Comprehensive Needs Analysis For Health Technology Assessment Studies and Improvement Proposal

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Abstract - Increase in chronic diseases prevalence, longer life expectancy, and improvements in science and engineering speed up the innovations in healthcare technology. In this study it is aimed to provide both a deep understanding in needs of recent health technology assessments and an improvement proposal for health technology assessment studies based on multi criteria decision making (MCDM). It is concluded that an integrated MCDM model is essential for satisfying the current needs of HTA studies.

Keywords - HTA; HTA needs; HTA users; MCDM for HTA

1. Introduction

Since last fifty decades technological innovation has yielded truly remarkable advances in health care. Health care delivery and patient outcomes have been improved by breakthroughs in a variety of areas. (Goodman, 2014; Bautyomi, 2012)

The recent speed of healthcare technology is influenced by driving forces like increase in chronic diseases prevalence, longer life expectancy, and improvements in science and engineering.

The major improvement areas are antivirals, anticoagulation drugs, antidiabetic drugs, antihypertensive drugs, antirheumatic drugs, vaccines, pharmacogenomics and targeted cancer therapies, cardiac rhythm management, diagnostic imaging, minimally invasive surgery, joint replacement, pain management, infection control, and health information technology. (Goodman, 2014)

The challenge of how to manage health-care delivery in conditions of resource constraint is the current struggle around the world both in developed or developing countries. Healthcare policy, practice and decisions are essential not only to maximize the positive impact of healthcare interventions on population health, but also maximizing the value from the cost of providing the interventions (WHO, 2011). The relationship between healthcare technology and related healthcare costs is complex.

The technology assessment (TA) term first used in 1960s. The need for TA arose from the critical role of the technology in modern society, which bears potential for unintended and harmful consequences.

Banta (1993), defined TA as a form of policy research that examines short- and long-term social consequences of the application of technology including societal, economic, ethical, legal aspects. Providing information on policy alternatives is the goal of technology assessment (Banta, 1993).

Before the introduction of Health Technology Assessment (HTA), health technologies had been studied for safety, effectiveness, cost, and other concerns. Healthcare technologies were among the
topics of early TAs due to widespread interest in immediate health effects.

The decision-making process should consider not only concrete criteria, such as technical and economic properties, but also social, environmental, and political factors. The application of decision-making systems or methodologies gives an organization a competitive advantage in the current highly competitive environment. The decision-making cases which includes more than one criterion to evaluate are called Multi-Criteria Decision Making (MCDM) (Ozturk and Tozan, 2015)

The aim of this study is to provide deep understanding in HTA, its purpose, techniques and current needs as well as an improvement proposal for HTA studies based on MCDM.

2. Health Technology Assessment (HTA)

HTA is defined by the World Health Organisation (WHO) as the systematic evaluation of properties, effects, and/or impacts of health technology. Further stated that it is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. (WHO, 2011)

<table>
<thead>
<tr>
<th>Organisation</th>
<th>HTA Definition</th>
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<tr>
<td>World Health Organisation (WHO)</td>
<td>Health technology assessment (HTA) refers to the systematic evaluation of properties, effects, and/or impacts of health technology. HTA is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. (WHO, 2011)</td>
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<td>International Network of Agencies for Health Technology Assessment (INAHTA)</td>
<td>HTA is the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies. HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods. (INAHTA, 2016)</td>
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<td>Health Technology Assessment International (HTAi)</td>
<td>HTA is a field of scientific research to inform policy and clinical decision making around the introduction and diffusion of health technologies…. HTA is a multidisciplinary field that addresses the health impacts of technology, considering its specific healthcare context as well as available alternatives. Contextual factors addressed by HTA include economic, organizational, social, and ethical impacts. The scope and methods of HTA may be adapted to respond to the policy needs of a particular health system. (HTAi, 2015)</td>
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<td>European Network for Health Technology Assessment (EUnetHTA)</td>
<td>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, robust manner. Its aim is to inform the formulation of safe, effective, health policies that 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. (Sacchini et al., 2009)</td>
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<td>UK NHS National Institute for Health Research Health Technology Assessment Programme</td>
<td>HTA asks important questions about these technologies (drugs, devices, procedures, settings of care, screening) such as: When is counseling better than drug treatment for depression? What is the best operation for aortic aneurysms? Should we screen for human papilloma virus when doing cervical smears? Should aspirin be used for the primary prevention of cardiovascular disease? It answers these questions by investigating four main factors: whether the technology works, for whom, at what cost, how it compares with the alternatives. (UK NHS, 2016)</td>
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<td>US Congress, Office of Technology Assessment</td>
<td>Health technology assessment … is a structured analysis of a health technology, a set of related technologies, or a technology-related issue that is performed for the purpose of providing input to a policy decision. (US Congress, 1993)</td>
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In last decades many institutions and organisations established to search and further develop HTA studies. Table 1 provides HTA definitions by some of these organisations such as International Network of Agencies for Health Technology Assessment (INAHTA), Health Technology Assessment International (HTAi), European Network for Health Technology Assessment (EUnetHTA), UK NHS National Institute for Health Research Health Technology Assessment Programme, and US Congress, Office of Technology Assessment.

