Technology assessment and radiological imaging

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Learning objectives

1. To become familiar with the concepts of health technology assessment.
2. To understand the multidisciplinary nature of health technology assessment.
3. To appreciate the value of health technology assessment in providing cost effective and evidence based procedures for the benefit of the patient.
Main

Abstract

Technology Assessment (TA) in health care is a multidisciplinary field of policy analysis. It involves the study of the medical, social, ethical, and economic implications of development, diffusion, and use of health technology. Health Technology Assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner. Its aim is to inform the formulation of safe, effective, health policies which are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method. HTA is an approach to meet those challenges and apply the cost effectiveness in the selection of new technologies that are advancing rapidly and becoming highly sophisticated with time. It can help to meet the ever-increasing demands on competence, specialization and cost effectiveness that modern health care services are faced in today's economically conscious world. The methodology developed by the EUnetHTA project will be used to demonstrate the value of HTA with particular emphasis in the evaluation of radiological imaging technologies.

Introduction

At the time of the introduction of promising health technologies into the healthcare system, there is often a lack of strong evidence not only on effectiveness and cost-effectiveness, but also on efficacy and safety. A comprehensive assessment of promising technologies (innovative technologies) is thus difficult at the time of its introduction into the healthcare system. Despite insufficient evidence, pressure groups including clinicians, manufacturers, and patient groups push strongly for rapid access to those technologies. This creates a pressure on regulators and decision makers to make decisions increasingly early in the life-cycle of an innovation, often under a level of uncertainty, increasing thus, the risk of an inappropriate decision. If it is positive, they may allow the introduction of technologies that may later turn out to be with a low benefit-risk ratio, ineffective, cost-ineffective, or even harmful.

A policy framework that enables the coordination of the necessary actions and that, at the end, can result in either an appropriate diffusion or a discontinuation of the use of the technology is shown in figure 1. Ideally, the implementation of such a policy framework should be preceded by horizon scanning to identify promising technologies and to inform prioritization of health technology assessment (HTA) which will in turn, support decisions made within this framework (see figure 2).

The following can be considered examples of such innovative and emerging technologies in radiological imaging:
q The continuing evolution of Computerised Tomography
q Cone Beam Computed Tomography
q Direct Digital Radiography and computed Radiography
q Tomosynthesis
q The introduction of Positron Emission Tomography in the clinical environment
q The continuing evolution of Molecular Imaging

Two essential questions that need to be answered by HTA that would satisfy the policy makers to make an informed decision are:

Are these technologies justified to be used in the clinical environment in terms of safety to the patient, efficiency and cost-effectiveness?

How these can be evaluated and justified for use in the clinical environment?

An attempt will be made to answer these questions, but first it is essential that some terms need to be defined in order to make the discussion that will follow comprehensible to those new to Health Technology Assessment.

**Definitions**

**Technology:** The application of scientific or other organized knowledge - including any tool, technique, product, process, method, organization or system - to practical tasks. In health care, technology includes drugs; diagnostics, indicators and reagents; devices, equipment and supplies; medical and surgical procedures; support systems; and organizational and managerial systems used in prevention, screening, diagnosis, treatment and rehabilitation.

**Health Technology:** Any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes the pharmaceuticals, devices, procedures and organizational systems used in health care.

**Technology Assessment (TA) in health care:** Is a multidisciplinary field of policy analysis. It involves the study of the medical, social, ethical, and economic implications of development, diffusion, and use of health technology.

**Health Technology Assessment (HTA):** Is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner.
Horizon Scanning: The systematic identification of technologies in development that could have important effects on health care, and which might be considered for Health Technology Assessment.

HTA Core Model: Is a novel method of performing and reporting HTA.

Discussion

The aim of HTA is to inform the formulation of safe, effective, health policies which are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method.

National settings differ in cultural, economical, social and ethical aspects. This has obviously resulted in each national HTA agency making its own assessments, combining systematic reviews with information relevant to its own country. The resulting HTA report is context-specific. It has so far been difficult to distinguish between the "core evidence" transferable to other settings and the nationally specific information.

Better coordination of HTA activities, and collaborative approaches to transfer the core HTA into health policy and guidance could achieve significant improvements in the health of the citizens while helping to contain costs of health services and achieve greater value for money. Figure 3 shows the steps of HTA.

An effort to increase the applicability of HTA produced of such organisations was attempted by the European Network for Health Technology Assessment (EUnetHTA). The concept of the HTA Core model developed by EUnetHTA for diagnostic technologies will be presented below with emphasis in the evaluation of radiological imaging technologies.

