Ideas & Solutions

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Are Health Systems In Latin America Effectively Coping With Current And Upcoming Innovative Medical Technologies?

Learnings about HTA system design and implementation in middle-income countries

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Disclaimer

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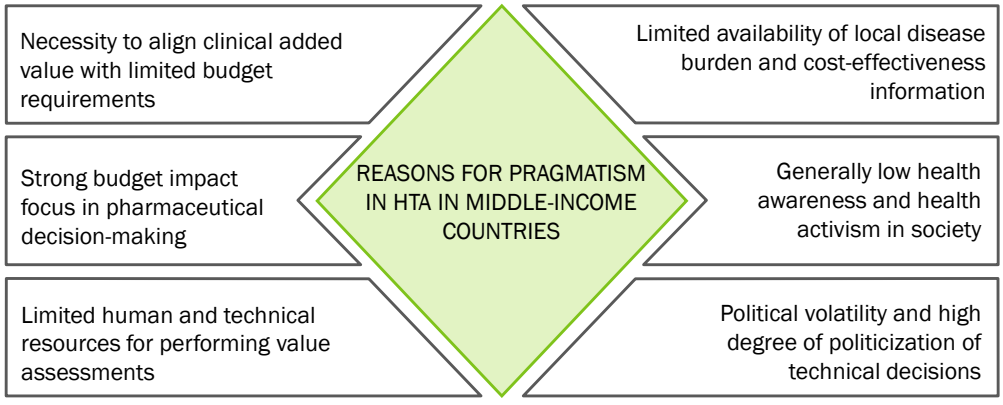
Conclusions first

1. *Don't want to calculate everything to the last digit if you don't have enough people or data.*
   → **It is not necessarily efficient and rational to pursue methodological sophistication in HTA in middle income countries. Pragmatism will bring better results.**
2. *Make sure that your HTA system fits policy goals, and it doesn't do more harm than good.*
   → **HTA systems should be designed based on the context, and they should be cost-effective.**
3. *Avoid building something on the past. Build it on the future.*
   → **HTA systems should already be designed in a way that they can cope with emerging new technologies such as gene therapy, combination therapy, companion diagnostics.**
4. *Look around the world and notice and you will see that HTA is quickly becoming less rigid.*
   → **HTA systems using rigid cost-effectiveness thresholds and decision rules are becoming outdated. They tend to be supplanted by more flexible assessment and decision frameworks.**

Decision-making contexts in middle-income countries make a strong case for pragmatism in HTA system design and implementation



Very similar factors have been identified in Latin America

International Journal of Technology Assessment in Health Care
cambridge.org/thc
Policy

Defining the Value of Health Technologies in Latin America: Developments in Value Frameworks to Inform the Allocation of Healthcare Resources

Andres Pichon-Riviere[1], Sebastian Garcia-Marti[1], Wija Oortwijn[2], Federico Augustovski[1] and Laura Sampietro-Colom[3]

Table 1. Potential Challenges to the Application of Value Frameworks in Latin America

Scarcity of human resources with the required technical capacity.
Difficulty to include criteria and values beyond clinical benefit and cost, such as fairness and transparency in the decision-making process.
Lack of institutionalization of HTA processes.
Lack of continuity in health policies.
The institutionalization of HTA and the use of value frameworks could be perceived by politicians as a loss of power.
Lack of education for the public and users to understand and participate in these processes.
Lack of basic local data such as epidemiological data on the incidence and prevalence of conditions, data about costs, or the real-world performance of technologies.
Lack of time for assessment processes and very short timelines for decision making.
Latin America, in general, is very "biased" toward the present, with few long-term policies.

