



Establishment of Negotiation Committee and HTA

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Stages of HTA implementation

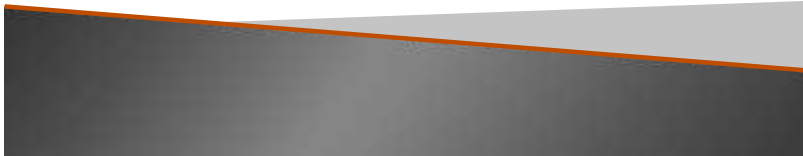
Assessment (the research part)

- ▶ public HTA agency
- ▶ academic researchers
- ▶ pharmaceutical companies
- ▶ consultants


Appraisal (the policy part)

- ▶ critical appraisal by public HTA office
- ▶ HTA recommendation

Key question:
**How HTA recommendation is taken
into account by MoH and/or
Health Insurance Committee?**



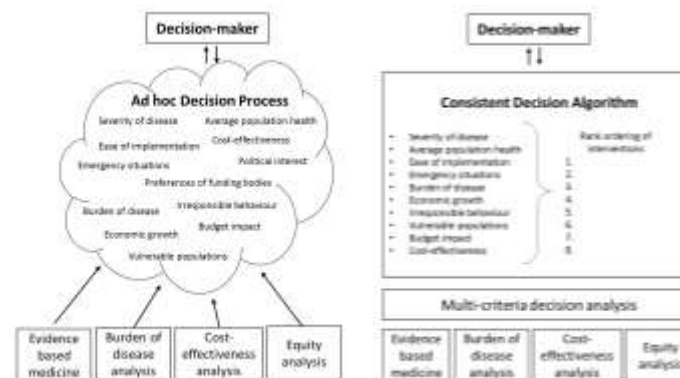
Verifiable criterion: cost-effectiveness

- ▶ Political attitude in lower income countries is based on implicit decision-making
 - ▶ How to interpret cost-effectiveness ratio?
 - no threshold
 - implicit threshold(s)
 - explicit soft threshold(s)
 - explicit hard threshold(s)
 - ▶ How many thresholds?
 - one
 - lower and upper
 - moving threshold according to disease severity or rarity (e.g. end-of-life therapies; orphan drugs)
 - ▶ How to determine threshold? In Visegrad countries
 - economic status (GDP or salary level)
 - Threshold in CEE countries is equal with NICE/SMC
- 

Verifiable criterion: budget impact

- ▶ In difficult economic periods policymakers may put more emphasis on budget impact analysis than cost-effectiveness analysis.
- ▶ explicit or implicit thresholds?
- ▶ portfolio deal?

Consistency and Transparency of Policy Decisions based on HTA domains



Adapted from: Baltussen R, Niessen L. Priority setting of health interventions: the need for multi-criteria decision analysis. *Cost Eff Resour Alloc.* 2006. 21;4:14.

Major Questions of HTA / MCDA Implementation

- HTA submission: confidential or published?
- Performance matrix or MCDA scores: confidential or published?
- rule vs. tool?
- management of uncertainties: risk-sharing?
- MCDA tool: single or repeated use?



Foundation work for MCDA

- "non-scientific" MCDA
- MCDA system developed by expert group with ongoing validation (revealed preferences)
- research based MCDA (stated preferences)



Case of Hungary (1)

- ▶ Mandatory HTA for pharmaceuticals and medical devices prior to pricing and reimbursement decisions
- ▶ HTA Office with trained professionals
- ▶ HTA process
 - HTA submission by pharmaceutical companies
 - critical appraisal by HTA Office
 - multistakeholder technology appraisal committee
 - pricing, budget impact and risk-sharing negotiation by health care payer
 - final decision by relevant ministries

Case of Hungary (2)

- ▶ Published methodological guidelines & critical appraisal checklist
- ▶ Explicit cost-effectiveness & implicit budget impact threshold
- ▶ No transparency: none of the below documents are in the public domain
 - submission dossier
 - critical appraisal and HTA recommendation
 - justification of pricing and reimbursement decisions
- ▶ HTA consultancy
 - driven by insights and relationships
 - annual turnover: 3-5 million Euros