HTA Core Model

In order to understand the meaning of Core HTA an analogy will be made with the way one can cut an onion. There are two ways to cut it, vertically and horizontally Figure 4 shows the vertical cut where each onion layer represents an HTA element. One may consider the core as the inner layers of the onion as indicated in figure 5. Figure 6 shows the horizontally cut onion where each HTA element covers all the onion layers. In the horizontally cut onion the core covers domains of each of the elements as indicated in Figure 7.

As HTA is a multidisciplinary field of policy analysis and it studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology, it is clear from figures 4 to 7 that HTA cuts the onion horizontally. The core model covers the domains of each element that are common of all HTA studies irrespective of the setting in which they are performed.
EUnetHTA has developed an HTA CORE MODEL FOR DIAGNOSTIC TECHNOLOGIES. The cover of the report is shown in figure 8.

**Basic structure and concepts**

The basic unit of the core model is the assessment element, defined further as the "element card". An element card provides a piece of information that describes the technology or the consequences or implications of its use. For example:

In clinical research: does the technology bring about reduction of symptoms?

In social science: does the technology change patients’ ability to work?

The nature of the elements may vary across research domains, since the consequences and implications are understood and studied differently in each domain. The common denominator for all elements is that they provide information that maybe useful when deciding on the use or non-use of any given technology.

**Basic concepts defining assessment elements:**

Figure 9 depicts the basic concepts of the assessment elements as these are defined below.

- **Domain:** Wide framework, angle of viewing, eg, "Current use of technology"
- **Topic:** A specific area within a domain. May be discussed under more than one domain, e.g. "Current use of technology / Regulatory status"
- **Issue:** An even more detailed area within a domain. Expressed as a question, eg, "Current use of technology / Regulatory status / Approved by EMEA"

The issues form a standard set of generic questions to be answered by Core HTAs. These questions aim at defining something of the following:

- What is being studied within an HTA?
- What should be studied within an HTA?
- What is being measured when conducting an HTA?

**Element Cards**

Element cards are a structured method of describing the elements. One card defines one element (see figure 10). They contain information such as:

- ID
- Importance / Relevance
Effectiveness can be considered an element for assessment. Efficacy of a health technology refers to its performance under ideal circumstances, such as study conditions. Effectiveness is the extent to which the technology works in day-to-day practice. Examples of questions to be answered under the element of effectiveness are given in Table 1.

**Table 1:** Examples of questions that may be required answering under the element of effectiveness.

<table>
<thead>
<tr>
<th>Category</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>What is the effect of the intervention on overall mortality?</td>
</tr>
<tr>
<td>Mortality</td>
<td>What is the effect of the intervention on the mortality due to other causes than the target disease?</td>
</tr>
<tr>
<td>Morbidity</td>
<td>How does the intervention modify the progression of disease?</td>
</tr>
<tr>
<td>Function / HRQL (Health-related quality of life)</td>
<td>What is the effect of the intervention on global improvement of function?</td>
</tr>
<tr>
<td>Function / HRQL</td>
<td>What is the effect of the intervention on health-related quality of life?</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>Was the intervention worth it?</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>Would the patient be willing to have the intervention again?</td>
</tr>
</tbody>
</table>

**Status of the Element**

A component of an element card that of its status indicates at a glance if the analysis of that particular element:

ü Indicates whether the element belongs to the HTA core
Is a function of Importance/Relevance and Transferability

Three categories: Core, Borderline, Not core

**Transferability**

Another important element of the element card is the transferability of the element analysis. The transferability can be analysed by using the matrix of Figure 11, that helps to identify in which category that particular element belongs to.

**An Example**

EUnetHTA to test the HTA Core Model for Diagnostic Technologies has carried out a Core HTA on MSCT Coronary Angiography, consisting of 235 pages (see Figure 12). To remind ourselves, Figure 13, shows an MSCT, Figure 14 shows axial MSCT Angiogram.

It includes the following domains:

- General design
- Health problem and current use of the technology
- Description and technical characteristics of technology
- Safety
- Accuracy
- Effectiveness
- Costs and economic evaluation
- Ethics
- Organisational Domain
- Social aspects
- Legal Aspects

As an example in the General Design element of this study the different steps for the diagnosis and treatment of Coronary Artery Disease (CAD) are analysed. These are shown in Figures 15 and 16.

In this report the assessment elements and their analysis is presented in table format, an example of which is shown in Figure 17.
Conclusions

Such Core HTAs do not include conclusions or recommendations since these will depend on the application setting of the final complete HTA.

Using the example of cutting the onion, we need to add the missing onion layers to complete the HTA. These will be different according to the application setting of the HTA (Country, National Health Service, Region, Public or Private Hospital).