These definitions contain several common terms and properties. In most of the definitions, HTA is defined as “systematic evaluation” and its “multidisciplinary” aspect is stressed. Commonly mentioned that the evaluation is mainly on economic, organizational, social, and ethical impacts. EUnetHTA further defined that HTA should be transparent, unbiased, and robust.

Today HTA is accepted as a tool to assist evidence-based health-care decisions (Stephens, 2012).

The organizations that operate formal HTA programs has an explicit objective to carefully consider a full range of clinical and economic evidence for rendering decisions to the acceptance, modification, or rejection on a rational basis. (Sullivan SD, 2009)

The process followed in HTA studies varies based on the type, scope, or selection methods. However, a standard HTA process starts with problem definition, continuous by data collection and processing, follows by evaluation and monitorisation (Fig. 1).

3. Different HTA Methods

HTAs can take different forms such as a full-scale HTA report, contextualization of HTA reports produced elsewhere, rapid reviews, health technology information services or horizon scanning reports depending on the issues involved, the time frame of decision-making, and the availability of resources. (Velasco-Garrido and Busse, 2005)

Furthermore, HTAs might consist of diverse group of methods. One distinction among HTAs can be done according to the methods they are using. Primary data methods and Integrative methods are the two main types of HTA methods (Goodman, 2014).

Another recent tendency is to standardize the research methods. The standardization in research methods among HTA organizations might be achieved a process for information sharing (Stephens, 2012). Developing generic framework to enable the collaboration between countries and institutions is one of the alternative processes. The Core Model of EUnetHTA is a successful example of the HTA frameworks.

3.1. Primary Data Methods

Primary data methods include collection of original data, like clinical trials and observational studies. The crucial point is the determination of the causal effect of health technologies. The studies can be comparative or non-comparative, with separate control group or no separate group, prospective or retrospective, interventional or observational. (Goodman, 2014)

Since it is not always possible to conduct the most thoroughly designed studies, some HTA programs collect primary data, or might be part of larger organizations that collect primary data. (Goodman, 2014)

3.2. Integrative Methods

Integrative methods contain combining data or information from existing sources, including from primary data studies. It may include quantitative, structured approaches such as meta-analyses or systematic literature reviews to informal, unstructured literature reviews. (Goodman, 2014)

An assessment group must then integrate the available relevant finding after having considered the merits of individual studies. There is no single definitive primary study, which settles whether one technology is better than another for a particular clinical situation. (Goodman, 2014)

Combining or integrating data from primary sources can be done by the methods such as systematic literature review, meta-analysis, modelling, group
judgment, unstructured literature review, and expert opinion. (Goodman, 2014)

3.3. HTA Core Model

HTA Core Model is methodological framework that is developed by the EUnetHTA in order to jointly produce and share HTA information.

The aim with the HTA Core Model is to overcome variance in the extent and scope of analysis, and differences in reporting the results. By means the international applicability of national or regional HTA reports could be possible. (Lampe et al., 2009; Banta & Oortwijn, 2000; Busse et al., 2002)

The structure of the HTA Core Model lets thorough production and transparent presentation of HTA information (Pasternack, 2009).

