

Exploring the Link Between Institutional Country-level Differences and Consideration of Additional Value Elements in HTAs: Results from a Pragmatic Review

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Background

- Health technology assessments (HTA) are a cornerstone of healthcare decision-making across many countries, each applying various context-specific criteria.
- While clinical and cost-effectiveness are traditionally the main drivers of determining the added value of a new treatment, considerations of additional HTA value elements differ across countries.
- In the European Union (EU), the upcoming Joint Clinical Assessment (JCA) seeks to standardize the pan-EU assessment process which is designed to create efficiencies and accelerate the availability of new treatments.
- However, a fully harmonized approach is likely to be difficult to implement given the heterogeneity in HTA value elements and methods for evaluating therapeutic value from country to country.

Objective

- This study aimed to assess whether the underlying culture and values embedded in the institutional context of an EU country, its healthcare system, and the HTA process may influence the country's predisposition toward higher acceptance of expanded value elements in HTAs.

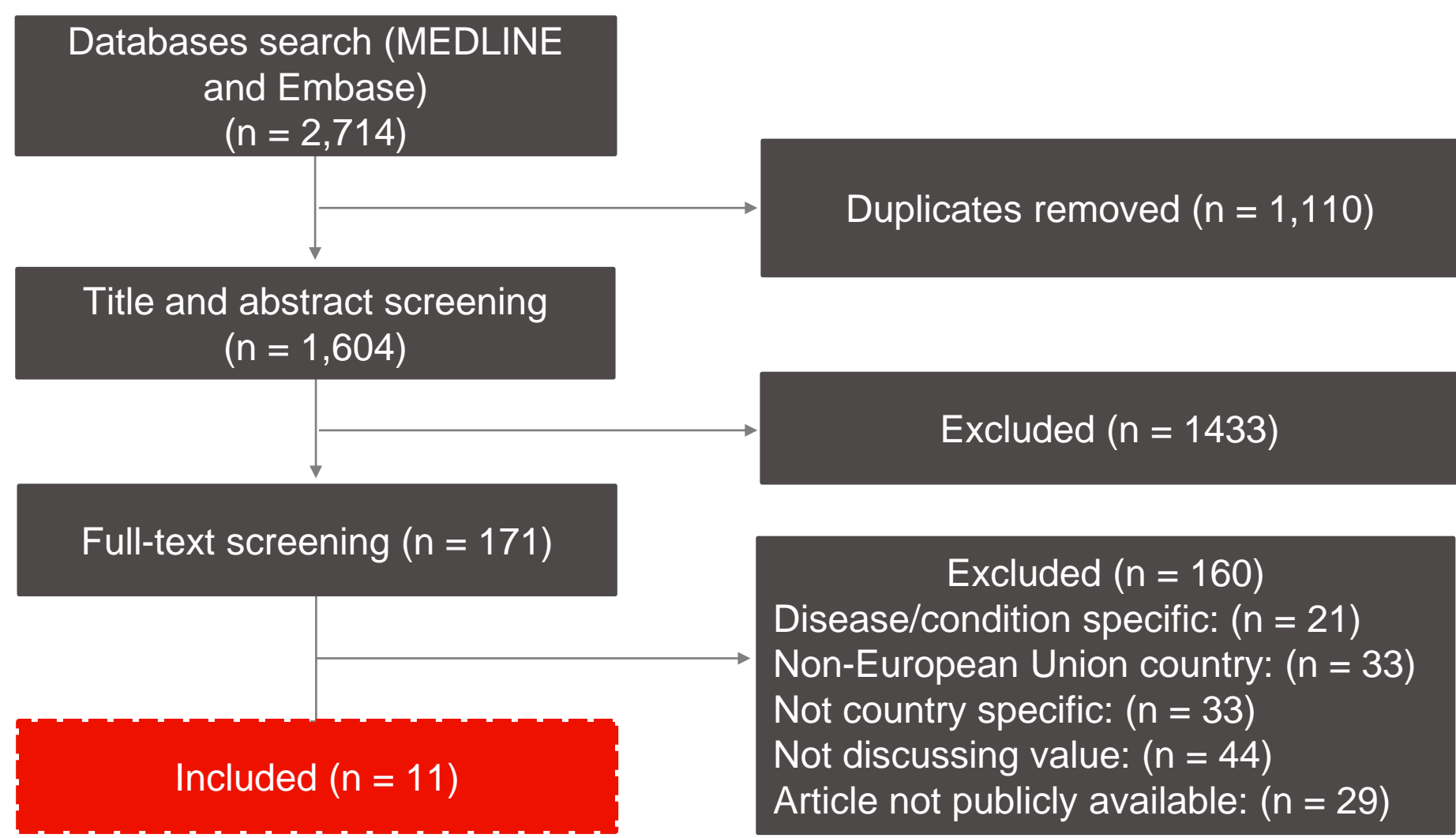
Methods

