

Towards integrated HTA and improved decision making

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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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Starting point – relevant and meaningful HTA

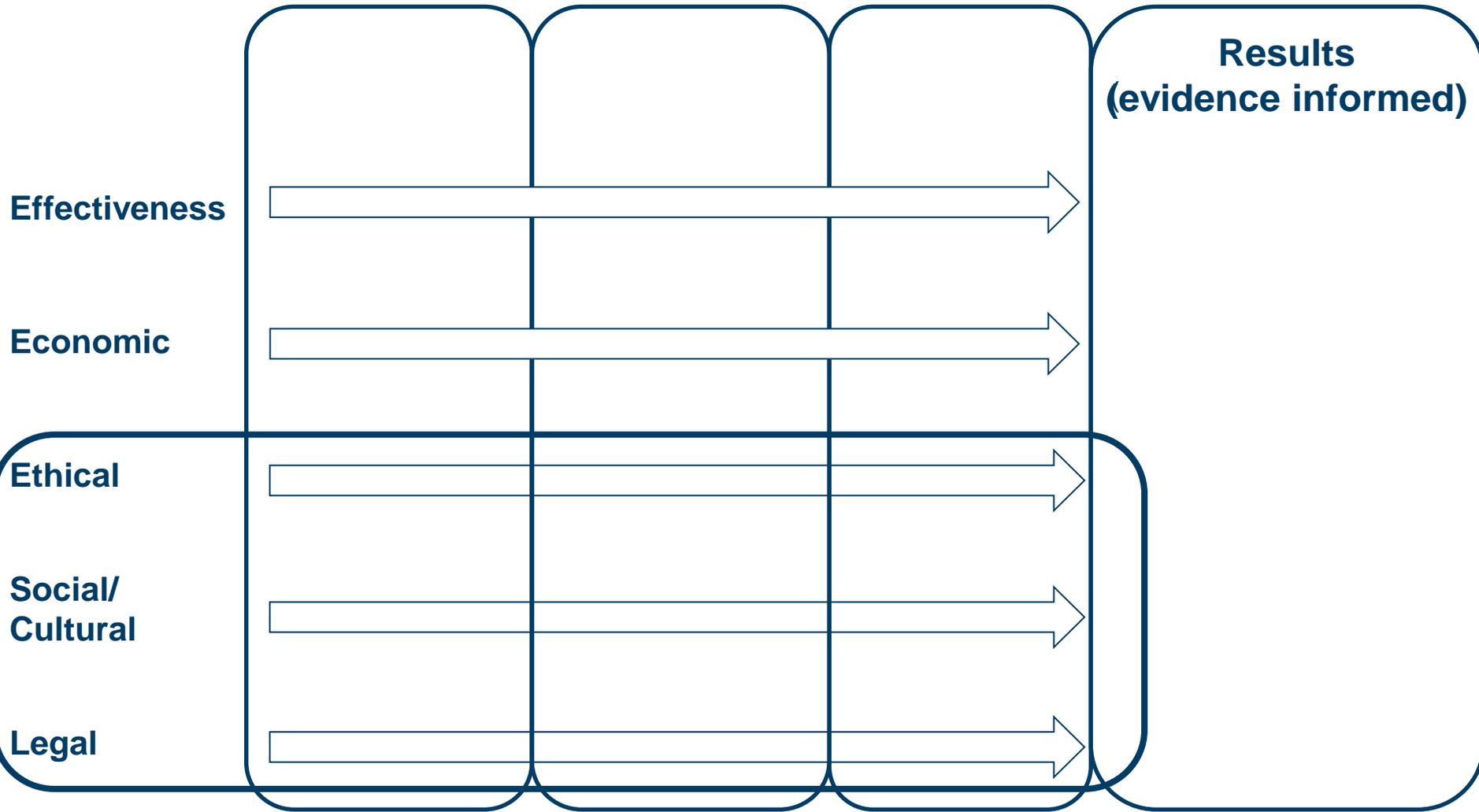
- Health technology assessment (HTA): ‘systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its *indirect and unintended consequences*’
- Decision makers need **assessments** that address the above and which:
 - Are contextualised
 - Involve a range of stakeholders
- Need for structured, explicit and transparent (**appraisal**) approaches