Source: Pichon-Riviere A, Garcia-Marti S, Oortwijn W, Augustovski F, Sampietro-Colom L (2019). Defining the Value of Health Technologies in Latin America: Developments in Value Frameworks to Inform the Allocation of Healthcare Resources. International Journal of Technology Assessment in Health Care 35, 64–68. https://doi.org/10.1017/S0266462319000072

Pragmatism can be incorporated into both HTA methods and processes

HTA pragmatism…

… in HTA methods

- Limiting HTA assessment to technologies which claim added clinical benefit (and using parity pricing rules for all other technologies)
- Using international benchmarks and assessment references
- Using pragmatic multi-criteria (MCDA) systems for technology assessment
- Offering non-binding early HTA advice

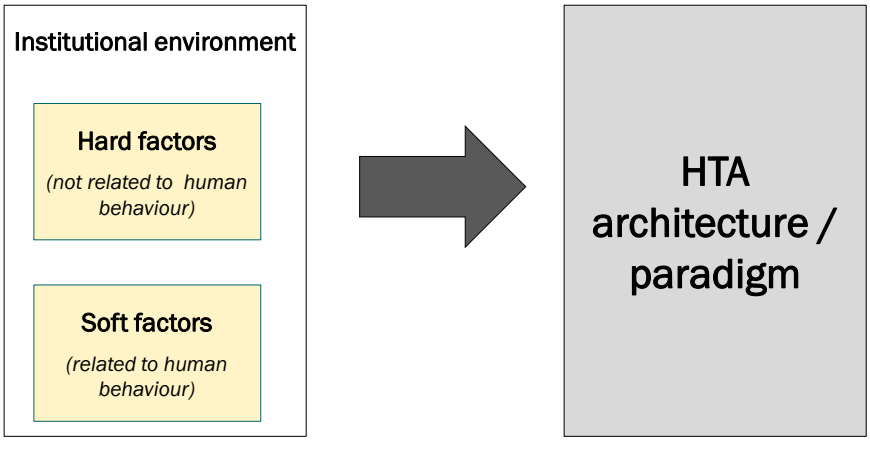
… in HTA processes

- Linking managed entry agreements (MEAs) to a 'quick HTA' (by focusing on key uncertainties)
- Maximising the number of assessment rounds before a decision must be taken
- Ensuring that there is a consultation for all stakeholders to be engaged
- Allowing access after marketing authorization and performing HTA assessment in parallel (Germany)

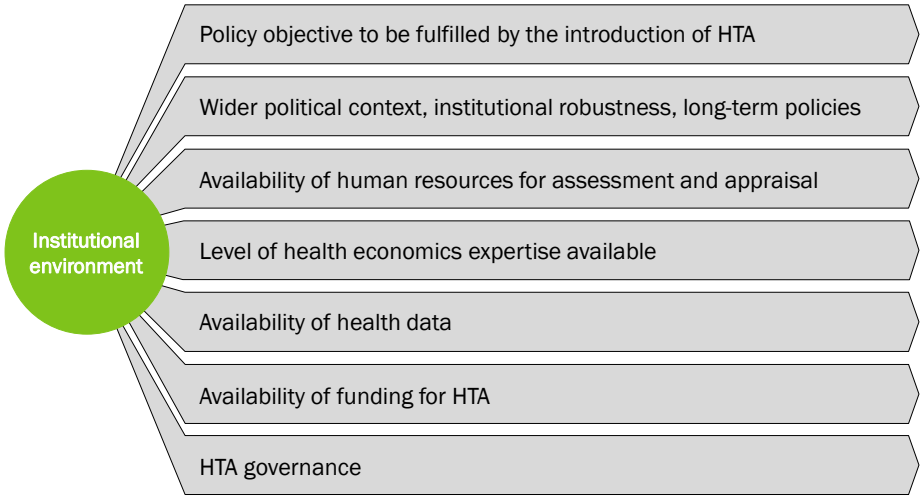
Examples of pragmatic solutions in international HTA systems

HUNGARY	▪ Cost-consequence analysis is an accepted form of cost-effectiveness analysis ▪ Societal perspective can be used in addition to payer perspective
ITALY	▪ Recent (2017) update of the AIFA innovation assessment scheme simplifies value assessment and ▪ Provides clear link between value drivers and assessment results
NETHERLANDS	▪ Only those novel technologies are submitted to cost-effectiveness assessment which claim added clinical benefit over the comparator (Annex 1B vs Annex 1a)
TAIWAN	▪ Pragmatic checklist and review of economic evidence (CEA) ▪ Decisions to be reached within 42 days

It is the institutional environment which defines the HTA architecture that will work properly

