ECONOMIC EVALUATION OF MEDICAL DEVICES: ARE THERE LESSONS TO BE LEARNT FROM EUROPE

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Background

- Commercial and government payers in the US use health technology assessment (HTA) to determine whether the benefits of innovative medical technology justify their coverage
- A key aspect of HTA is an economic evaluation of new technology
- Standard methodologies for economic evaluations are well established for pharmaceuticals, but such a framework is missing for medical devices
- Europe has many HTA guidelines and may therefore help inform development of a framework for medical devices

Aim

- Review European HTA health-economic guidelines to identify a potential framework for evaluation of medical devices

Methodology

- HTA economic guidelines published by European countries were systematically reviewed for details on the assessment of medical devices
- Reviewers were available for English, French, and German language
- Extraction and tabulation of key categories allowed for identification of any consensus between guidelines
- Combined with a systematic review of published recommendations (2000-2018) for economic evaluation of medical devices, an initial framework for HTA economic evaluations was developed

Results

European medical device HTA guidelines

- 22 of the 41 (52.4%) investigated European countries provided HTA guidelines for assessment in English, French, or German (**Fig.1**)
- Specific information on the assessment of medical devices was presented in only four (England[1], France[2], Netherlands[3], and Sweden[4], **Fig.1**)
- Even when medical device specific information was provided it was less detailed than its pharmaceutical focused counterpart
- Clear consensus between guidelines was rare, but the majority of guidelines stipulated a time horizon sufficient to capture all effects of the intervention and recommended discounting at longer time horizons