Aim of the study

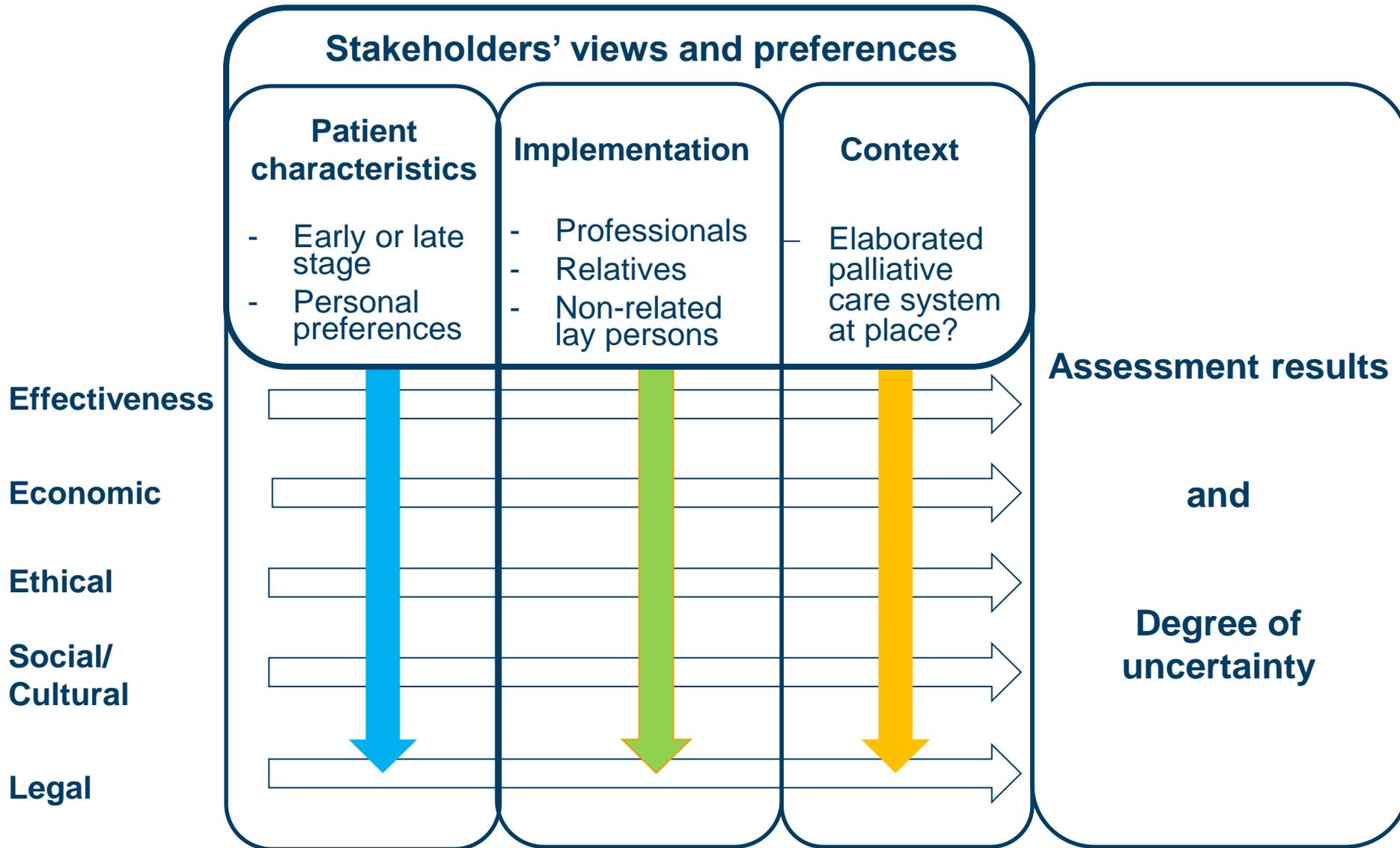
- To examine how HTA practice can better assemble the most appropriate evidence and information, and apply that in the most appropriate decision making framework enhancing both legitimacy and fairness:
 - *What could be considered best practices to obtain relevant and meaningful assessment results?*
 - *How might the HTA community move towards an integrated decision making process?*

Based on two theoretical frameworks that are empirically tested: INTEGRATE-HTA model & A4R framework

'Traditional' HTA (side by side analysis)



INTEGRATE-HTA – FP7 project (2013-2016)



How?

