

A Review of HTA Guidelines on Societal and Novel Value Elements

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Disclaimers

- BR at the time of the study was affiliated with the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center
- NP, CJ are affiliated with the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center
- DJ is an Employee and shareholder of Bristol Myers Squibb Pharmaceuticals Ltd in the United Kingdom
- HP was an employee of Bristol Myers Squibb AB, Solna, Sweden
- GR at the time of the study was providing services to Celgene International. He is a current employee and shareholder of MSD Innovation & Development GmbH in Switzerland
- This project developed by the Center Evaluation of Value and Risk in Health at Tufts Medical Center through a research grant from BMS.
Views presented are the sole of the authors and do not represent any endorsement of their employers

Introduction: *“Do as I say and not as I do”*

“

HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. Its purpose is to inform decision-making in order to promote an equitable, efficient, high-quality health system

These dimensions often include clinical effectiveness; safety, costs, and economic implications; ethical, social, cultural and legal issues; and organizational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population

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O'Rourke et al. (2020) Int J Technol Assess Health Care. Jun;36(3):187-190.

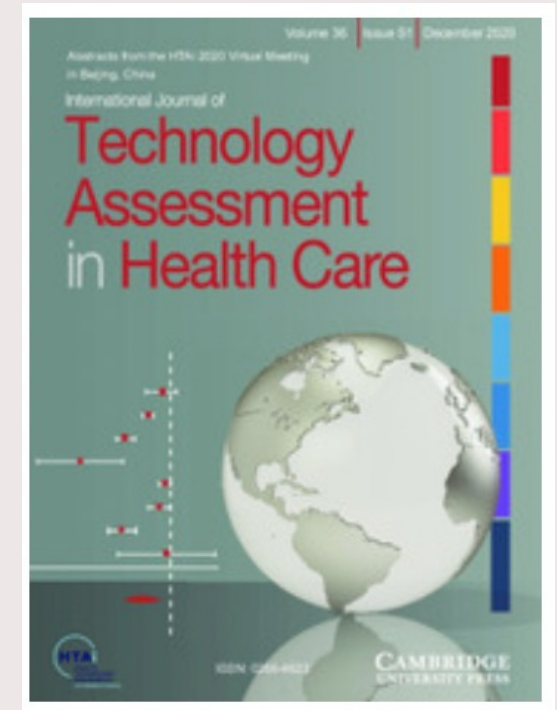


How novel elements of value are perceived by HTA agencies (HTAs), it is still unclear.





Given the growing importance of HTAs in informing reimbursement decisions, and the ongoing debates about appropriate methods for value assessment, we consider relevant to explore whether and how global HTAs incorporate novel and societal elements of value in their assessment guidelines.