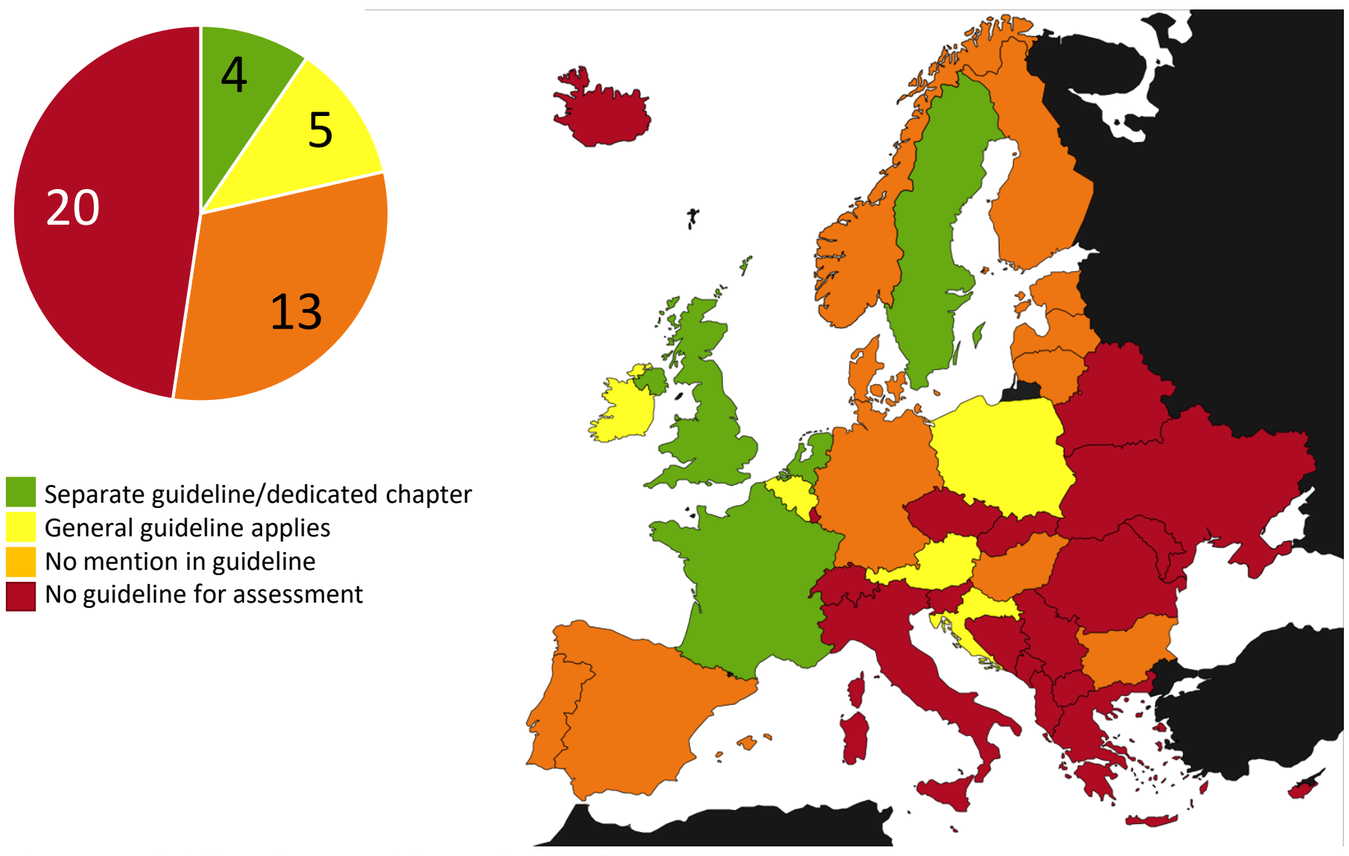

Fig. 1 Availability of HTA guidance for medical devices across 42 Europe, Gray: Not investigated, Red: no guidelines in English, French or German available, Orange: No mention of medical devices in the provided guidelines, Yellow: General guidelines apply for medical devices, Green: Separate chapters or documents for the HTA of medical devices

Issues identified in peer-reviewed literature

- Of 422 returned articles, 28 underwent full-text review
- The following medical device specific issues were most frequently identified:

1. Weak evidence base
2. Learning curve effects
3. Organizational impacts
4. Incremental innovation
5. Diversity
6. Dynamic pricing
7. Transferability

Suggested solutions

- Suggested solutions were rare (**Fig.2**) and in only a few instances were these specific implementations
- Designing suitable studies for evidence generation was covered by Bernard et al. who provided a decision tree linking product characteristics to study design[5]
- One example of estimating and modelling the learning curve was presented by Varabyova et al.[6]
- For other identified issues no directly actionable recommendations were made, rather general suggestions such as Bayesian methods

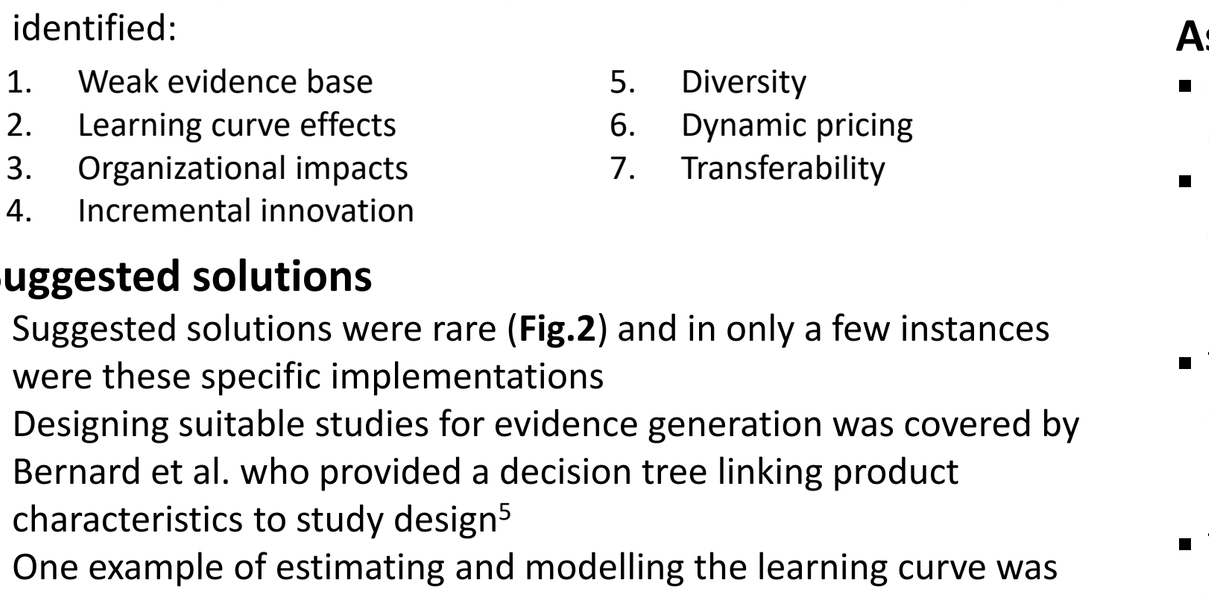

Fig. 2 Commonly mentioned issues of medical device HTA in published literature. Percentages represent how often potential solutions were suggested beyond just mentioning each issue