HTA is an approach to meet the challenges and apply the cost effectiveness in the selection of new technologies that are advancing rapidly and becoming highly sophisticated with time.

It can help to meet the ever-increasing demands on competence, specialization and cost effectiveness that modern health care services are faced in today’s economically conscious world.

Acknowledgements

Most of the material used in the preparation of this presentation has been taken from the public access area of the EUnetHTA website at www.eunethta.net.

In particular the following documents were used:

1. Timely access to promising health technologies with evidence development: a toolkit for information exchange
2. EUnetHTA WP4 - HTA Core Model for diagnostic technologies - Version 1.0r
3. EUnetHTA WP4 - Core HTA on MSCT Coronary Angiography

Additional material was used from the INAHTA Health Technology Assessment (HTA) Glossary, c/o SBU, Stockholm, Sweden and a presentation given by Dr Kristian Lempe with the title: Common Core HTA: EUnetHTA Work Package 4.
**Fig. 0:** A policy framework that enables the coordination of the necessary actions that can result in either an appropriate diffusion or a discontinuation of the use of the technology

© Timely access to promising health technologies with evidence development: a toolkit for information exchange, http://www.eunethta.net

**Fig. 0:** The diagram shows the link between horizon scanning activities, HTA and this policy framework of figure 1.

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Fig. 0: Health Technology Assessment steps

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**Fig. 0:** Vertical cut of the onion where each onion layer represents an HTA element.

© Dr Kristian Lempe, Common Core HTA: EUnetHTA Work Package 4.
**Fig. 0:** The core of a vertically cut onion.

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Fig. 0: Horizontal cut of the onion where each HTA element covers all the onion layers.

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**Fig. 0:** The core of a horizontally cut onion.

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**Fig. 0:** The EUnetHTA HTA core model for diagnostic Technologies.

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Fig. 0: The element card of the EUnetHTA HTA core model.

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**Fig. 0:** An element card example.

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**Fig. 0:** The transferability matrix.

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**Fig. 0:** The EUnetHTA Core HTA on MSCT Coronary Angiography.

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**Fig. 0:** An Example of a Multi-Slice Computed Tomography System

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**Fig. 0:** Axial MDCT angiogram of the heart shows separate origin of LAD and LCX. (LAD: left anterior descending, LCX: left circumflex artery). Fig. 2: A, B. Volume-rendered images from the superior view (A) and anterior view (B) show absent left main coronary artery with separate origins of LCx

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**Fig. 0:** pathway for mild to moderate coronary symptoms in patients with low probability for severe coronary artery disease. This can be considered as part of the General Design domain.

© EUnetHTA WP4 - Core HTA on MSCT Coronary Angiography, http://www.eunethta.net

**Fig. 0:** Expansion of the Diagnostic Tests to exclude severe CAD component of Figure 15

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### Assessment elements table

