on split-samples§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-sequential study, or without consistently applied reference standards	Non-sequential cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies****)	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

http://www.csbm.net/levels_of_evidence.aspx#levels

Mini-HTA is a flexible tool, which may be of assistance when decisions on the introduction of health technology are made locally.

Mini-HTA is based on a form with a number of clarifying questions on the technology. The form and the accompanying guide is included as appendix in the publication.

The form may also be downloaded from the DACEHTA home page <http://www.dacehta.dk/> and it can then be completed in the electronic form. Clarifying material on the mini-HTA is available on the home page.

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