

Assessing health technologies through the HTA approach: the basic methodology to be used

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OUTLINE

1. HTA and decision analysis
2. Principles and development of HTA
3. Overview of tools for HTA

HTA AND DECISION ANALYSIS

Decision analysis is a systematic, explicit and quantitative approach for decision making under uncertainty

What is needed?

- Data
- Tools to estimate the impact of choices under uncertainty

HTA AND DECISION ANALYSIS

- *Health technology assessment (HTA) is a form of **policy research** that examines short- and long-term consequences of the application of a health-care technology. Properties assessed include evidence of **safety, efficacy, patient-reported outcomes, real-world effectiveness, cost, and cost-effectiveness as well as social, legal, ethical, and political impacts***

→ Identification of the "optimal strategy"

EVIDENCE BASED...

Medicine

The conscientious, explicit and judicious use of *current best evidence* in making decisions about the care of individual patients. The practice of evidence-based medicine requires the integration of individual clinical expertise with the best available external clinical evidence from *systematic research* and our patient's unique values and circumstances

Sackett et al. Churchill Livingstone 2000

Management

Evidence-based management is the *systematic application* of the *best available evidence* to business processes, strategic decisions, and the evaluation of managerial practices

Kovner et al., 2010

Policy

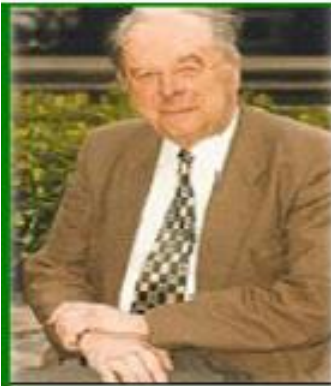
People making well-informed decisions about policy, programs and projects by putting the *best available evidence from research* at the heart of policy development and implementation

Nutley et al., 2007

MILESTONES

All effective treatments should be provided free of charge

Archie Cochrane, 1971



All the cost-effective treatments should be provided free of charge

Alan Williams, 1997

FURTHER ASSESSMENT ELEMENTS

Box 2. Key evidence used to support decision-making

- Health benefit (mortality, morbidity)
- Cost-effectiveness (cost per quality-adjusted life year (QALY))
- Necessity (e.g. disease burden, severity)
- Availability of treatment alternatives
- Public health impact (population level)
- Equity
- Innovative characteristics (e.g. pharmacological properties, ease of use)
- Budget impact
- Ethical/legal considerations
- Feasibility of decision/guidance implementation
- Projected uptake/utilization

THE BIRTH OF TA

“Technical information needed by policymakers is frequently not available, or not in the right form.

A policymaker cannot judge the merits or consequences of a technological program within a strictly technical context. He has to consider social, economic, and legal implications of any course of action”

US Congress 1967

- Purpose: support to decision-makers!

WHAT IS HTA

- Broadly speaking, HTA can be defined as the systematic evaluation of the properties, effects and/or other impacts of health-care technologies

INAHTA glossary

- HTA is “a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe effective health policies that are patient focused and seek to achieve best value”

CHARACTERISTICS

The HTA is a **multidisciplinary approach** which involves **different professionals/experts/stakeholders** in the evaluation of health technologies.

Nevertheless, HTA is not simply research; four features distinguish it:

- a) policy orientation: it is policy-oriented and should be policy-driven;
- b) interdisciplinary content and process;
- c) collection and synthesis of evidences and primary data: it is a tool of the Evidence Based Medicine;
- d) central role played by the dissemination and the communication of information.

HTA:

- Shows how to invest money (not how to save money),
- Allows to provide technologies in an appropriate and timely way,
- Guarantees the satisfaction of stakeholders' expectations,
- Permits to pursue sustainability.

