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.

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.

Specific information on the assessment of medical devices was presented in only four (England, France, Netherlands, and Sweden, 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 and discussed longer time horizons.

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

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.
- One example of estimating and modelling the learning curve was presented by Varabyova et al.
- For other identified issues no directly actionable recommendations were made, rather general suggestions such as Bayesian methods.

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.
- The device-clinician interaction dictates the need for including learning curves and/or organizational impact.
- If either 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.

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. 4).
- Specific information on the assessment of medical devices was presented in only four (England, France, Netherlands, and Sweden, Fig. 1).
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- 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 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.

Conclusion

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