

Appraisal of the multi-criteria decision analysis method to improve value assessment of new therapies

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Introduction and objectives

- > Traditional approaches to estimating and defining the value of emerging treatments, such as head-to-head cost-effectiveness analysis, have limited scope and as such may not be sufficient or complex enough to capture the holistic value of interventions.<sup>1</sup> This may lead to challenges in the reimbursement process and delay patient access to valuable treatments.<sup>2</sup> Therefore, there is a need to broaden the view of healthcare “value”, to promote innovation and enable patient access to novel therapies.
- > An ISPOR task force has previously outlined a “Value Flower” of commonly and rarely examined aspects of healthcare value, and concluded that further research is needed on how best to measure and assess the relevance of each of the concepts for inclusion in HTA decision-making (Table 1).<sup>3</sup> Further research has highlighted the variability in value aspects that may or may not be considered as part of decision-making, across different therapy areas and assessment bodies.<sup>4</sup>

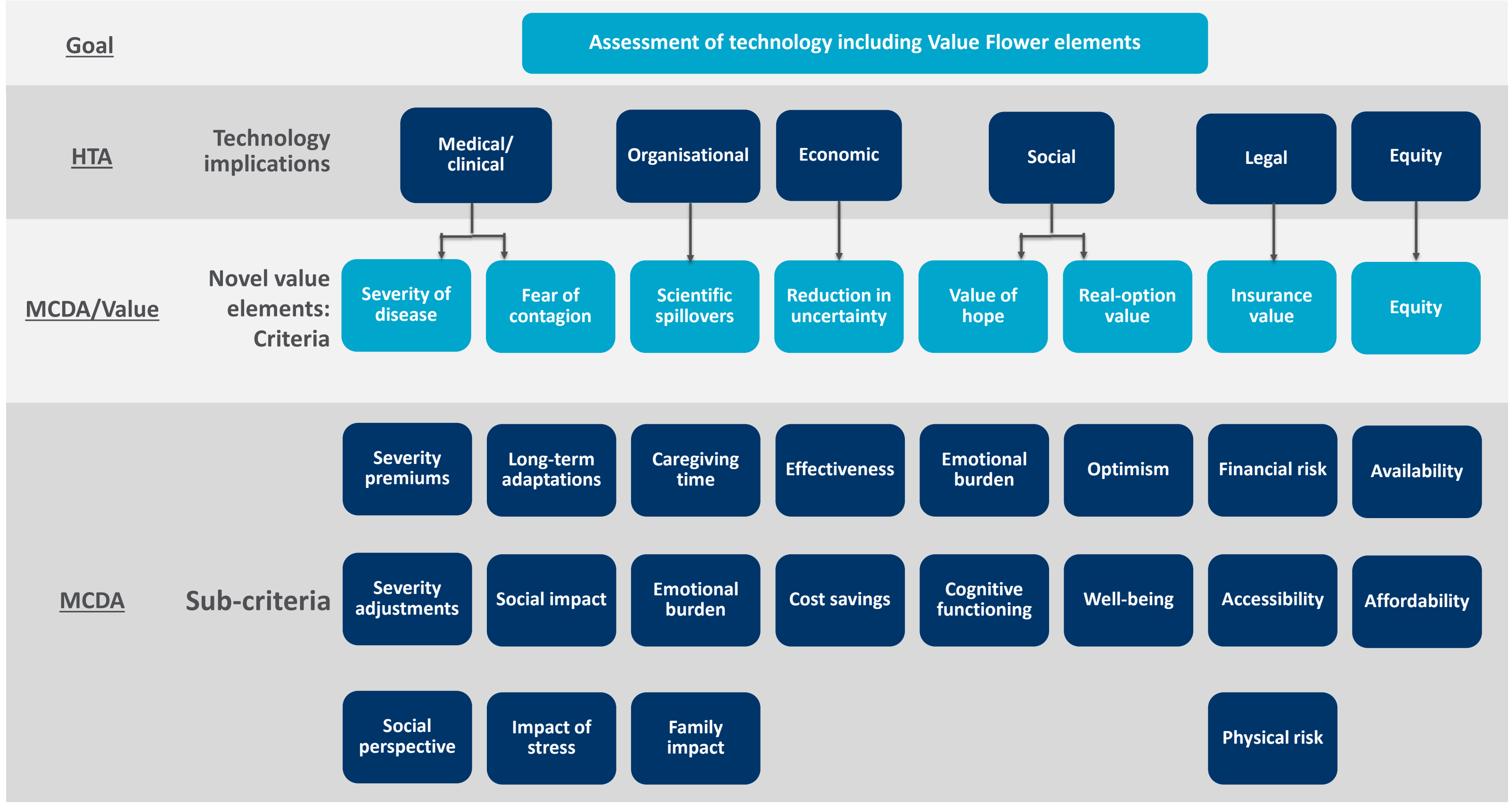
Methods

- > A targeted literature review was undertaken to understand how MCDA could be further applied to improve HTA decision-making.
- > Literature exploring the uptake of value elements and MCDA in HTA decision-making was captured within MEDLINE and reviewed to assess the prior use of MCDA, and the potential to leverage MCDA as a methodology to explore value in HTA decision-making.
- > As this review was seeking to identify any precedent for previous use of MCDA methodology in HTA decisions, no time limit was applied.
- > Following the review of articles, a framework was developed for the use of MCDA to assess the novel aspects of value outlined by ISPOR, and facilitate their use in HTA decision-making.

Results

- > Precedent of MCDA use within HTA decision-making were identified. Key examples included: structured decision models for trade-off analyses, development of new decision support tools, and assessment of emerging therapies for rare diseases.
- > Use of MCDA has also been considered by HTA agencies globally when incorporating stakeholder preferences, weighting multiple endpoints, prioritizing public health interventions for investment, assessing novel technologies, and conducting benefit/risk assessment (Table 2).
- > The use of MCDA as a research technique within healthcare decision-making is therefore well-established and may serve as an appropriate methodology to explore or evaluate research questions where there are multiple criteria that impact the end decision.