APPLICATIONS

- *Health technology refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives.*

Health Technologies	Examples
<i>Drugs</i>	<i>beta-blockers, antibiotics, etc.</i>
<i>Biologics</i>	<i>vaccines, blood products, cellular and gene therapies, etc.</i>
<i>Devices, equipment and supplies</i>	<i>cardiac pacemakers, CT scanners, diagnostic test kits, etc.</i>
<i>Medical and surgical procedures</i>	<i>nutrition counseling, coronary angiography, gall bladder removal, etc.</i>
<i>Support systems</i>	<i>electronic patient record systems, telemedicine systems, blood banks, etc.</i>
<i>Organizational and managerial systems</i>	<i>prospective payment using diagnosis-related groups, clinical pathways, quality management programs, etc.</i>

GOALS

PRIORITY SETTING with respect to health needs and available resources:

- **Choice of health technologies,**
- **Reimbursement systems,**
- **Delivering procedures.**

DECISIONAL LEVELS

- The HTA is aimed at supporting decision-making; thus it can be applied to preventive, diagnostic, therapeutic and rehabilitative measures.
- Indeed, HTA could be a useful tool to support decision-makers at different levels:
 - National Health Policy (Macro level),
 - Hospital/Local Health Unit level (Meso level),
 - Clinical decision - making (Micro level).

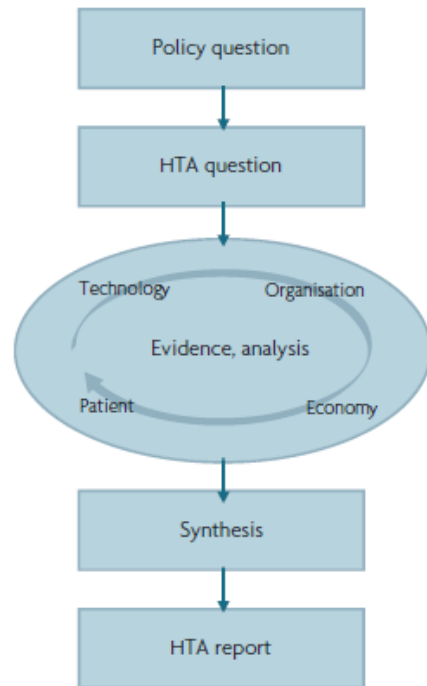
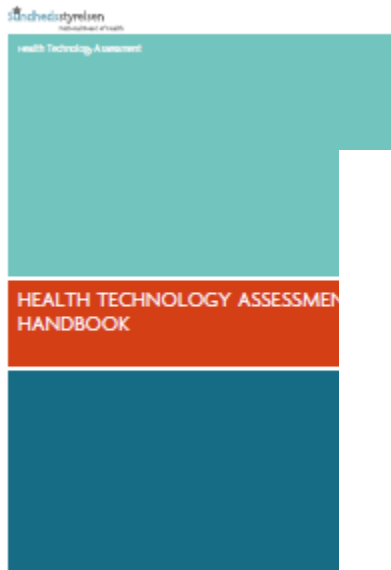
DECISIONAL LEVELS

Levels	Dimension	Objective	Decision-maker
MACRO	Health Policy	<ul style="list-style-type: none"> - Regulation - Innovation 	Regulatory Institutions
MESO	Hospital/Local Health Unit Management	<ul style="list-style-type: none"> - Priority setting - Optimization of use 	Top Management
MICRO	Clinical Management	<ul style="list-style-type: none"> - Appropriateness of use 	Department, scientific societies

10 PRINCIPLES TO GUIDE HTA

1. The Goal and Scope of the HTA Should Be **Explicit and Relevant** to Its Use
2. HTA Should Be an **Unbiased and Transparent** Exercise
3. HTA Should Include **All Relevant Technologies**
4. A Clear System for **Setting Priorities** for HTA Should Exist
5. HTA Should Incorporate **Appropriate Methods** for Assessing Costs and Benefits
6. HTAs Should Consider a **Wide Range of Evidence and Outcomes**
7. A **Full Societal Perspective** Should Be Considered When Undertaking HTA
8. HTAs Should Explicitly Characterize **Uncertainty** Surrounding Estimates
9. HTAs Should Consider and Address Issues of **Generalizability and Transferability**
10. Those Conducting HTAs Should **Actively Engage All Key Stakeholder Groups**

HTA CONTENTS



Four topics to be addressed:

- Technology:** efficacy, safety, performance, technical features;
- Patient:** clinical impact but also quality, acceptability, ethical profile, etc.;
- Economy:** costs and cost-effectiveness;
- Organisation:** need for reengineering.

