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## Towards Integrated Health Technology Assessment for Improving Decision Making in Selected Countries

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### ABSTRACT

**Objectives:** To assess the level of comprehensiveness of health technology assessment (HTA) practices around the globe and to formulate recommendations for enhancing legitimacy and fairness of related decision-making processes. **Methods:** To identify best practices, we developed an evaluation framework consisting of 13 criteria on the basis of the INTEGRATE-HTA model (integrative perspective on assessing health technologies) and the Accountability for Reasonableness framework (deliberative appraisal process). We examined different HTA systems in middle-income countries (Argentina, Brazil, and Thailand) and high-income countries (Australia, Canada, England, France, Germany, Scotland, and South Korea). For this purpose, desk research and structured interviews with relevant key stakeholders ( $N = 32$ ) in the selected countries were conducted. **Results:** HTA systems in Canada, England, and Scotland appear relatively well aligned with our framework, followed by Australia, Germany, and France. Argentina and South Korea are at an early

stage, whereas Brazil and Thailand are at an intermediate level. Both desk research and interviews revealed that scoping is often not part of the HTA process. In contrast, providing evidence reports for assessment is well established. Indirect and unintended outcomes are increasingly considered, but there is room for improvement. Monitoring and evaluation of the HTA process is not well established across countries. Finally, adopting transparent and robust processes, including stakeholder consultation, takes time. **Conclusions:** This study presents a framework for assessing the level of comprehensiveness of the HTA process in a country. On the basis of applying the framework, we formulate recommendations on how the HTA community can move toward a more integrated decision-making process using HTA.

**Keywords:** decision making, fairness, HTA process.

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### Introduction

The tension between rising health care costs and the ability to finance health care for everyone in the society at sustainable costs is well recognized but has gotten more intense, especially after the economic crisis in 2008 [1]. Health care decision makers increasingly want value for money when assessing the opportunities of health technologies.

Health technologies include pharmaceuticals, medical devices, procedures, and the organizational and support systems within which health care is delivered. Health technology assessment (HTA) is defined as “a 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” [2]. Nevertheless, the aspects considered by decision makers regarding reimbursement of a health technology traditionally mainly include the direct and intended effects, such as the level of clinical benefit (compared with the current standard) and incremental cost-effectiveness. It is, however, increasingly argued that indirect and unintended outcomes should also be considered to allow for value-based decisions [3]. After all, decision makers need assessments that are

contextualized, involve a range of stakeholders, take interdependence and interactive aspects into account, and consider varying patient characteristics as well as implementation issues. Current HTA methodologies and decision making informed by HTA only partly respond to these requirements [4]. Furthermore, there is a need to improve the quality of decision making. This asks for structured, explicit, and transparent (appraisal) approaches. It has been increasingly acknowledged that it is the decision-making process, and not the robustness of relevant evidence or the formal procedure followed that warrants the legitimacy of reimbursement decisions [5].

The aim of this study was to examine how HTA practice can better assemble the most appropriate evidence and information and apply them in the most appropriate decision-making framework, enhancing both legitimacy and fairness. We therefore assessed the level of comprehensiveness of HTA practices (compared with traditional HTA) across selected HTA systems around the globe ( $N = 10$ ), and formulated recommendations to enhance legitimate and fair decisions using HTA. Although there are several publications in which an overview of HTA practices of different countries is given [6,7], our study adds value to the current knowledge base because we built on a recently developed

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framework (INTEGRATE-HTA model [8]). Because comprehensive strategies for an integrated assessment of all dimensions of information in HTA were missing, this new approach was developed (see “Development of the Evaluation Framework” section).

## Methods

### Selection of Countries

We selected 10 HTA systems (Argentina, Australia, Brazil, Canada, France, Germany, South Korea, Thailand, Scotland, and England [United Kingdom]) for the study. We aimed to include countries with a diverse set of HTA systems as well as countries with different levels of economic development (i.e., both middle- and high-income countries) as we have done in a previous study. Australia, Canada, and England are well known for their established HTA systems and are often used as reference countries. Brazil is rapidly developing effective HTA with clear links to the health needs of the country. Nevertheless, HTA processes in Brazil are not yet fully developed, for example, in terms of inclusiveness [9]. Thailand is considered interesting because it has used an explicit quantitative approach for reimbursement decisions [10]. Argentina, France, Germany, South Korea, and Scotland were chosen to represent different continents and to reflect both established HTA systems and emerging markets. South Korea is also the first Asian country that introduced economic evaluations for reimbursement decisions, on the basis of countries such as Australia, Canada, and England [11].

### Development of the Evaluation Framework

An HTA system is considered to be moving toward a more integrated/comprehensive reimbursement decision-making process when certain elements are covered [8]. First, all relevant stakeholders are given “a voice” throughout the HTA process (from the identification of emerging technologies to scoping, assessment, appraisal, and to the final decision making). This means that HTA should be organized as a learning process [12]. Second, all processes, including the assessment aspects and decision criteria, are clearly defined and specified (by guidelines and/or legislation; grounded in evidence or ethical underpinning), become publicly available, and are contestable. Third, the process of deliberation should be transparent [13]. Fourth, the processes need to be coherent with overall decision making (i.e., taking into account the local context) [5].