- > Focusing on qualitative aspects, MCDA is highlighted as a framework to incorporate additional criteria into value assessments, as well as providing stakeholders with an opportunity to incorporate the patient’s voice and preference into the assessment of the value of a treatment.<sup>30</sup>
- > In an effort to improve the conventional assessment of the “value” of therapies and further explore the novel elements included within the Value Flower, we have recommended a framework as a potential solution to explore the importance of each of the novel elements of value in the context of HTA decision-making (see Table 3).
- > Utilizing this framework would enable those from the industry to assess ways in which the novel value elements may be incorporated into HTA decision-making in relation to an emerging technology.
- > The recommended steps adopt a flexible and hypothetical framework that is adaptable dependent on both the technology (e.g. treatment or medical device) and the context (e.g. therapy area) of a given scenario. The figure below has been developed for illustrative purposes and demonstrates how MCDA may be used to map each of the novel value elements from the ISPOR Value Flower onto HTA decision-making.
- > It is anticipated that the criteria (novel value elements) and sub-criteria (concepts of importance) will be derived from key stakeholders’ input throughout the stages of the recommended framework and therefore would likely vary across market access scenarios.

Figure 1. Illustrative application of our recommended MCDA-focused HTA framework.



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- > Multi Criteria Decision Analysis (MCDA) is a structured decision-making process that offers the flexibility of incorporating multiple objectives and criteria into one overall appraisal. MCDA allows various criteria to be objectively ranked or evaluated, thus generating a more definitive result than conventional discussions.<sup>1</sup>
- > The potential for MCDA to support health technology assessment (HTA) has been widely discussed, and various HTA agencies are piloting or applying MCDA in their decision-making.
- > We propose that MCDA, may help enhance HTA decision-making and help broaden the view of what constitutes “value”.

Table 1. Components of the Professional Society for Health Economics and Outcomes Research (ISPOR) task force Value Flower<sup>3</sup>

Use	Element of value	Perspective
Core elements of value	Quality adjusted life-years (QALYs), Net costs	Payer of health plan
Common but inconsistently used elements of value	Productivity, Adherence-improving factors	Societal
Novel element of value	Reduction in uncertainty, Fear of contagion, Insurance value, Severity of disease, Value of hope, Real option-value, Equity, Scientific spillovers	Societal

Table 2. An overview of real-world examples of MCDA utilization to support healthcare decision-making