The HTA Core Model composed of 9 domains (Fig. 2), which are divided into more specific topics and further issues. An assessment element is defined as the combination of domain, topic and issue. (Pasternack, 2009)

HTA Core Model consists of three components:

1. Ontology – a set of generic questions to define the content of an HTA
2. Methodological guidance – assisting to answer the questions
3. Reporting – common structure enabling standardised reporting of HTAs

(Lampe et al., 2009)

Usage tendency may differ from country to country or regionally. For instance in England it is mostly used for value of money assessments. But in rest of Europe, HTA is a source for evidence of cost-effectiveness.

Some of the HTA user groups are regulatory agencies, payers, clinicians, patients, health professional associations, hospitals, standards-setting organizations, government health department, lawmakers and other political leaders, health care technology companies, investors, and research agencies. Table 2 includes the list of users with the main purpose of use.

### Table 2. HTA users and purposes. (Facey, 2008; Goodman, 2014)

<table>
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<tr>
<th>HTA Users</th>
<th>Purpose</th>
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<tr>
<td>Regulatory agencies</td>
<td>Commercial use or marketing of a drug, device or other technology</td>
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<tr>
<td>Payers</td>
<td>Technology coverage, coding, and reimbursement</td>
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<tr>
<td>Clinicians and patients</td>
<td>Appropriate use of health care interventions for a particular patient’s clinical needs and circumstances</td>
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<tr>
<td>Health professional associations</td>
<td>Clinical protocols or practice guidelines</td>
</tr>
<tr>
<td>Hospitals</td>
<td>Technology acquisition and management</td>
</tr>
<tr>
<td>Standards-setting organizations</td>
<td>Health technology and health care delivery regarding the manufacture, performance, appropriate use, and other aspects of health technologies</td>
</tr>
<tr>
<td>Government health department</td>
<td>Public health programs</td>
</tr>
<tr>
<td>Lawmakers and other political leaders</td>
<td>Technological innovation, research and development, regulation, payment and delivery of health care policies</td>
</tr>
<tr>
<td>Health care technology companies</td>
<td>Product development and marketing decisions</td>
</tr>
<tr>
<td>Investors and venture capital funding</td>
<td>Acquisitions and divestitures, and other transactions concerning health care product and service companies</td>
</tr>
<tr>
<td>Research agencies</td>
<td>Evidence gaps and unmet health needs</td>
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Many of the user groups mentioned in Table 2 have their own HTA units or functions, which might be affiliated with national or regional governments or
On one hand HTA supports or is used for development and updating of a wide range of standards, guidelines, and other health care policies, on the other hand HTA is used to support decision making by clinicians and patients, payers, hospitals, government health department, and healthcare technology companies for various decisions under diverse conditions.

5. Needs of HTA studies

HTA has been in a rapid and steady expansion worldwide since last four decades. Healthcare organizations, stakeholders, and interested groups have been enlarged based on the expansion as well. Some of these groups are mainly interested in producing HTAs some are more in user side. They use HTAs as a source of information or for decision making.

Since the stakeholder group of HTA is diverse their needs are varying from each other as well. Depending on type of HTA, issuing organization, purpose of use needs of HTA studies are also different. However the basic needs that are required to be fulfilled by each HTA study are similar.

HTA studies as the source of comprehensive information or the basis for decision making need to be systematic, structured, transparent, comprehensive, consistent, flexible, bi-directional, multi-disciplinary to be able to provide basis for decision making (Fig. 3). (Dolan, 2010; Devlin and Sussex, 2011; Tony et al, 2011; Thokala and Duenes, 2012; Goetghebeur et al., 2012; Diaby and Goeree, 2014; Wahlster et al., 2015)

The attempt to improve HTA by satisfying those needs is increasing. For instance decision making frameworks have been developed and strengthened with guidelines to provide structure and bring transparency to the assessment of health technology (Diaby and Goeree, 2014).

Nevertheless the decision making process in HTA is a multi-disciplinary process due to the varying stakeholders, like physicians, pharmacists, pharmacologists and health economists (Johnson-Masotti and Eva, 2006; Goetghebeur et al., 2012). That causes two important constraints. Firstly, decisions in HTAs to be restricted to the deliberative process which can take only specific criteria into consideration. Secondly, the varying group of stakeholders with different value judgments is not transparent in the
6. Improvement proposal: Multi Criteria Decision Making (MCDM)

Decision making in healthcare is a complex process due to requiring various scientific, medical, economic, social, and ethical elements. Currently HTA studies are either do not contain a decision making or they mostly rely on cost effectiveness based analysis.