To assess the level of comprehensiveness of the HTA practices in the selected countries, we used two theoretical models: the INTEGRATE-HTA model and the Accountability for Reasonableness (A4R) framework developed by Daniels and Sabin [14].

The INTEGRATE-HTA model was developed as part of a 3-year project funded by the European Commission, under the 7th Framework Programme for Research and Technological Development [8]. The project developed concepts and methods that enable a patient-centered, comprehensive, and integrated assessment of the effectiveness, economic, ethical, sociocultural, and legal issues of health technologies that takes context and implementation into account. The INTEGRATE-HTA model (Fig. 1) enables a coordinated assessment of all these aspects and addresses their interdependencies. This model includes five

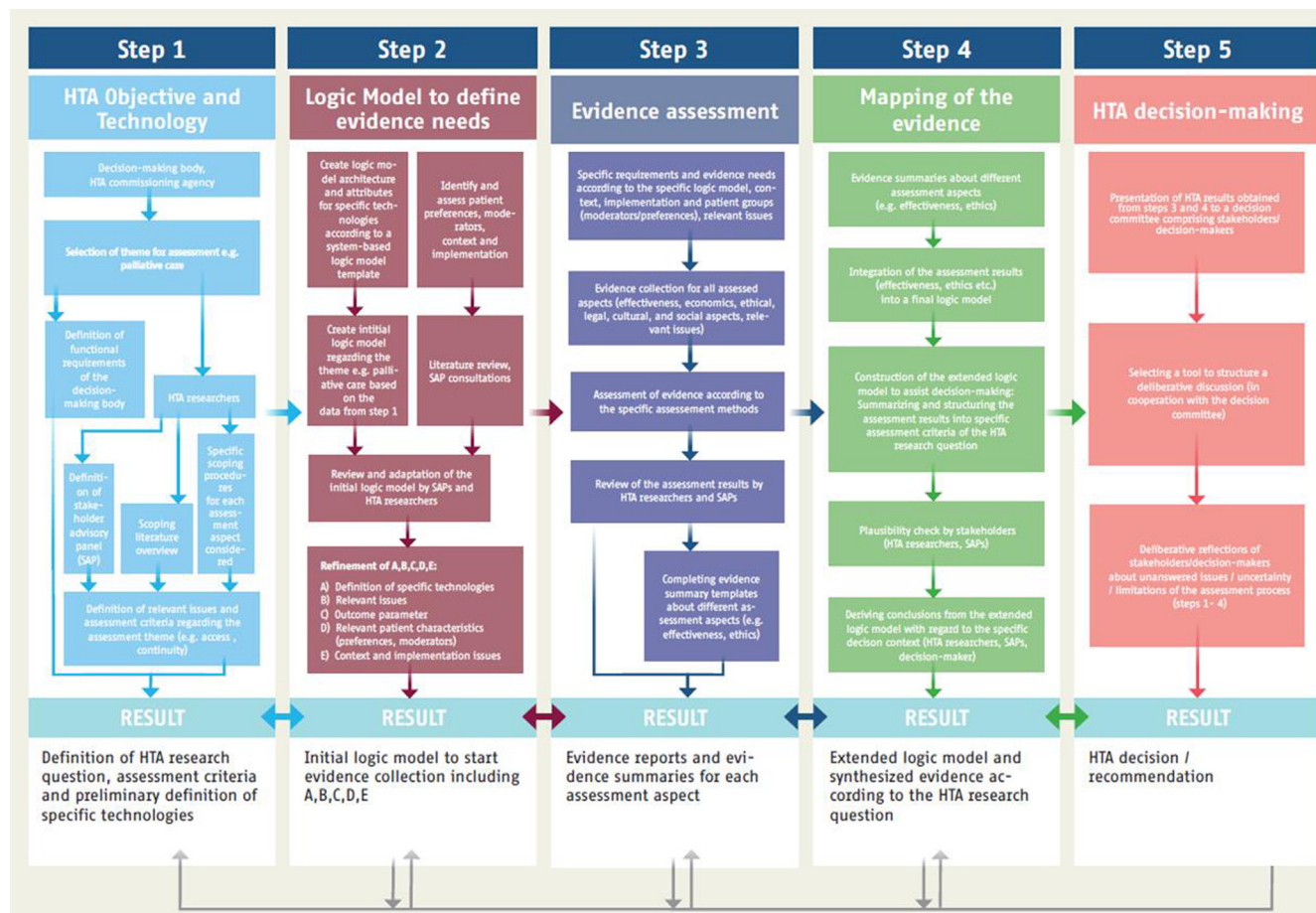


Fig. 1 – The INTEGRATE-HTA model. HTA, health technology assessment.

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