How to choose health technologies to be assessed by HTA? A review of criteria for priority setting

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Abstract

Introduction. Health Technology Assessment (HTA) plays a key role in the policy and decision-making process. Nevertheless, it is time- and resource-consuming, and therefore requires proper resource allocation. Priority setting, as a best way to organize effective and explicit resource allocation systems, may be applied even in this field.

Objective. The aim of this study was to provide an overview of criteria used for priority setting in HTA at European level.

Methods. A systematic review of the scientific literature was performed through PubMed alongside consultation of the websites of the European HTA Agencies belonging to the INAHTA. The search was limited to papers written in English and provided with the full text. Documents were considered eligible if providing criteria for priority setting in HTA.

Results. Seven scientific articles were retrieved from PubMed and 14 European HTA Agencies released prioritization criteria were analyzed. The most relevant criteria were: frequency/burden of disease, economic impact and costs, potential benefits, impact on ethical, social, cultural and/or legal aspects.

Conclusion. This work is meant to contribute to supranational discussion on priority setting at European level and shows that, despite the available evidence, work still needs to be done toward harmonization and sharing of the criteria to adopt.


Key words: health technology assessment, priority setting, resource allocation

Riassunto

Introduzione. La valutazione delle tecnologie sanitarie (HTA) riveste un ruolo chiave nel processo di policy e decision-making. L’HTA è tuttavia time- and resource-consuming e, pertanto, richiede strumenti per una corretta allocazione delle risorse. Il priority setting, inteso proprio come strumento per la definizione dell’uso efficiente ed esplicito delle risorse, trova spazio anche in tale ambito.

Obiettivo. Obiettivo del lavoro è stato fare una revisione dei criteri di prioritarizzazione proposti a livello europeo per l’HTA.

Metodi. E’ stata condotta una revisione sistematica della letteratura scientifica attraverso la consultazione di PubMed e sono stati consultati i siti web delle agenzie europee di HTA aderenti all’INAHTA. La ricerca è stata limitata ai documenti in lingua inglese e disponibili in full text e sono stati inclusi nella review gli studi che hanno fornito criteri per il priority setting nell’HTA.

Risultati. La revisione ha preso in considerazione 7 lavori scientifici e i documenti di 14 Agenzie europee di HTA. I criteri di prioritarizzazione più comunemente riportati sono stati: frequenza/carico di malattia, costi e impatto economico, benefici potenziali della tecnologia e suoi impatti/aspetti etici, sociali, culturali e/o legali.

Conclusione. Questo lavoro ha inteso contribuire alla discussione sul priority setting a livello europeo e ha messo in luce che, nonostante le evidenze, è necessario continuare a lavorare per l’armonizzazione e la condivisione dei criteri da adottare.


Parole chiave: health technology assessment, priority setting, allocazione delle risorse
INTRODUCTION

According to the International Network of Agencies for Health Technology Assessment (INAHTA) and the Health Technology Assessment international society, health technology assessment (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".

Assessing the efficacy, cost-effectiveness, safety, and organizational as well as ethical issues of available drugs, devices, and practices has become necessary because of the increasing costs of health care and inappropriate use of technology in medicine.

New technologies are increasingly available today, but time and human and economic resources for HTA are limited and HTA agencies must therefore choose which research projects to undertake. Technologies to be studied are not equivalent in terms of potential impact on public health and the economy. Different diseases have, indeed, different burdens, and their management with different technologies or protocols has different costs. Moreover, the pressure of stakeholders (including the varied and varying value systems of public opinion and the ruling political forces) may sometimes make it mandatory for HTA agencies to focus on current "hot topics" in health and, consequently, on certain research projects rather than others. However, choosing the technologies on which to focus efforts should retain a scientific and systematic approach, hence HTA agencies need to develop, implement, and disclose valid methods for priority setting.

The first priority setting models became available in the 1990s and include the well-known Donaldson method (adopted by many HTA agencies) and practical approaches which were developed within the EUR-ASSESS Project. Even though it soon became clear that no standard method of prioritization will ever be universally valid, prioritization processes usually follow a few widely accepted rules. In particular, those involved in the priority setting should always review available health technologies, health policies, and clinical practices; identify issues that are relevant for decision-makers and technologies potentially to be assessed; set priorities; inform the institutions and agencies involved in HTA; keep monitoring and reviewing assessments and priorities. Criteria for priority setting have a central role in every model and are different or show different weights in the various methodologies.