Country	Example
Canada <sup>10-12</sup> USA <sup>5-8,13-14</sup>	Healthcare priority settings and reallocation of scarce resources; Budgeting; Interventions for chronic non-cancer pain; Diagnosis and treatment decisions; Clinical trial design; ICER value assessment; Benefit-risk analysis for regulatory bodies.
EU <sup>16-17, 21</sup>	Incorporation of patient involvement with MCDA; quantitative approaches, IQWiG; Introduction of screening programs and policies; EVIDEM framework used for medical devices; Diagnostic assessments and pharmaceuticals.
England/Scotland <sup>9,25</sup>	AGNSS: Orphan drugs and the prioritization of rare conditions; NICE: Special weightings applied to cost-effectiveness judgements based on severity, end of life treatments, stakeholder insights, innovation, disadvantaged populations and children; respiratory, mental, children's health, cardiovascular and cancer interventions, NHS/primary care trusts, major capital expenditures within the NHS.
Northern EU <sup>9,16, 18, 20, 26, 2, 28, 29</sup>	TLV: orphan drug coverage; TLV: high-cost biologics; Obesity research and prevention, stakeholder appraisal of policy options; Healthcare priority settings and key drivers in decision-making; Publicly funded healthcare priority-settings; Ankle foot repair in stroke.
Other <sup>9,19, 22,23,24</sup>	Health interventions in the universal health coverage benefit package, Healthcare priority settings exploring trade-off between equity, efficiency and societal health concerns; Hospital medical technologies, OEP; New healthcare technologies, Health Basket Committee assessing benefits to Israel population, net cost, quality of evidence, ethical and or strategic considerations.

AGNSS: Advisory Group for National Specialised Services; EVIDEM: Evidence and Value: Impact on decision-making; FDA: Food and Drug Administration; ICER: Institute for Clinical and Economic Review; IQWiG: Institute for Quality and Efficiency in Health Care; MCDA: Multi Criteria Decision Analysis; MOH: Ministry of Health; NHS: National Health Service; OEP: National Health Insurance Fund Management; TLV: The Dental and Pharmaceutical Benefits Agency.

Table 3. Framework to explore the importance of novel value elements in the context of HTA decision-making

- Step 1: Defining the goal:** To explore and validate the relative importance of each of the novel value elements listed within the ISPOR Value Flower with key stakeholders, providing consensus recommendations for concepts that may warrant consideration in HTA decision-making.
- Step 2: Defining the stakeholders:** Key stakeholders’ (healthcare professionals, key opinion leaders, payers and patient advocacy group representatives etc) interests and perception of the relative importance of each concept listed with the Value Flower serves as the criteria for evaluation within the MCDA framework.
- Step 3: Decision alternatives:** Based upon initial qualitative exploration of concepts with key stakeholders, a hierarchal framework could then be developed that highlights accepted alternative concepts (from those outline in the Value Flower) for stakeholders dependent on different settings (e.g. potential to explore how perceived importance varies across markets/disease area).
- Step 4: Evaluation criteria:** Once the key interests/concepts of importance have been mapped within the theoretical framework that would be considered in the evaluation of a therapy, the stakeholders would then be tasked with weighting and rating the “alternatives” relative to how well they satisfied the core principles underpinning value assessments.
- Step 5: Outcomes or consequences associated with alternative/interest combination:** Consensus-style meeting, stakeholder groups would be able to compare their scores for each of the concepts listed within the HTA assessment. Results can be discussed until consensus is reached.

Discussion and Conclusion

- > Research by ISPOR has identified potential novel aspects of value. Lakdawalla et al., have suggested that further research is needed on how best to measure and assess the relevance of each of the concepts for inclusion in HTA decision-making.<sup>3</sup>
- > MCDA may serve as an appropriate methodology to help broaden the view of what would typically be considered “value in healthcare”, and to continue to encourage innovation in evidence-generation for emerging therapies through use of additional elements and/or domains than those typically assessed in an economic value assessment.
- > While specific elements of the Value Flower have already received attention within the published literature, such as within research aiming to explore and incorporate wider perspectives in healthcare decision-making, when considering societal values and resource allocation within disease areas,<sup>31</sup> there is still a need to explore and outline how best to measure and assess the relevance of the Value Flower concepts for inclusion in HTA decision-making.
- > We recommend leveraging the MCDA framework discussed to obtain key stakeholder insights and map the novel value elements listed within the Value Flower onto a given market access scenario to inform HTA decision-making.