HTA CORE MODEL

“A methodological framework for shared production and sharing of HTA information”

Assessment element: The basic unit of the model. Defines a piece of information that describes the technology or the consequences of implications of its use, or any other implication that is relevant for the assessment, such as the patients and the disease for which it is applied. Each assessment element contains an "issue", which is a question that should be answered in an HTA. Not all issues, however, are relevant to all technologies/settings, and hence their relevance is considered separately for each assessment. Elements are defined through a combination of domain, topic and issue

HTA CORE MODEL

- **Domain:** A wide framework within which technology is considered. It provides an angle of viewing the use, consequences and implications of technology.
- **Topic:** A more specific area of consideration within the domains. One domain is divided into several topics.
- **Issue:** An even more specific area of consideration within any of the topics. One topic typically consists of several issues, but it may also contain only one issue. An issue is always expressed as a question.

HTA CORE MODEL



Table 1. Domains of an HTA

1. Health problem and current use of technology (CUR)
2. Description and technical characteristics of technology (TEC)
3. Safety (SAF)
4. Clinical effectiveness (EFF)
5. Costs and economic evaluation (ECO)
6. Ethical analysis (ETH)
7. Organisational aspects (ORG)
8. Social aspects (SOC)
9. Legal aspects (LEG)

JOINT ACTION 2 - WORK PACKAGE 8

The HTA Core Model[®]

EUnetHTA works to develop **tools** for the **sharing of methodological frameworks and scientific evidence**, reducing duplication and saving time and resources

HTA METHODS - SUMMARIZING

“Systematic review” should always be considered as the preferable method of gathering, assessing and synthesising evidence and information for an issue in this domain. Quality assessment of the information obtained, using approved and transparent criteria for including and excluding information, is another requirement”

HTA METHODS - OTHER TOOLS

- Data query and processing
- Development of mathematical models
- Cost-effectiveness analysis
- Budget impact analysis
- Surveys
- Elicitation of expert opinion (focus group, Delphi, consensus conference)

FRAMING HTA

1. *Definition of the policy question*
2. *Methodological protocol*
3. *Systematic review of available evidence*
4. *Mathematical modeling*
5. *Analysis of further impacts*
6. *Final report*

HOW TO BEGIN

- Project definition
 - ✓ Description and analysis of technology
 - ✓ Health problem
 - ✓ Target population
 - ✓ Alternatives
 - ✓ Identification of the assessment elements
- Project design
 - ✓ Topics and Issues definition

CONCLUSION

- The HTA approach allows studying and evaluating all the implications of the introduction/use/dismissal of health technologies.
- Multi-criteria assessment → more than cost-effectiveness evaluation.
- Support value for money.

FUTURE DEVELOPMENTS

The application of HTA should be promoted for all technologies, to cover all healthcare innovations.

More efforts should be made in each country to make the HTA a common ex-ante approach to the evaluation of new technologies.

The integration of HTA and research in decisional and political processes should be pursued and achieved.

GAPS TO BE MET

Partnership between Companies and researchers in order to plan and carry out R&D programs useful for future evaluations;

Accessibility to data and patient information in the view to make the evaluation possible and reliable and to trace personalized medicine;

Collaboration between policy-makers and researchers in order to allow a rational allocation of resources in the different healthcare fields, but also to promote health in all policies.

THANKS FOR YOUR KIND ATTENTION

For further information

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