Noorani et al. reviewed the criteria for priority setting in 2007. HTA agencies usually used criteria taking into account clinical and economic impact and the burden of the disease, but they generally ignored the potential availability of new technologies in the near future, the variation in their rates of use, and their ethical, legal, or psychosocial implications. Above all, the review from Noorani et al. highlighted the limited participation of stakeholders in most of the analyzed prioritization processes. In fact, only the US Agency for Healthcare Research and Quality (AHRQ) explicitly involved stakeholders (a volunteer group including clinicians, researchers, third-party payers, consumers of Federal and State beneficiary programs, and healthcare industry professionals) in their priority setting methods.

These considerations eventually led many HTA agencies to renew and improve their priority setting methods and, among others, even the Donaldson method was updated. How and how much have these criteria changed in Europe in recent years? Aim of this review is to provide an overview of criteria for priority setting in HTA, either published in the literature or promoted by the European HTA agencies that are members of the INAHTA.

METHODS

In order to identify criteria used for priority setting in Europe, a systematic literature review was performed on PubMed and on the websites of HTA Agencies belonging to the INAHTA. The literature review on PubMed was carried out without any starting date and up to 30 November 2014. The algorithm for the search was as follows: (priority setting OR setting priorities OR priority setting criteria OR prioritisation criteria) AND (health technology assessment OR Technology assessment OR HTA OR technologies evaluation) AND (Europe"[MeSH Terms] OR Europ* OR Austria OR Belgium OR Bulgaria OR Croatia OR Cyprus OR Czech Republic OR Denmark OR Estonia OR Finland OR France OR Germany OR Greece OR Hungary OR Ireland OR Italy OR Latvia OR Lithuania OR Luxembourg OR Malta OR Netherlands OR Norway OR Poland OR Portugal OR Romania OR Russia OR San Marino OR Serbia OR Slovakia OR Slovenia OR Spain OR Sweden OR Switzerland OR United Kingdom).

The search was restricted to full-text articles published in English. Articles found on PubMed were screened according to titles and abstracts with respect to the following inclusion criteria:

- setting of the study: European countries;
- objective of the study: provision of criteria for priority setting in HTA.

Articles were excluded if they addressed only methods used to develop priority setting criteria or dealt with priority setting in fields other than HTA (clinical research, public expenditure, adoption of technologies, health care organization, etc.). Reviews were also excluded, even though their references were checked for potential eligible primary studies. The full text of potential eligible articles was retrieved and assessed for final inclusion in the review. The screening process of eligible articles was performed by two researchers independently and disagreements were solved with the involvement of a third one. From articles finally included in the review the following data were extracted and reported in table 1: author, country, objective, methods, identified criteria.

The websites of European HTA Agencies were accessed through the INAHTA platform. Each website was screened through the use of the following key words in the query box: priority setting, prioritization, decision making, horizon scanning, HTA. Each report or documentation dealing with priority setting frameworks and prioritization criteria applied in...
the selection of the technologies submitted to HTA was read and assessed for eligibility. Tables were used to report both information about agencies (country, date of foundation, population served) and suggested criteria.

RESULTS
The search on PubMed identified a total of 121 articles, of which seven5,7-12 satisfied the inclusion criteria and were considered in the qualitative review (figure 1).

The included articles involved a total of 6 European countries: the Netherlands (2 articles), Germany, Hungary, Lithuania, Spain, and the UK. All articles dealt with the development of a theoretical framework which resulted in procedures and criteria for the priority setting process. From a methodological point of view, a Delphi technique with weighting of criteria was adopted by Jankauskiene et al.5 and Berra et al.9 Oortwijn et al.11,12 used a rating and weighting system based on both scientific and societal criteria in order to propose a new multi-steps procedure for prioritization. A theoretical priority-setting framework was developed by Bastian et al.8 using a poll and the principles of multi-criteria decision analysis and involving patients and the general public. Finally, Gulacci et al.9 and Townsend et al.10 drew on international experiences to develop their models.

The prioritization criteria resulting from the articles are summarized in table 1. The most reported criteria were: potential benefits; costs/cost effectiveness associated to the introduction of the new technology; burden of disease. The search on the European HTA agency websites showed 14 reported prioritization criteria out of 30 (table 2). Five agencies also reported the description of the priority setting process (GÖG, LBI-HTA, AETS, AVALIA-T, OSTBEA). AVALIA-T reported a scoring and weighting process, as well. Twelve out of 14 agencies considered as criteria the «economic impact/costs/maintenance costs» and 11 the «impact on ethical, social, cultural and/or legal aspects» (table 3). «Frequency of disease» was reported by 9 out of 14, «burden of disease» by 8, and «impact on clinical practice» by 7. All other criteria were adopted by less than 50% of agencies (table 3).