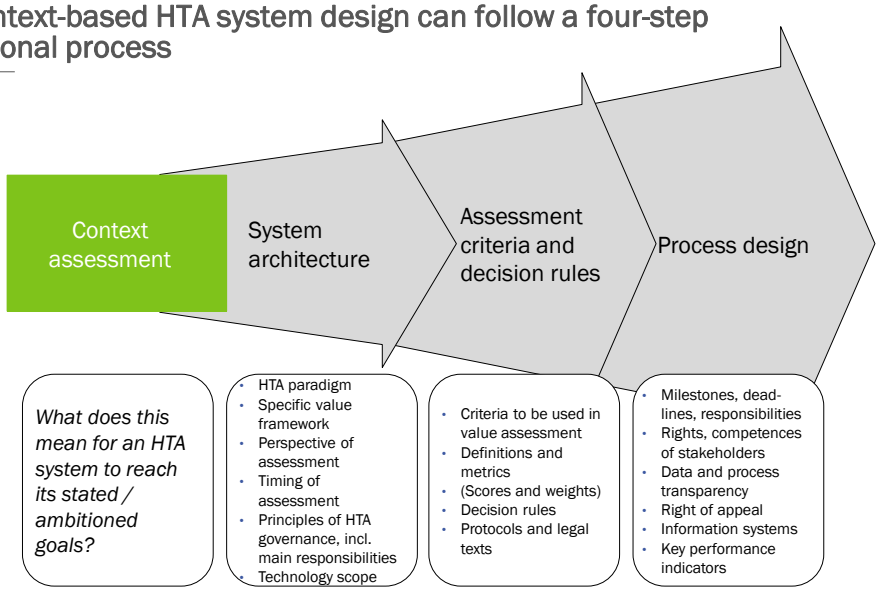


The institutional environment is complex and comprises several elements



Source: Dankó D., HTA system design – a contingency-theory approach. HTAi 2017 General Meeting, Rome, 19 June 2017 (*modified*)

Context-based HTA system design can follow a four-step rational process



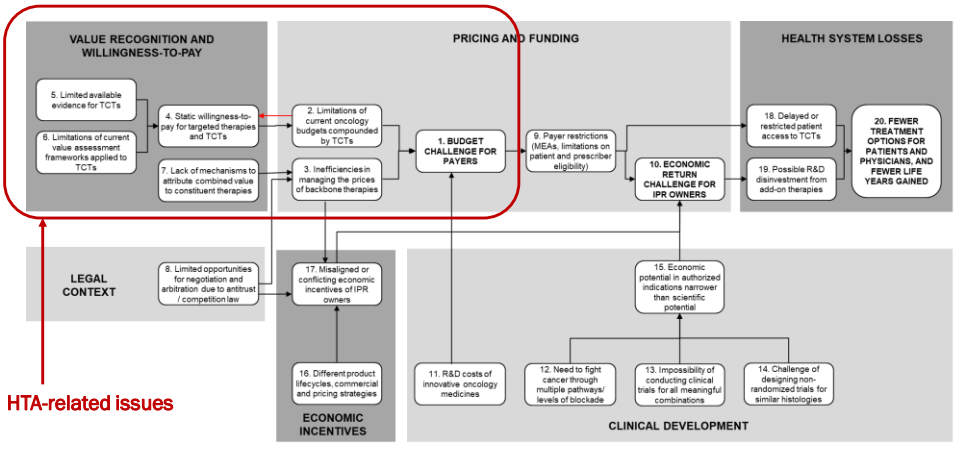
Examples for context-based HTA system elements

 KOREA (SOUTH)	▪ Mediation committee sets the prices for essential drugs that fail post-HTA price negotiations ▪ Important role in an hierarchical cultural setup
 LITHUANIA	▪ Simple, scoring-based HTA system in place for several years (therapeutic value, pharmacoeconomic value, budget impact) ▪ Currently, more robust economic analysis is being considered
 ROMANIA	▪ *Pro:* Checklist based MCDA system with many external references (e.g positive assessments by NICE, SMC, HAS, G-BA) ▪ *Con:* Irrelevant or restrictive criteria, lack of balance in weights
 UNITED STATES	▪ Several emerging applications of MCDA (’value frameworks’) with different purposes and stakeholder focuses ▪ Common goal: explain and inform about ’value’