Conclusion

- Medical-device-specific economic HTA guidance is scarce
- Our framework is an initial discussion point to start standardizing economic evaluations of medical devices

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Assessment framework

- Our framework is built around a classification of the device-patient interaction (transient or long-term) that influences the time horizon to be used (**Fig. 3**)
- Subsequently, the medical device type indicates the most likely choice of cost-effectiveness analysis (**Fig.3**)
  - A budget-impact model is always possible and would use the shorter time horizon (generally not exceeding five years)
- The device-clinician interaction dictates the need for including learning curves and/or organizational impact
  - If either is relevant to the analysis, at least 3 years should be modelled to capture the corresponding effects
- This framework is an initial starting point for discussion, but should not override case where specific country guidance exists

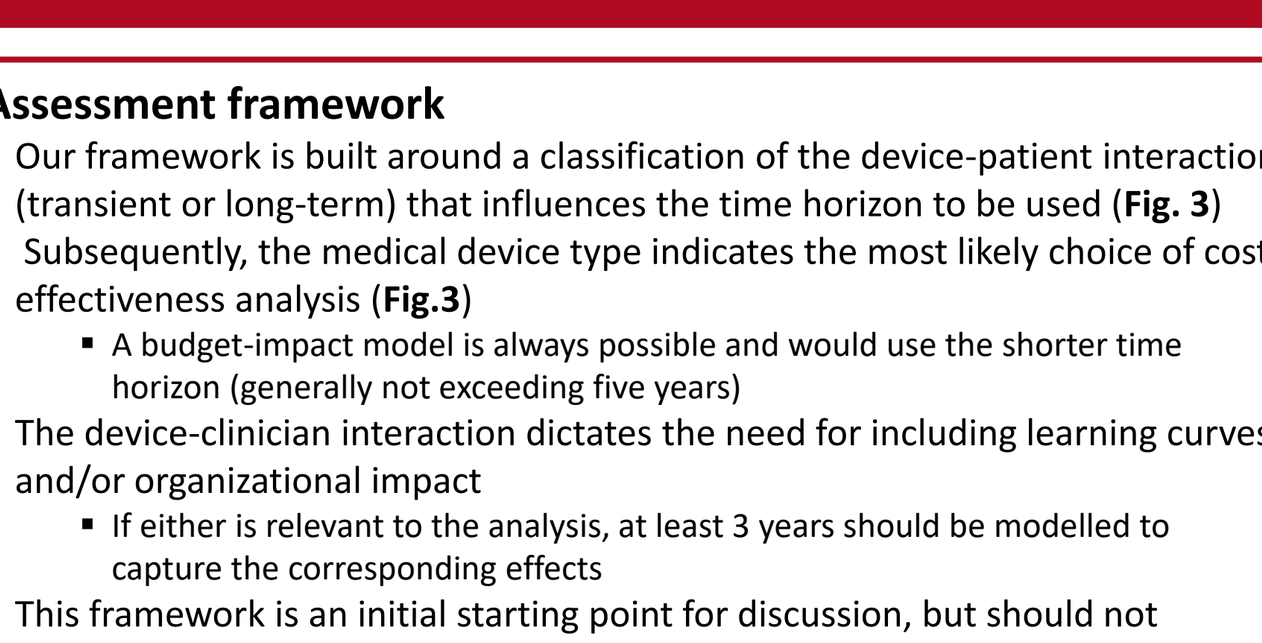

Fig. 3 Suggested analysis framework based on model parameters. CBA: Cost-benefit analysis, CUA: Cost-utility analysis

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2. HAS (Haute Autorité de Santé): Medical device assessment in France. (2009)
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Poster: PNS176
Poster Board: H3

ISPOR 2019
May 18-22. 2019
New Orleans, LA, USA

Disclosure
RS is the owner and MB, VM, RTT are employees of Coreva Scientific