- A targeted search was conducted on June 19, 2023 in Embase and MEDLINE (via Ovid) for English language articles published since 2013 presenting country-level information, and variation in considerations or implementation of value elements (beyond clinical, economic) in HTA decision-making.
- Keywords included HTA, cost-effectiveness, value, decision-making, and related synonyms.
- All study designs were eligible, and studies had to be publicly available and discuss additional elements of value in HTA decision-making for EU countries to be included.
- A single reviewer conducted screening at both title/abstract and full-text levels, while a second, more experienced reviewer performed quality checks on 15% of the records that were excluded at each level.
- Data extraction of included studies was carried out in a pre-specified template and validated.
- The findings were synthesized narratively.

Results

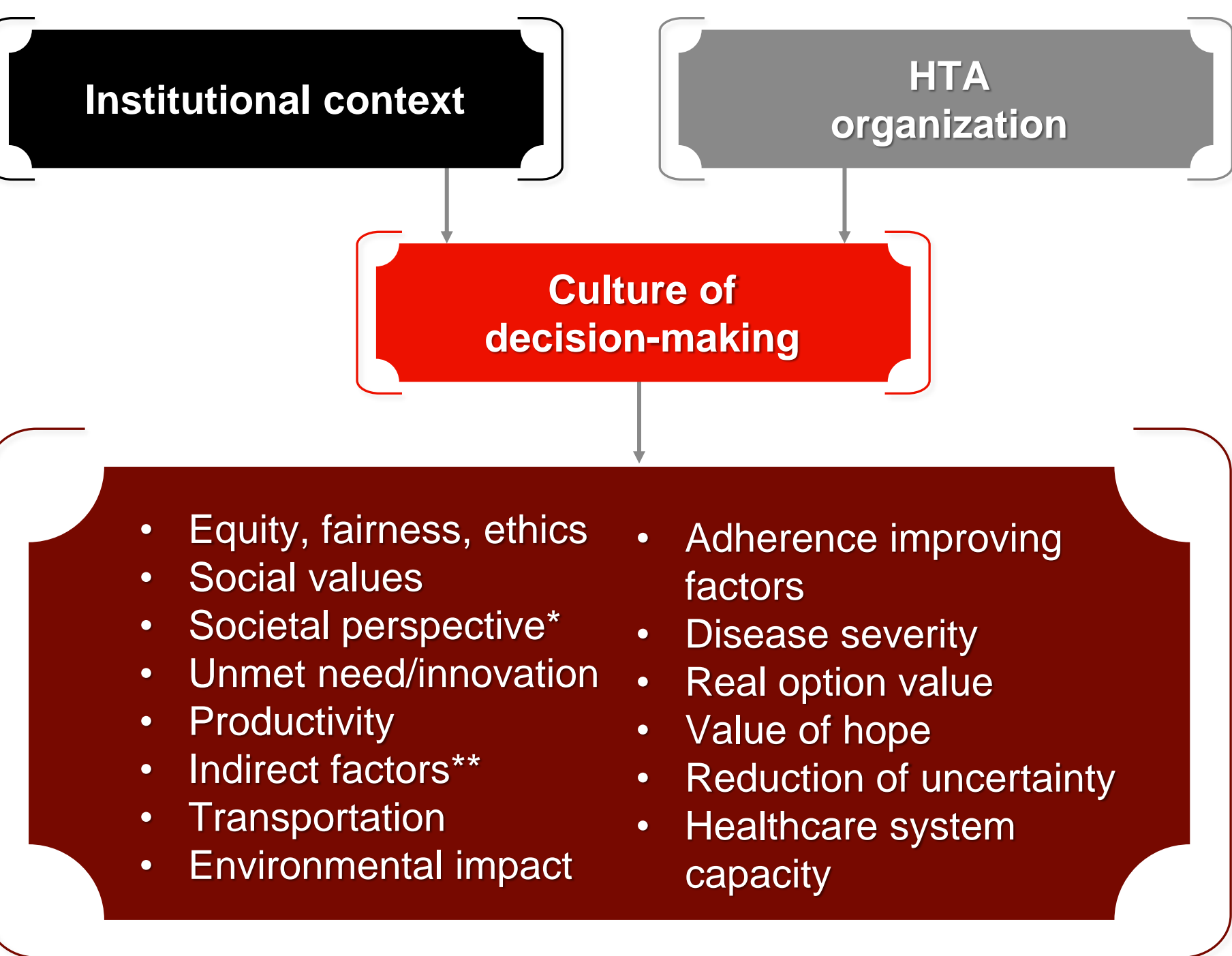
- Eleven studies were included in this review (Figure 1).¹⁻¹¹
- Most included studies were reviews (n = 6),^{1,6-10} followed by reports of Delphi/focus panels (n = 2),^{2,5} one multiple-criteria decision analysis,¹¹ and one case study.⁴ One study presented a conceptual framework.³
- One or more additional value elements were discussed by 25 of the 27 EU member states. No studies reporting on Malta or Romania were identified.
- The identified additional value elements (beyond purely clinical and economic metrics) varied across countries and were grouped into broader categories based on 14 core themes as identified by the included publications (Table 1).