Established HTA approaches and decision rules may be of limited help when novel technologies are considered

TARGETED ONCO-HEMATOLOGY DRUGS	▪ Unlikely to ever meet conventional cost-effectiveness thresholds ▪ Funding for ethical reasons, option value etc.
COMBINATION THERAPIES	▪ Conflicting economic incentives between backbone therapy and add-on therapy ▪ Lack of value attribution mechanisms and re-assessment methods
GENE THERAPIES	▪ Do not meet conventional cost-effectiveness thresholds ▪ Impact on health care organization can be critical (patient referrals, ’enabling costs’)
COMPANION DIAGNOSTICS	▪ Technology enablers whose ’own’ value is seldom properly recognized ▪ May belong to different IPR holders and may not themselves be subject to HTA

Example: targeted combination therapies in onco-hematology have the potential to bust HC budgets, but payers are ill-equipped to manage them



Source: Dankó D., Garrison, LP., Blay, JY., 2019: Challenges in the value assessment, pricing and funding of targeted combination therapies in oncology, Health Policy, in press, https://doi.org/10.1016/j.healthpol.2019.07.009

Willingness-to-pay thresholds are supposed to reflect policy and/or societal judgement…

COST-EFFECTIVE = VALUE FOR MONEY = WORTH BUYING

THRESHOLD = UPPER LIMIT FOR 'VALUE FOR MONEY'

Implicit threshold	Threshold in guideline	Threshold in law
(e.g. Sweden, Australia)	(e.g. Hungary, Poland)	(Slovakia)

… but it often leads to perverted incentives and funding systems

Delay in access to health technologies

- HTA as 'scientific' legitimation to postpone decisions or block technologies

Incompatibility with broader pricing & funding considerations

- Novel medicines may be funded for reasons other than cost-effectiveness
- Senior decision-makers and non-governmental stakeholders may not find cost-effectiveness easy-to-understand or decision-relevant

Parallel access systems

- Name-the-patient programmes (e.g. Hungary)
- Individual / exceptional reimbursement (e.g. Slovakia, Czech Rep.)
- Parallel sources of funding, in which cost-effectiveness is not enforced (e.g. UK)

Reinforcement of fiscal mindset

- Budget impact as key decision driver
- After the introduction of cost-effectiveness analysis, it will still continue to be the key driver but the analysis of added therapeutic benefit will lose significance

High running costs of HTA institutions

Such dysfunctions have led HTA systems in Europe to move away from rigid cost-effectiveness assessment

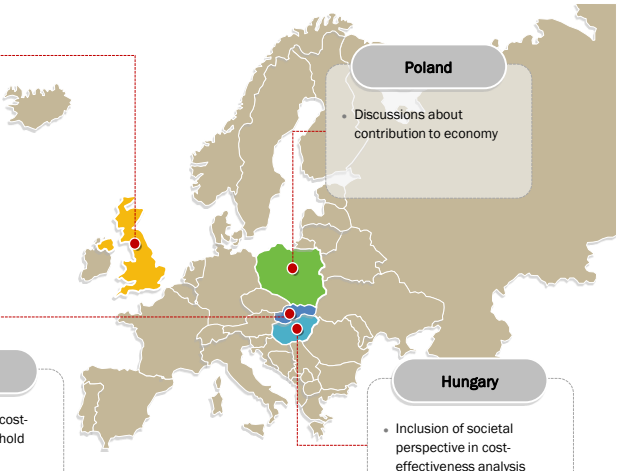
United Kingdom

- Cancer Drug Fund (CDF)
- Highly Specialized Technologies (HST)
- Budget impact test