An efficient and cost-effective decision-making process should apply decision-making techniques (Ozturk and Tozan, 2015). In HTA decision-making cases, there are more than one criterion to evaluate. Decision-making processes that incorporate more than one criterion called Multi Criteria Decision Making (MCDM) (Ozturk and Tozan, 2015).

In last decade there have been many studies on bridging the HTA and MCDM (Thokola and Duenas, 2012; Dolan, 2008; Diaby and Goeree, 2014). In these group of studies mainly the necessity of MCDM in HTA is discussed and some MCDM techniques are illustrated by examples. However, no further direct applicable models proposed.

In the study of Baltussen and Niessen, the prioritisation in health interventions by MCDM is done (Baltussen and Niessen, 2006).

The EVIDEM framework developed by Goetghbeur et al. is the most mature application of MCDM in HTA. In EVIDEM the evidence and value impact on decision making was designed to provide a MCDA model adaptable to the context of decision makers using a contextual tool to provide synthesized evidence at the criteria level. (Goetghbeur et al., 2012; Wahlster et al., 2015)

Karacan introduced a hybrid decision support tool to select health technology. The developed model consists of five criteria such as cost, risk, clinical characteristics, quality, and recovery from comorbidities. (Karacan, 2015)

The most frequently used MCDM technique in healthcare decision making is the Analytic Hierarchy Process (AHP). Followed by DEA (Data Envelopment Analysis), VIKOR (Vise Kriterijumska Optimizacija I Kompromisno Resenje), TOPSIS (Technique for Order Preference by Similarity to Ideal Solution), MAVT (Multi Attribute Value Theory), ELECTRE (Elimination and Choice Expressing Reality). (Ozturk and Tozan, 2015; Diaby and Goeree, 2014; Stephens, 2012; Rosina et al., 2015; Ivlev et al., 2015)

Each of the MCDM techniques bear advantages and disadvantages within their methodology. Current lack is not the application of one technique and not using the other one but the lack of right model that can be applicable to various HTA studies. If the right MCDM model for HTA studies is developed different decision support techniques can be applied.

In different studies, the needs of HTA are pointed to be solved by introduction of MCDM. For instance Devlin and Sussex state that MCDM is an aid to HTA based decision making in the National Health System of United Kingdom. They further claim that MCDM eases to hold decision-makers to account for the decisions they make on behalf of the public, than decisions are based on more opaque deliberative processes. In healthcare decision making it is necessary to provide greater public confidence in the decisions. (Devlin and Sussex, 2011)

However the right MCDM model for HTA is still lacking. The common problem of the current available models is not being integrated in HTA itself but rather provide totally separate models or concentrate on self defined criteria. This surely limits the usage either on specific HTA or couple of health decision related problems.

The right MCDM model should be integrated to the HTA. The criteria that are basis of evaluation in MCDM should be the core of HTA. The explicit identification and weighting of the criteria upon which health care resource allocation decisions are made should be comprehensive, consistent and transparent.

The recent standardization attempts on HTA studies for reproducibility and wider usage in different regions is also promising for a right MCDM model for HTA. HTA frameworks developed can be basis for developing an MCDM model that can be applicable to various decision making cases.

7. Conclusion

High healthcare expenditures for healthcare systems, the emergence of new health technologies and the scarce resources motivated the expansion of HTA
studies. HTA viewed as a bridge between evidence and decision making.

Although several developments have been done in HTA field including different metrics and parameters, the necessity on systematic, structured, transparent, comprehensive, consistent, flexible, bi-directional, and multi-disciplinary structure is still lacking.

Mostly decision making is considering only part of the HTA which can be applicable by basic parameters or totally ignored. The HTA itself may include decision making. Even if it is not as it is discussed in the users and purposes section HTA is widely used for decision making so the decision making in HTA is inevitable.

Development of an MCDM model for generic HTA use is proposed in this study to satisfy the current needs of HTA studies. Such a model will further be potential to include various stakeholders’ commitments. Stakeholders like physicians, pharmacists, pharmacologists and health economists could make implicit and different value judgements for the decision-making criteria.

In conclusion, an integrated MCDM model is essential for satisfying the needs of HTA. Moreover, it will be potential for further use of HTA studies. It will enable the reproducibility and effectiveness by means reach to new users.

References