- 1) Involve stakeholders to elicit needs, topics, outcomes – scoping the relevant question
- 2) Take patient characteristics, implementation issues and context into account – make use of logic models;
- 3) Assess the evidence regarding effectiveness, and economic, ethical, socio-cultural, and/or legal aspects
- 4) Integrate the evidence in a structured way to respond to the needs of the stakeholders
- 5) Use a structured process of decision making

Structured decision making process: A4R

- Accountability for reasonableness (A4R) framework of Daniels and Sabin (2008):
 - Resource allocation decisions and the underlying reasons must be transparent and made public
 - The arguments underlying the actual decisions must be clear and accepted by stakeholders
 - There must be a mechanism in place that give stakeholders to appeal against decisions, propose revisions, and receive a reasoned response

Methods (1) – Judgment criteria

- **Definitions based on literature/existing indicators**

Assessment phase	Appraisal / decision making phase
Scoping	Decision making process is explicit
Context	Decision making process is transparent
Implementation issues	Underlying reasons are made public
Patient-related factors	Stakeholder consultation is clearly specified
Patient preferences	Mechanism(s) for appeal are in place
Evidence reports	Monitoring and evaluation of the process
Stakeholder consultation	

Methods (2) – Examples of definitions

- **Assessment phase**

Criterion	Definition used
Scoping	Defining the objective and research questions of the HTA, by a systematic exploration of relevant aspects from multiple perspectives (e.g. patients, informal caregivers, health professionals, decision makers)

- **Appraisal phase**

Criterion	Definition used
Decision making process is transparent	The procedures used are well described in a publicly available document and the process is open to the public (e.g. public hearings), as well as the agenda and notes on the meeting are provided in the public domain

Methods (3)

- Country selection



Methods (4)

- **Literature review**

- Peer reviewed journals, grey literature sources
- Quick scan of websites of relevant organisations

- **Structured stakeholder interviews (N=32)**

- Validated criteria to map the level of HTA
- Key stakeholders (representatives of appraisal committees, industry, patient advocates, HTA thought leaders, etc.)
- At least three (telephone) interviews per country

- **Analysis**

- Results summarized in country profiles
- Scoring system to identify best practices by mapping the level of comprehensiveness/ inclusiveness of the HTA/ appraisal process in a country on a specific date

Results

Level of comprehensiveness of the HTA process

- None of the countries addressed all selected criteria

- Best practice assessment phase (overall)



- Best practice appraisal phase (overall)



- Best practices according to stakeholders



Results assessment phase

Best practices

- Scoping



- Context



- Implementation issues



- Patient-related factors



- Patient preferences



- Evidence reports



- Stakeholder consultation



Examples - Scoping

CA, THA,
UK

CA: For each assessment of a new pharmaceutical product, patient groups are invited to submit their views with regard to the impact of the disease on patients and their families, experiences with current therapies, and expectations regarding and/or experiences with the product under assessment. The input from patients is sought early in the process in order to include the views within the assessment protocol and the assessment reports.

THA: Representatives of relevant stakeholders, such as policy-makers, health professionals, academics, patient associations industry, civil society and lay citizens, may annually suggest topics for assessment. Scoping and prioritization of HTA takes place in the form of a panel including representatives from health professionals, academics, patients, and civil society that make use of criteria, such as severity of the disease and practice variation.

Examples – Patient preferences

AU, CA, GER, SCOT CA: CADTH developed a formal approach for incorporating patients' perspectives on health outcomes and issues in both the assessment and the appraisal phase. Calls for patient input and the respective deadline are posted on CADTH's website, by CADTH E-Alerts and CADTH's Twitter accounts. A total of 35 business days are provided for preparing and submitting patient input by means of the Patient Input Template. Updates of these templates are used since December 2016. In very few cases, patient group input is not submitted. This may for example happen when patients are difficult to reach or have a very short life expectancy. In those cases, CADTH may search for grey literature and/or go to patient groups outside of Canada.