Breslau et al. (2023) Int J Technol Assess Health Care. In Press

Methods

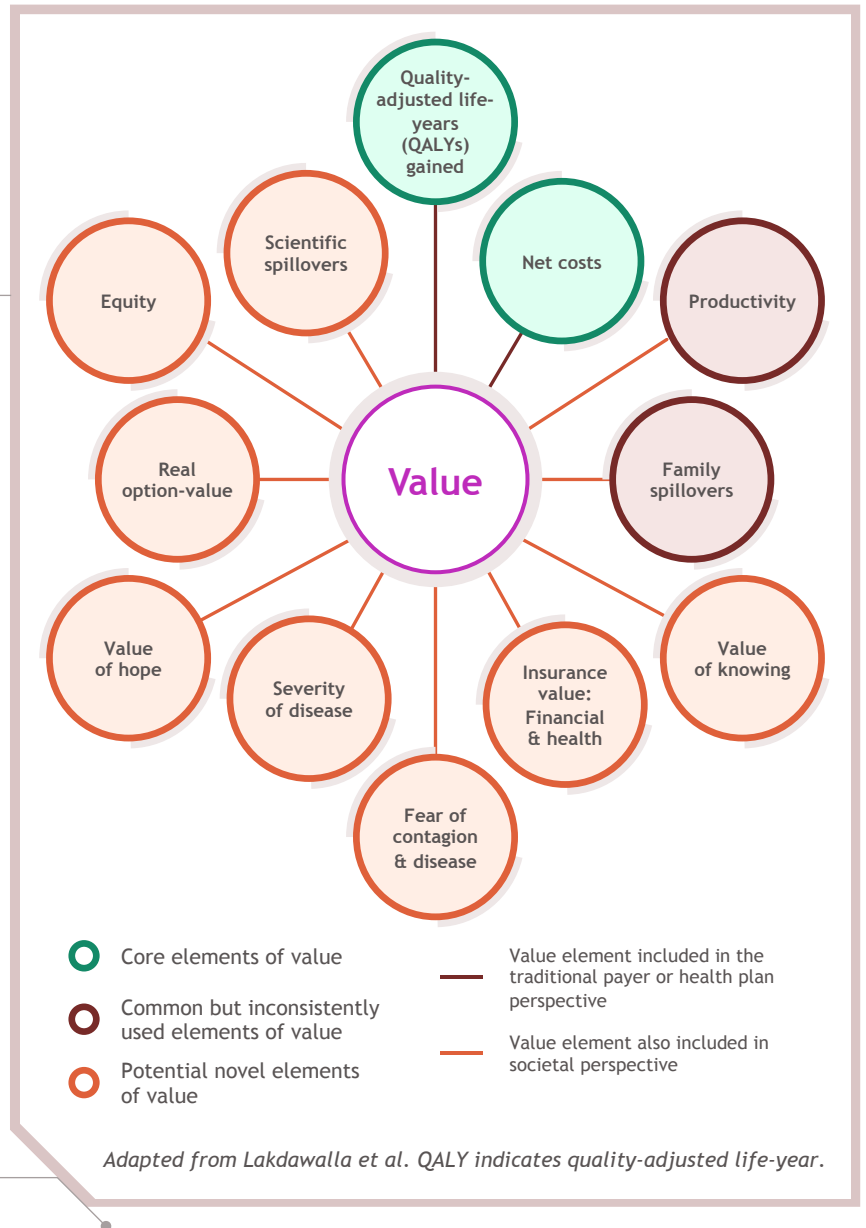


Definition of Societal vs Novel element

- Societal: Components beyond health impacts to the treated individuals and costs beyond the costs incurred by the healthcare sector to deliver those interventions.
- Novel: Additional elements, that may reflect value but are not normally captured in conventional value assessment (e.g., insurance value, severity modifiers, and value of hope)



We recognize some arbitrariness in how these terms were categorized or included in the study.



Methods (cont.)



10 Societal and 11 novel elements were defined (Total 21 elements)

Search criteria:

- Guidelines that mention any the value elements, and whether the guideline recommended their inclusion in the base case, sensitivity analysis, or qualitative discussion
- HTAs and Ministry of Health websites and ISPOR inventory of PE Guidelines around the world were screened

Data classification:

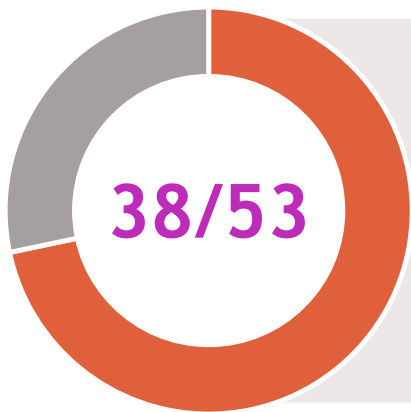
- Country level segmentation (The World Bank) as high (HIC), upper middle (UMIC), lower-middle (LMIC) and lower (LIC)) income level
- Type of Organization: Independent vs Government run HTAs* or private organization
- Benefit Assessment: Clinical Effectiveness, Economic Evaluation, other type of assessment



Results



53 guidelines representing **52** countries and three supranational guidelines were analyzed



- 38/53** Guidelines were country specific
- 43% HIC
 - 15% UMIC
 - 5% LMIC



From six global non-government guidelines, five of them mentioned any novel element of value

