
COLOGNE
HTAi 2019 ANNUAL MEETING · GERMANY
HTAi

Limitations in health-economic guidance for medical devices

M. Blüher, V. Mittard, R. Torrejon Torres, and R. Saunders

Coreva Scientific, Königswinter, Germany

COREVA Scientific

COLOGNE
HTAi 2019 ANNUAL MEETING · GERMANY

HTAi

Disclosure

Coreva Scientific is a consultancy for health economics and value-based healthcare with a focus on medical devices, working with multiple medical-device manufacturers.

This research was performed independently with no external funding or input.

COREVA Scientific

COLOGNE
HTAi 2019 ANNUAL MEETING · GERMANY

HTAi

Background & aims

- **Balance –** HTA considers clinical and economic data

- **Lack of clarity –** Current guidance for health-economic evaluation of a medical device (MD) is rarely provided

- **Review –** Assess European health-economic guidelines and recent research to inform development of economic guidelines

COLOGNE
HTAi 2019 ANNUAL MEETING · GERMANY

HTAi

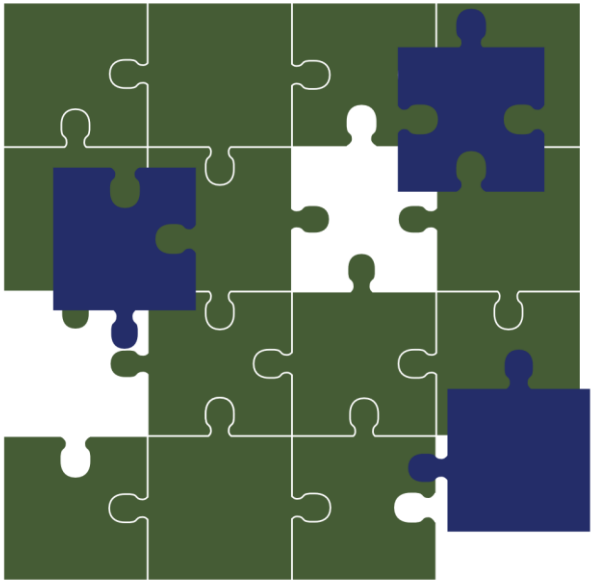
Assess the current situation: Data sources

European HTA guidelines	Literature on HTA of MD
Manual search of official websites	Structured search of PubMed and EMBASE
No limitation	2000–2017
English, French, German	
Reviewed by two independent reviewers	
Tabulation of key information	

Original aim: Bringing it together

- **Comparison –** Identifying discrepancies between current guidance and published literature

- **Integration –** Plug potential gaps in regulation with published suggestions

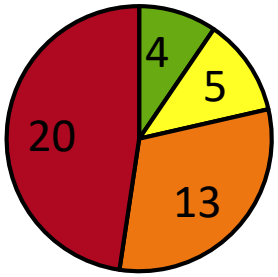


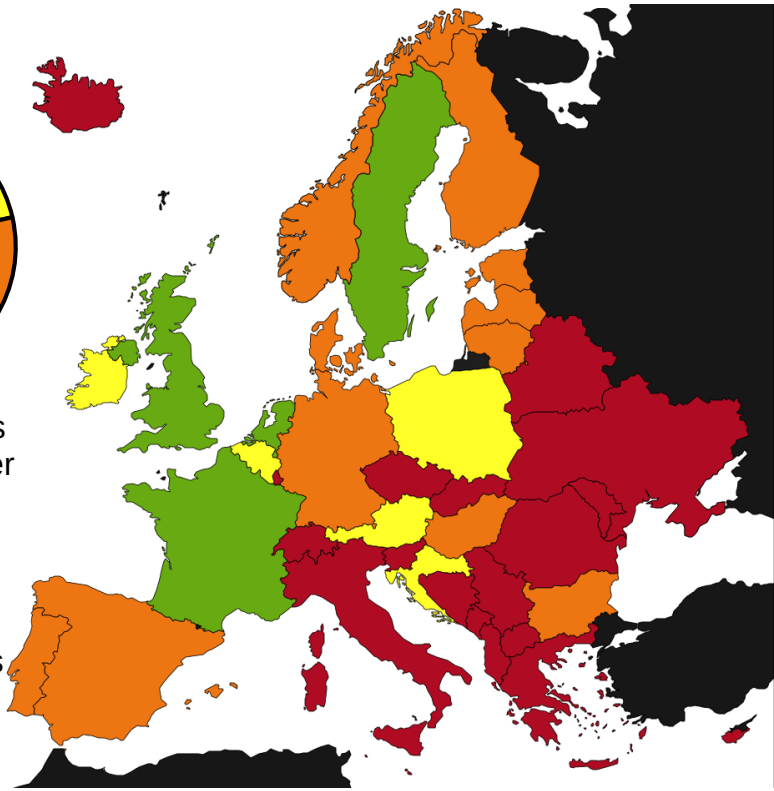
COLOGNE
HTAi 2019 ANNUAL MEETING · GERMANY
HTAi