DISCUSSION
Priority setting has been defined as the best way to organize effective and explicit resource allocation systems.13 Growing attention has been paid to this issue over time because of its relevance for decision making. In fact, priority setting is used as a tool for rationing resources in several contexts, from public policies and economy to healthcare. With respect to the latter, priority setting is considered necessary to fairly allocate resources in the delivery of healthcare.14 It is also needed in order to appropriately allocate resources for the assessment of health technologies, given the fact that this is a time- and resource-consuming process and that more and more health technologies enter the market each year.

Demographic and epidemiological changes and consumer empowerment have determined an increase in health demand and pressure and competition among companies is rising. Nevertheless, although a standardization of criteria and methods has been developed for the application of HTA,15 the same is not completely true for priority setting in HTA. At any rate, the interest and experiences available in the field are growing both nationally and internationally. In particular, at the international level, methodological efforts are being made to define recommendations and frameworks for proper priority setting that emphasize transparency.3-4 Application of the different methodologies has led to the development and definition of several criteria as shown by Noorani et al.6 and by our review. Noorani et al.6 also grouped criteria used by HTA agencies for priority setting in categories which could represent the starting point for an in-depth discussion involving all relevant stakeholders. This discussion should be conducted by a multidisciplinary group representative of all the European countries and including public participation and citizen involvement.16,17 It should also rely on a structured and standardized approach calling for the identification of criteria for priority setting and the role to be played by the various stakeholders. These two issues have been addressed by the Health Policy Forum (HPF) of the Italian Society of HTA (SIHTA) in a paper contributing to the definition of priority setting in the Italian National Health Service.18 The final aim of the multidisciplinary European discussion should be the delivery of a shared document encompassing categories of criteria to be considered as pillars of the priority setting process across Europe. This is particularly relevant in consideration of the EU 24/2011 directive on the cross-bor-
<table>
<thead>
<tr>
<th>First author/ publication date</th>
<th>Objective</th>
<th>Methods</th>
<th>Identified criteria</th>
</tr>
</thead>
</table>
| Jankauskiene D 2013<sup>7</sup> | To design a model for HTA priority setting, which would address national needs for a country with little experience in the field of HTA, and assess its feasibility for the health system. | A three-round Delphi study was conducted in the form of an electronic questionnaire distributed to a panel of national experts. | ■ health benefit  
■ evidence  
■ timeliness  
■ expected level of interest from policy makers  
■ ethical, legal, and social implications |
| Bastian H 2011<sup>8</sup> | To develop a priority-setting framework based on the interests of patients and the general public. | A poll was used to determine level of lay and health professional interest and needs. | ■ patients’ concerns  
■ patients’ information seeking  
■ patients’ use |
| Berra S 2010<sup>5</sup> | To review the set of criteria of the Institute of Medicine (IOM) for priority-setting in research with identification of potential new criteria, and to develop and evaluate the reliability and validity of the final priority score. | A three-round modified Delphi technique was used to identify, rate, and weigh criteria for priority setting. | Traditional criteria:  
■ prevalence of the condition (or use of service)  
■ cost of services to manage the condition  
■ variation in use of the service  
■ burden and importance of the illness  
■ potential to change health outcomes  
■ potential to change costs  
■ potential to inform ethical, legal, or social issues  
New criteria:  
■ financial opportunity  
■ potential to translate new knowledge into clinical or health service practice  
■ political interest  
■ need for knowledge about the problem |
| Gulacsi L 2004<sup>9</sup> | To outline the needs and current development of the “fourth hurdle” (i.e., requirement of effectiveness and cost-effectiveness data for drug coverage policy decisions) in Hungary. | International experiences were considered. | ■ evidence  
■ effectiveness  
■ cost-effectiveness |
| Townsend J 2003<sup>10</sup> | To develop a method of economic evaluation and triage for prioritization, before the funding decision. | Existing models were reviewed on the basis of the EUR-ASSESS project and authors’ previous experience. | ■ impact of research results on policy and practice  
■ effects on health benefits  
■ costs  
■ cost-effectiveness |
| Oortwijn WJ 2002<sup>11</sup> | To provide a new procedure and one of the first examples of the application of theoretical principles for priority setting. | Different procedures for categorizing, scoring, and weighting policy criteria were defined and different classification strategies were explored. | ■ burden of disease  
■ benefit for the patient  
■ number of patients  
■ direct costs of the intervention per patient  
■ financial consequences of applying the intervention over time (impact on total costs of health care)  
■ additional aspects with an impact on health policy (i.e., rapid uncontrolled diffusion) |
| Oortwijn WJ 1999<sup>12</sup> | To describe a new model proposed by the Health Insurance Council for the definition of priorities based not only on scientific criteria but also on societal criteria. | Different procedures for categorizing, scoring, and weighting policy criteria were defined and different classification strategies were explored. | ■ burden of disease  
■ Uncertainty about the (cost-)effectiveness of the intervention  
■ potential benefits of the research project  
■ potential impact on healthcare |