Figure 1. PRISMA flow diagram



- Equity (n = 23),^{1-4,7,9} social values (n = 22),^{3,4,9} and societal perspective (n = 18)¹⁻³ were the three most frequent additional HTA value elements** whereas value of hope, reduction of uncertainty, and healthcare system capacity were the least reported topics.
- To investigate if the type and number of additional value elements reported by EU countries was related to the institutional context of each country, we categorized them in three groups based on the type of general welfare paradigm or type of health care system: national health system (NHS), social health insurance (SHI), or system in transition (SIT) (Table 1).
- While there was considerable variability in the number of types of value elements listed, in general a **higher number of value elements corresponded with the sophistication of country-data infrastructure, the existence of a national health system and HTA processes (Figure 2).**

Figure 2. Context around additional value elements



- This analysis was exploratory in nature and provided a preliminary presentation of trends of incorporating “broader value” in HTA as derived from additional elements (beyond strictly on clinical and/or economic impact) that could provide a richer evaluative space for informing resource allocation.
- This research does not provide further details on the weight of each element in final decision-making, or the types of methodologies that are being used to integrate these elements across different disease areas.

Conclusions

- Understanding and addressing variability of HTA acceptance drivers at a more granular level is important from the perspective of equal patient access to (innovative) treatments across Europe.
- HTA acceptance thresholds of additional value elements by country level varied widely. However, a growing trend was observed toward higher acceptance over time with a link between countries having universal care systems and higher income levels.
- Different trends in value considerations between national assessments may threaten the weight of EU JCA in local HTAs and decision-making.

Table 1. Additional HTA value elements considered across EU countries

Country	Institutional context	Equity, fairness, ethics	Social values	Societal perspective*	Unmet need/ innovation	Productivity	Indirect factors**	Transportation	Environmental impact	Adherence improving factors	Disease Severity	Real option value	Value of hope	Reduction of uncertainty	Healthcare system capacity
Austria	SHI														
Belgium															
Bulgaria	SIT														
Croatia															
Cyprus	SHI														
Czechia	SIT														
Denmark	NHS														
Estonia	SIT														
Finland	NHS														
France	SHI														
Germany	SHI														
Greece	NHS														
Hungary	SIT														
Ireland	NHS														
Italy	NHS														
Latvia	NHS														
Lithuania	SHI														
Luxembourg	SHI														
Malta	NHS														
Netherlands	SHI														
Poland	SIT														
Portugal	NHS														
Romania	SIT														
Slovakia	SIT														
Slovenia	SIT														
Spain	NHS														
Sweden	NHS														

*Influence on family, caregivers (spillover); **Social services, education, housing, legal etc.
Abbreviations: NHS, national health system; SHI, social health insurance, SIT, system in transition

References

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Disclosures

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