GER: Opinions and experiences of patients are collected through qualitative research methods. IQWiG consults patients/patient representatives in processing the research questions and in the production of assessment reports. The Federal Joint Committee (G-BA), responsible for reimbursement decisions regarding social health insurance in Germany, is a member of the advisory group for PREFER. This project under the Innovative Medicines Initiative, recently started on when and how to include patient preferences in decision making.

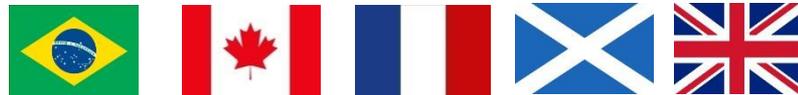
Results appraisal phase

Best practices

- Explicit process



- Transparent process



- Reasons are made public



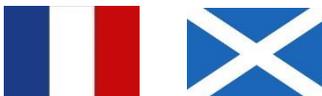
- Stakeholder involvement



- Appeal mechanisms



- M&E in place



Examples – Transparency

**BRA,
CA,
FRA,
SCOT,
UK**

BRA: Legislation (Law 12.401/2011) includes regulations that aim to make the decision making process for new technologies increasingly transparent. The law states that the rules of procedures for HTA must include a maximum period and a mandatory public consultation and an optional public hearing as part of the process.

SCOT: Appraisal meetings are open for the public since May 2014. During these meetings, all eligible SMC members vote individually regarding the decision, taking into account the available evidence and the discussion.

Examples – M&E

FRA,
SCOT

FRA: According to the literature, there is a re-assessment of pharmaceutical products to be maintained on the list of reimbursed pharmaceutical products. The re-assessment takes place every five years for pharmaceutical products listed for admission to community pharmacies and at any time for pharmaceutical products when significant new information becomes available.

SCOT: Following a governmental review on access to new medicines in 2013, several changes have been made to the HTA process in Scotland (e.g. 'PACE', SMC meetings in public). During the summer of 2016, a second review (the so-called Montgomery review) has evaluated how these changes have improved the process, especially focused on patient access to medicines for rare and end-of-life conditions.

Overall conclusions

- Countries with a well-established HTA system, i.e., Australia, Canada, England, France, Germany, and Scotland appear to be more aligned with what we perceive as a best practice, compared to countries that have a relative shorter history in HTA (Argentina, Brazil, South Korea, and Thailand)
- Best practices that may work well in some countries might not necessarily work evenly well in other countries
- Also, none of the countries addressed all selected criteria – room for improvement!

Towards a more integrated HTA process (1)

Key result	Adopting transparent and robust processes, including stakeholder consultation, takes time
Recommendations	<p>Engagement of relevant stakeholders should start from the beginning of the HTA process</p> <p>Present HTA as a process that includes not only assessment and appraisal, but constitute a broader process</p>
Aim	To increase accountability and predictability for all stakeholders

Towards a more integrated HTA process (2)

Key result	Scoping is often not part of the HTA process
Recommendation	HTA is not a matter of collecting the facts, but a matter of collecting facts that are relevant, plausible to stakeholders and which are amendable to scientific inquiry → scoping is highly recommended
Aim	To increase accountability and predictability for all stakeholders

Towards a more integrated HTA process (3)

Key result	Indirect and unintended outcomes influence treatment outcomes. These aspects are increasingly considered in HTA, but there is room for improvement
Recommendation	The HTA process should include standardised methods to identify and appraise: <ul style="list-style-type: none">• Evidence for clinically important moderators or predictors of treatment effects; and/or• How patients differ in their appreciation of various treatment outcomes
Aim	To contribute to a deeper understanding of the value of health technologies

Towards a more integrated HTA process (4)

Key result	Monitoring and evaluation of the HTA process is not (yet) well established, even though it is considered to be a key principle of HTA
Recommendation	Monitor and review the processes and results at certain intervals to assess its efficiency, consistency and sustainability over time
Aim	Demonstrate the impact of HTA and increase publicly legitimate reimbursement decisions

THANK YOU!

For more information:

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