The current situation

- MD-specific guidance is rare

- Less detailed than for pharmaceuticals



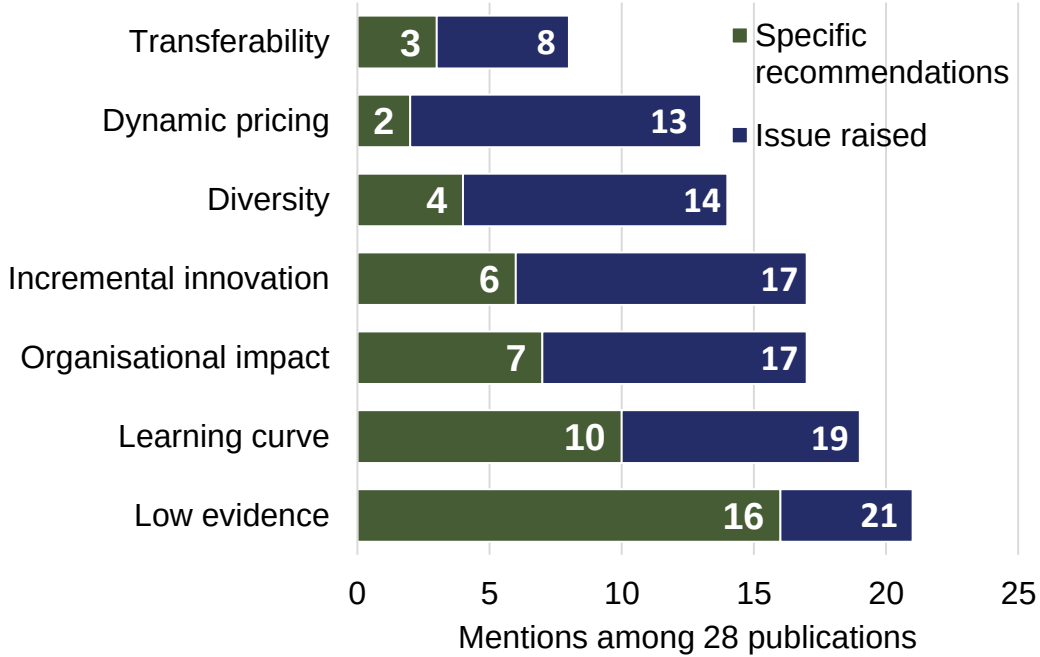


- Separate guidelines or dedicated chapter
- General guidelines apply
- Not mentioned in reviewed guidelines
- No HTA guidelines available

COLOGNE
HTAi 2019 ANNUAL MEETING · GERMANY
HTAi

Common themes in academic literature

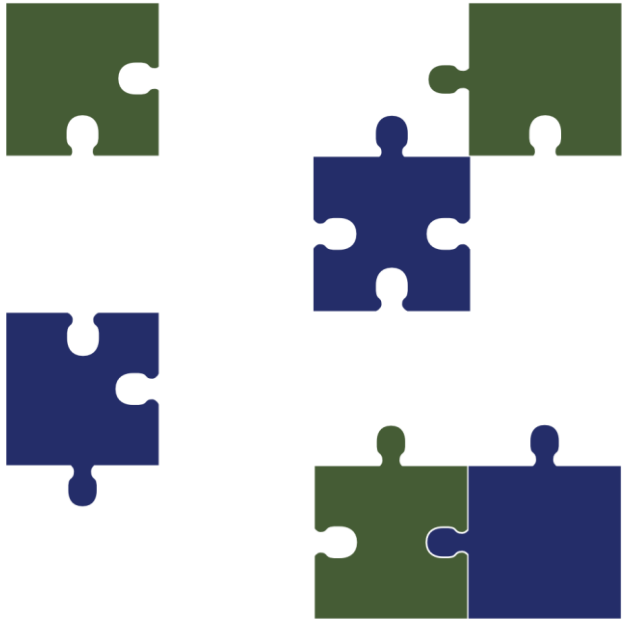
- 472 unique abstracts were screened
- 28 articles underwent full-text review
- 7 common issues
- Mentions were frequent, actionable suggestions rarer



COLOGNE
HTAi 2019 ANNUAL MEETING · GERMANY
HTAi

Hard reality

- Very little guidance exists
- We need a framework from where to start
- Needs to be a cooperative effort
- Holds the chance for standardization