World bank income category	Number of HTA guidelines	Number (%) of HTA guidelines mentioning any value element	Countries with HTA guidelines mentioning any value element
High income	34	23 (67%)	Australia, Belgium, Canada, Chile, Croatia, Czech Republic, Denmark, England, France, Germany, Hungary, ICER, Ireland, New Zealand, Norway, Poland, Scotland, Slovenia, South Korea, Spain, Switzerland, Taiwan
Upper-middle income	10	8 (80%)	Brazil, China, Colombia, Cuba Malaysia, MERCOSUR , Mexico, Thailand
Lower-middle income	4	3 (75%)	Egypt, Indonesia, Philippines
Low income	0	NA	NA
Non-country	6	5 (83%)	AMCP, Drummond et al, ISPOR, the Second Panel, Wilkinson et al
Total	53	38 (72%)	

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Value element	HTA guideline mentioned value element	HTA guideline recommended value element inclusion in:		
		Base case analysis	Sensitivity analysis	Qualitative discussion
Productivity (N)	42 (79%)	14 (26%)	23 (43%)	2 (4%)
Family spillovers (S)	41 (77%)	18 (34%)	18 (34%)	5 (9%)
Equity (N)	35 (66%)	0 (0%)	5 (9%)	23 (43%)
Transportation (S)	27 (51%)	14 (26%)	10 (19%)	0 (0%)
Adherence-improving factors (N)	25 (47%)	5 (9%)	3 (6%)	5 (9%)
Severity of disease (N)	21 (40%)	0 (0%)	3 (6%)	4 (8%)
Social services (S)	15 (28%)	7 (13%)	4 (8%)	0 (0%)
Genericization (N)	15 (28%)	9 (17%)	7 (13%)	1 (2%)
Education (S)	8 (15%)	2 (4%)	3 (6%)	0 (0%)
Housing (S)	8 (15%)	2 (4%)	3 (6%)	0 (0%)
Consumption (S)	8 (15%)	2 (4%)	5 (9%)	0 (0%)
Legal or criminal justice (S)	7 (13%)	3 (6%)	1 (2%)	0 (0%)
Scientific spillovers (N)	4 (8%)	0 (0%)	0 (0%)	2 (4%)
Reduction of uncertainty (N)	4 (8%)	0 (0%)	1 (2%)	0 (0%)
Real option value (N)	3 (6%)	0 (0%)	0 (0%)	1 (2%)
Economic activity (S)	3 (6%)	0 (0%)	0 (0%)	2 (4%)
Value of hope (N)	2 (4%)	0 (0%)	0 (0%)	1 (2%)
Healthcare capacity (S)	2 (4%)	0 (0%)	0 (0%)	0 (0%)
Environment (S)	1 (2%)	1 (2%)	0 (0%)	0 (0%)
Insurance value (N)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Fear of contagion (N)	0 (0%)	0 (0%)	0 (0%)	0 (0%)



The proportion of HTA guidelines considering each value elements ranged from 0-79%



6 of the 21 value elements were identified (Societal: 23% (2/10), Novel: 33% (4/11))



Only four value elements appear in >50% of HTAs guidelines (productivity, family spillovers, equity, and transportation)

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Conclusions



Individual societal and novel elements of value varied substantially across HTAs



Appropriate methodological guidelines will support best practices to translate societal and novel value elements into decision making processes are required



No strong consensus on how to include these elements in base case, sensitivity analysis, and qualitative discussion were noted



There is a big gap between theory (*As I said*) and practice (*As I Do*) as HTAs guidance states novel and societal elements are included when we know they are not.

Recommendations



01

Take advantage of the ISPOR value flower as well as the “updated” HTA definition to highlight that novel and societal elements of value should be considered for holistic HTAs

02

Product manufacturers should be proactive in generating timely, robust and fit for purpose evidence on the holistic and long term value of their technologies. further explore the novel and societal value when creating their evidence packages