Across EU

Increasing payer interest in

- Long-term cost-effectiveness
- Caregiver quality of life



Poland

- Discussions about contribution to economy

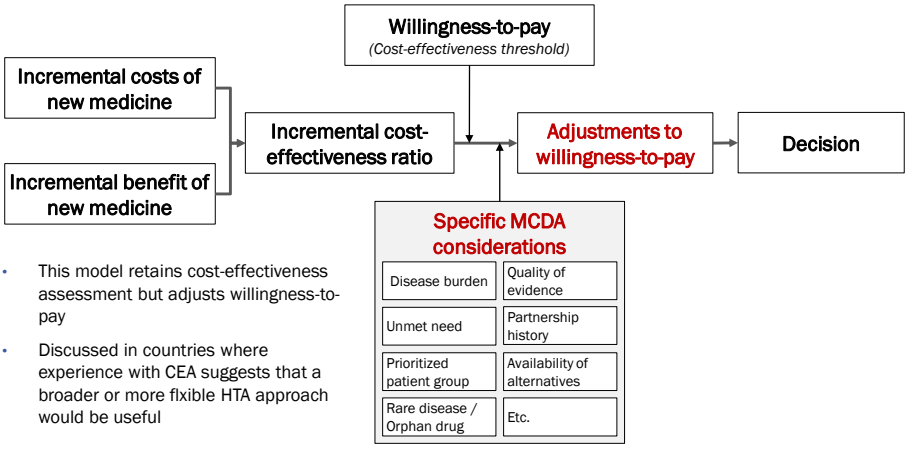
Slovakia

- MCDA modifiers to cost-effectiveness threshold

Hungary

- Inclusion of societal perspective in cost-effectiveness analysis

One example is combination of cost-effectiveness assessment with MCDA criteria and thereby adjusting the thresholds



- This model retains cost-effectiveness assessment but adjusts willingness-to-pay
- Discussed in countries where experience with CEA suggests that a broader or more flxible HTA approach would be useful

Source: own compilation

Example: NICE Highly Specialized Technologies Framework

Highly specialised technology (HST) evaluations are recommendations on the use of new and existing highly specialised medicines and treatments within the NHS in England.

Selection process	▪ Only drugs for very rare conditions are considered ▪ Most are identified by the National Institute for Health Research Innovation Observatory
Higher cost-effectiveness threshold	▪ 'Value for money' is defined as an ICER of GBP 100,000 per QALY gained, or lower (as opposed to the standard threshold) ▪ Negative exceptions can be made due to sensitivity analysis results / low generalizability
Weighting based on incremental QALYs	▪ For technologies with an ICER above GBP 100,000 per QALY gained, the magnitude of the incremental therapeutic improvement is assessed, defined as number of additional QALY's gained
Example HST guidance	▪ Migalastat for treating Fabry disease ▪ Strimvelis for treating adenosine deaminase deficiency–severe combined immunodeficiency ▪ Ravulizumab for treating paroxysmal nocturnal haemoglobinuria ID1457 ▪ Onasemnogene abeparvovec for treating spinal muscular atrophy type 1

Weighting of QALYs in HST

Incremental QALYs gained (per patient, using lifetime horizon)	Weight
Less than or equal to 10	1
11 – 29	Between 1 and 3 (using equal increments)
Greater than or equal to 30	3

Source: https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-highly-specialised-technologies-guidance/HST-interim-methods-process-guide-may-17.pdf

Example: MCDA as 'ICER-modifier' in Slovakia

28 (–7 points) ← Base 35x* → **40** (+5 points)

A) Number of positive international assessments of clinical value (France, Germany, Scotland, England)	0	1	2	3	4		
Score	*0*	*0.25*	*0.5*	*0.75*	*1*		
B) Number of alternative medical interventions available with public funding	> 5	4	3	2	1	0	
Score	*-2*	*-1*	*-0.5*	*0*	*0.5*	*1*	
C) Expected reimbursement outflow (million euro)	> 4.0	3.51–4.00	3.01–3.50	2.51–3.00	2.01–2.50	1.51–2.00	0–1.50
Score	*-3*	*-2.5*	*-2*	*-1.5*	*-1*	*-0.5*	*0*
D) Number of QALYs gained	< 0.10	0.10–0.30	0.31–0.50	0.51–1.00	1.01–2.00	> 2.00	
Score	*-2*	*-1*	*0*	*0,5*	*1*	*2*	
E) Orphan medicine	no	yes					
Score	*0*	*1*					

? How to define an assessment as 'positive' ?

? When to measure ?

? Why to exclude non-orphan medicines for orphan diseases ?

Source: AIFP Slovakia, Inova Health

* multiplicator of monthly wage (912 € in 2018)

And once again: the conclusions

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