COLOGNE
HTAi 2019 ANNUAL MEETING · GERMANY
HTAi

Categorization beyond Class I – III

- **Patient-device interaction**

  Transient

  Long term

- **Medical-device use**

  Monitoring

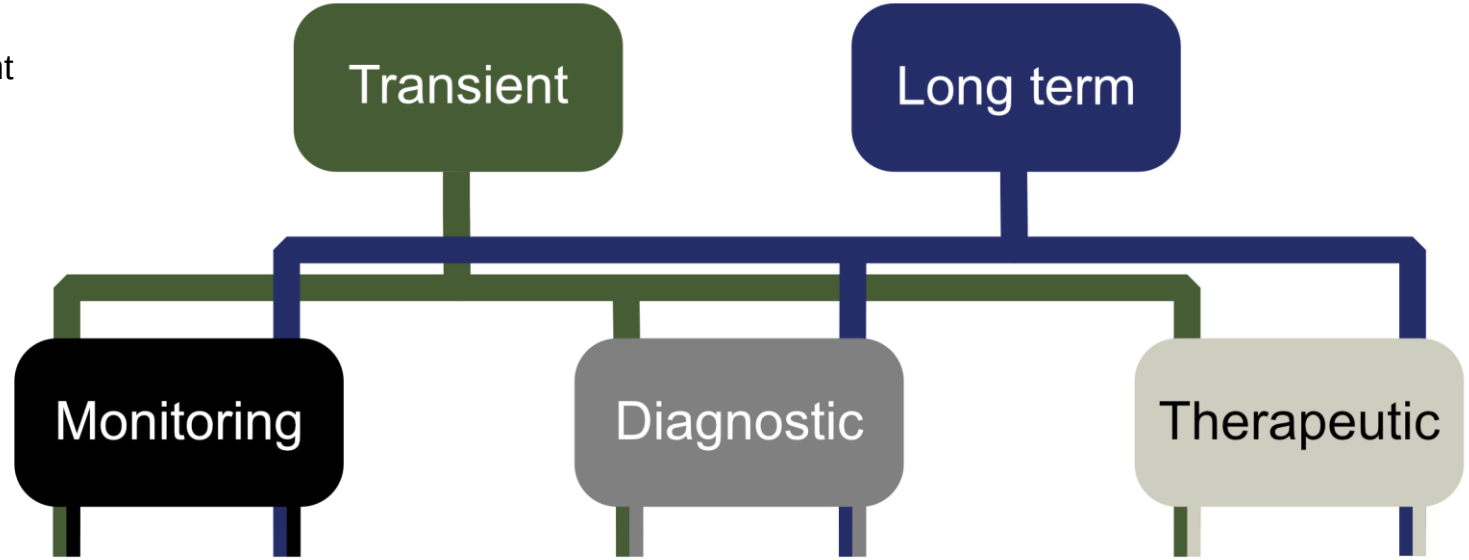
  

  Diagnostic

  Therapeutic



Health outcome	Events	Events	Events	Events/QALY	Events/QALY	QALY
Time horizon (yrs)	1-5	5-10	1-5	5-20	1-10	10-20
Discounting	No	Yes	No	Yes	Yes	Yes

COLOGNE
HTAi 2019 ANNUAL MEETING · GERMANY
HTAi

Events: E.g. death, complications; QALY: Quality-adjusted life years

Thank you

Any questions?

Contact: max@coreva-scientific.com

Website: www.coreva-scientific.com

COREVA Scientific

COLOGNE HTAi

HTAi 2019 ANNUAL MEETING · GERMANY

Source	IQWiG Methoden 5.0
Year	2017
Perspective	Insurer, societal, social care. specifics vary based on the research question
Target population	Specified in preliminary report
Comparator	All therapeutic alternatives relevant in a particular therapeutic area should be included
Method of analysis	CEA preferred, CUA only for very specific populations
Results of analysis	Efficiency frontiers
Subgroup analysis	If relevant, subgroups should be defined a priori if possible
Time horizon	Long enough to reflect relevant costs and effects of the interventions in question
Outcome measure	Patient relevant natural units QALYs can be used under specific circumstances: Data used was gathered from actual patients currentky or previously afflicted
Equity	The use of QALYs is generally not recommended

Method to derive QOL score	Generic and specific methods (but the use of QALYs is generally not recommended)
Mapping	Not recommended
Sources of clinical data	Systematic review (follow provided guidelines: http://dgepi.de/fileadmin/pdf/leitlinien/GPS_fassung3.pdf)
Indirect comparison	For CEA allowed, but needs to be comparable between study arms.
Costs to be included	Depends on the specfic perspective chosen (table on page 94)
Sources of costs	Datenbank der Informationsstelle für Arzneispezialitäten (IFA), dem EBM, dem DRG-Katalog
Estimation of productivity loss	Friction costs (only used when societal perspective is additionally provided)
Discount rate	3% (0,5% in sensitivity analysis)
Modeling	Choice of model type should be based on the research question. As complex as it needs to be to anser the research question
Sensitivity analysis	Univariate and multivariate (deterministic and probabilistic) sensitivity analyses
Reporting	Technical report and full version of the model required
Medical devices	Not mentioned