<table>
<thead>
<tr>
<th>ID</th>
<th>Domain</th>
<th>Topic</th>
<th>Issue</th>
<th>Relevance in the context of MSCT or Comment (if regarded as a not relevant issue in this context)</th>
<th>Research question(s) in the context of MSCT-coronary angiography?</th>
</tr>
</thead>
<tbody>
<tr>
<td>C3008</td>
<td>Safety</td>
<td>Technology dependent safety risks</td>
<td>What is the spectrum of technology dependent harms; their incidence, severity and duration?</td>
<td>yes</td>
<td>What are the safety risks of MSCT coronary angiography?</td>
</tr>
<tr>
<td>C3010</td>
<td>Safety</td>
<td>Technology dependent safety risks</td>
<td>What is the timing of onset of harms; immediate, early or late?</td>
<td>yes</td>
<td>What are the immediate and long term consequences of the radiation exposure from MSCT coronary angiography?</td>
</tr>
<tr>
<td>C3033</td>
<td>Safety</td>
<td>Technology dependent safety risks</td>
<td>What is the dose relatedness of the harms?</td>
<td>yes</td>
<td>What is the dose relatedness of harms of using radiation in MSCT coronary angiography?</td>
</tr>
<tr>
<td>C3039</td>
<td>Safety</td>
<td>Technology dependent safety risks</td>
<td>What kind of psychological harms can the technology cause to the patient?</td>
<td>yes</td>
<td>What kind of psychological harms does coronary MSCT potentially have?</td>
</tr>
<tr>
<td>C3027</td>
<td>Safety</td>
<td>Technology dependent safety risks</td>
<td>Which are the means to reduce the risk of harms?</td>
<td>yes</td>
<td>Which are the means to reduce the radiation dose of MSCT coronary angiography?</td>
</tr>
<tr>
<td>C3026</td>
<td>Safety</td>
<td>Technology dependent safety risks</td>
<td>How does the safety profile of the technology vary between different devices or generations of devices?</td>
<td>yes</td>
<td>By what means may the risk of harms from different coronary angiography be reduced?</td>
</tr>
<tr>
<td>C3022</td>
<td>Safety</td>
<td>Technology dependent safety risks</td>
<td>What is the safety of the technology in comparison to alternative diagnostic technologies?</td>
<td>yes</td>
<td>Are there differences in the safety profile of different MSCT devices or generations?</td>
</tr>
<tr>
<td>C3040</td>
<td>Safety</td>
<td>Accuracy problems and incidental findings</td>
<td>Consequences of false positive, false negative and incidental findings</td>
<td>yes</td>
<td>Which is the safety of MSCT coronary angiography in comparison to alternative diagnostic technologies?</td>
</tr>
<tr>
<td>C3041</td>
<td>Safety</td>
<td>Use of user dependent safety risks</td>
<td>What are the special features in using (applying, interpreting, monitoring) the technology that may increase the risk of patient safety?</td>
<td>yes</td>
<td>What is the incidence and consequences of incorrect diagnostic findings?</td>
</tr>
<tr>
<td>C3042</td>
<td>Safety</td>
<td>Use of user dependent safety risks</td>
<td>Which are the means to reduce the user dependent safety risks?</td>
<td>yes</td>
<td>What are the safety consequences for patients receiving false positive test result?</td>
</tr>
<tr>
<td>C3028</td>
<td>Safety</td>
<td>Patient dependent safety risks</td>
<td>Are there patient related (individual or disease specific) factors that modify the safety of the diagnostic technology?</td>
<td>yes</td>
<td>What are the safety consequences for patients receiving false negative test result?</td>
</tr>
<tr>
<td>C3043</td>
<td>Safety</td>
<td>Patient dependent safety risks</td>
<td>Which are the means to improve the safety of patients undergoing MSCT coronary angiography?</td>
<td>yes</td>
<td>What are the psychological harms for families of patients with false positive test result?</td>
</tr>
<tr>
<td>C3035</td>
<td>Safety</td>
<td>Occupational safety</td>
<td>Is there evidence of occupational harms?</td>
<td>yes</td>
<td>What is the occupational radiation exposure in a patient undergoing MSCT coronary angiography?</td>
</tr>
<tr>
<td>C3036</td>
<td>Safety</td>
<td>Occupational safety</td>
<td>Is there any evidence of environmental harms?</td>
<td>yes</td>
<td>What is the occupational radiation exposure in a patient undergoing MSCT coronary angiography?</td>
</tr>
<tr>
<td>C3037</td>
<td>Safety</td>
<td>Environmental safety</td>
<td>Is there evidence of environmental harms?</td>
<td>yes</td>
<td>What kind of environmental protection is needed?</td>
</tr>
<tr>
<td>C3038</td>
<td>Safety</td>
<td>Environmental safety</td>
<td>Is there evidence of environmental harms?</td>
<td>yes</td>
<td>What kind of environmental protection is needed?</td>
</tr>
</tbody>
</table>

**Fig. 0:** Figure showing the image of an assessment element table analysis.

© EUneTHTA WP4 - Core HTA on MSCT Coronary Angiography, http://www.eunethta.net
References

The interested to learn more about HTA are encouraged to make a start by visit the following websites:

1. European Network for Health Technology Assessment (http://www.eunethta.net)

2. International Network of Agencies for Health Technology Assessment (http://www.inahta.org)
Personal Information

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Experience: 25 years experience in Medical Physics. Involved in the "Public Health" Committee of the Ministry of Health of Cyprus on harmonisation with the EU, the preparation of equipment specifications, calibration and testing of equipment, Delegate of the Cyprus Standards Organisation for the CEN TC 251 "Health Informatics", CENELEC TC62 "Medical Electrical Equipment" and CENELC TC 106X "Electromagnetic Fields in the Human Environment", member of the Ministry of Health's Tender, Specifications and Procurement Committees. Extensive experience in monitoring safety aspects in both the private and public sectors and was faculty member and organiser of many training courses organised in collaboration with IAEA & WHO. Participated as a Work Package leader in the SENTINEL European Project. Participated actively in Work Packages 2 and 8 of the EUnetHTA European project and represented the Ministry of health of Cyprus in the PHGEN European project. Member of the group currently revising the European Report RP91 "Criteria for of Radiological (including Radiotherapy) and Nuclear Medicine installations" (leader of the Nuclear Medicine section). Also a member of the Consultants review team of the IAEA document "Diagnostic Radiology Physics: A Handbook for Teachers and Students".

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