**Table 1.** Characteristics of studies included from PubMed.

**Tabelle 1.** Caratteristiche degli studi inclusi da PubMed.

der healthcare, which entails harmonization of practices. In order to comply with the EU directive, the HTA network was established: it aims to facilitate an efficient use of HTA resources in Europe, create a sustainable system of HTA knowledge sharing, and promote good practice in HTA methods and processes. In our view, the first goal entails working on the development of a structured and shared approach to priority setting. Our focus on Europe was justified by these recent developments in the HTA landscape. However, the extra-European perspective and priority setting systems – such as those reported by Noorani et al. from several extra-European agencies belonging to Canada, USA, and Israel – may also be taken into consideration in the discussion. Categories and criteria resulting from the multidisciplinary discussion should undergo a validation at European level so they may be adopted and tailored to each specific context for – as also stated in the SIHTA HPF document – prioritization criteria may assume different weight according to the specific health system model and the level of evaluation. In this process of drawing up a shared document, assessment
of priority setting efforts and results should also be considered. It should be based on criteria such as those proposed by Sabik and Lie.\(^{14}\) According to their publication, the first criterion might be ensuring adequate public input in the process, which calls for public participation.\(^{16,17}\) The second might be the adoption of appropriate principles, including the evaluation of costs and benefits.\(^{14}\) In this respect, although the EUR-ASSESS project\(^3\) recommended to evaluate the costs and benefits of the assessment process, the latter were not well represented in the priority setting frameworks identified by the literature review.\(^6\) The third criterion concerns the impact on policy and practice.\(^{14}\) The SIHTA HPF addressed the requisites needed to have an impact on HTA with priority setting.\(^{18}\) Among them, the following have been reported and, in our view, may play an important role:

- Clarity of the question to be addressed
- Accountability and sharing of methods and results
- Timeliness of the evaluation

Aim of this review has been to contribute to the supranational discussion on the topic and to posing the challenge of harmonization and sharing of priority setting practices. Our search, performed by assessing both the scientific literature and the deliverables of HTA agencies, has shown that available evidence cannot be considered particularly copious and definitive. On the other hand, as the results of the literature review performed on PubMed show, there is a considerable interest of the scientific community in the topic. It is therefore time to come to an agreement and to put it in practice.

**Conflicts of interest:** none declared
Table 3. Prioritization criteria proposed by HTA agencies. / Tabella 3. Criteri di prioritarizzazione suggeriti dalle agenzie di HTA.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Agency (A)</th>
<th>Agency (AETS)</th>
<th>Agency (AE)</th>
<th>Agency (AHTRA)</th>
<th>Agency (AL)</th>
<th>Agency (CD)</th>
<th>Agency (DA)</th>
<th>Agency (G)</th>
<th>Agency (LBHTA)</th>
<th>Agency (OSTEB)</th>
<th>Agency (SB)</th>
<th>Agency (NHHS)</th>
<th>Agency (ZONMW)</th>
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<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<td>x</td>
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<td>x</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Public interest</td>
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<td>3 (21%)</td>
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<td>Technical performance</td>
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<td>1 (7%)</td>
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<td>Efficacy/Effectiveness/validity</td>
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<td>6 (43%)</td>
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<tr>
<td>Impact on health/quality of life</td>
<td>x</td>
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<td>x</td>
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<td>2 (14%)</td>
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<td>Impact on ethical, social, cultural and/or legal aspects</td>
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<td>x</td>
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<td>x</td>
<td>x</td>
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<td>1 (7%)</td>
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<tr>
<td>Impact of HTA results dissemination of technology</td>
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<td>Availability of scientific evidence</td>
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