Modeling Challenges and Critiques in Economic Evaluations of Medical Devices: A Review of NICE Medical Technologies Guidance

MT25

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BACKGROUND

Context: Medical devices (MD), as a heterogeneous group of products intended for different purposes, are also addressed by many HTA institutions. Europe is one of the biggest markets for MD, encompassing over 500 000 registered products from wound dressings to PET/CT scanners.[1]

The challenges in assessing MD include scarcity of well-designed randomized controlled trials, inconsistent real-world evidence data sources and methods, device-user interaction, short product lifecycles, inexplicit target population, and a lack of direct medical outcomes.[2]

Aim: This study aims to review the modelling approaches and key critiques reported for economic evaluation (EE) of MD in NICE's Medical Technologies Guidance (MTG) and suggests potential strategies to address the identified challenges.

METHODS

- We reviewed MTG documents published on the NICE website from January 1, 2020, to December 2, 2024.
- MTGs that have been withdrawn, terminated, in-development, or had insufficient data were excluded.
- For each included MTG, we extracted information on the type of economic analysis, model structure, and the critiques raised by the NICE or external reviewers.

References
1. Fuchs S. HTA of medical devices: Challenges and ideas for the future from a European perspective. Health Policy. 2016
2. Ming et al. Cost Effectiveness and Resource Allocation. 2022
3. National Institute for Health and Care Excellence (NICE)

This review highlights the range of EE methods and model structures in MTG submissions to NICE. Common issues included poor data quality, unrealistic assumptions, and limited transparency. The authors note that device evaluation differs from drugs and warrants a distinct approach. Interestingly, the issues observed resemble those commonly seen in drug assessments.

Fig 1: Number of studies identified, included, and categorized by EE approach

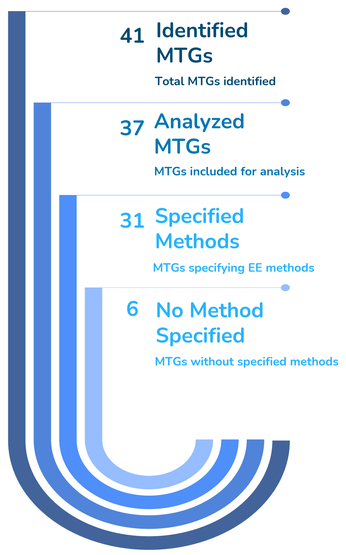


Fig 2: EE methods used among included studies

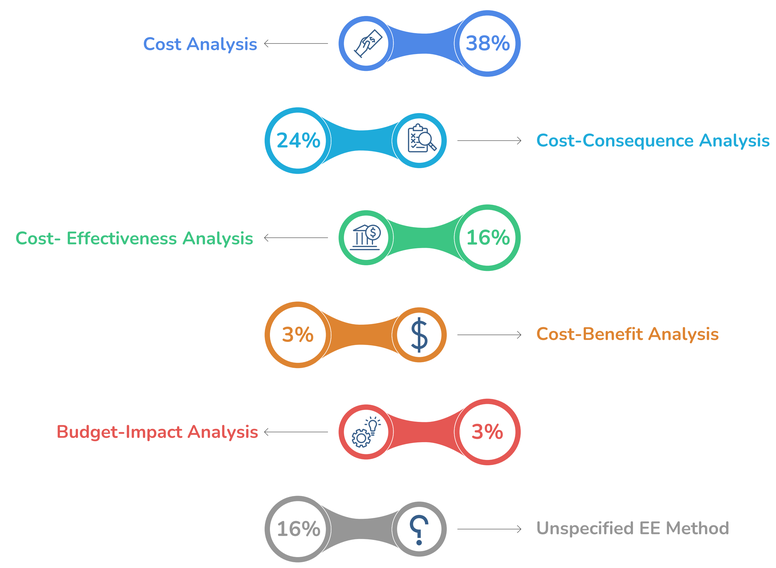


Fig 3: Distribution of model structures reported in included MTGs

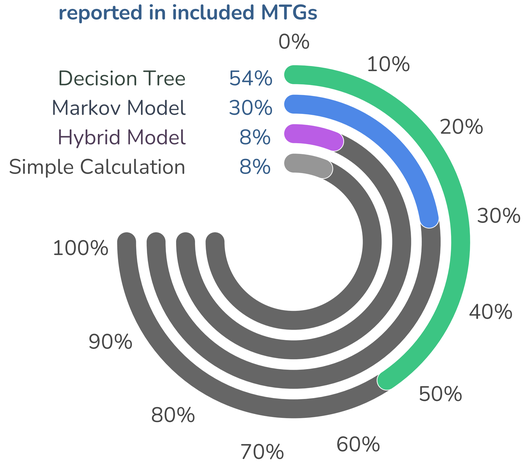
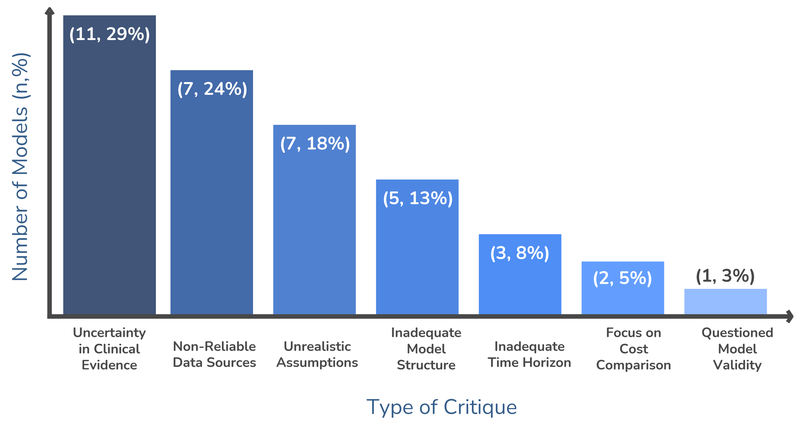


Fig 4: Types of model critiques observed across included MTGs



Abbreviations: EE, economic evaluation; MD, medical devices; MTG, Medical Technology Guidance.

RESULTS

- A total of 41 MTGs were identified, of which 37 were included in the analysis. Four studies were excluded due to insufficient data **(Fig 1).**
- The top three economic evaluation (EE) methods used in MTGs were cost analysis, cost-consequence analysis, and cost-effectiveness analysis. EE method was not specified in 16% of MTGs **(Fig 2).**
- Among the MTGs that employed modeling approaches, decision tree was the most frequently used structure, followed by Markov model **(Fig 3).**
- The most common critiques in the reviewed MTGs were **uncertainty in clinical evidence, use of unreliable data sources, and unrealistic model assumptions (Fig 4)**.
- Uncertainty in clinical evidence often resulted from limited or low-quality data. Reliance on data sources that were not appropriate or well-validated raised concerns about the reliability of the findings.
- Additionally, unrealistic assumptions—such as oversimplified disease progression or treatment effects—undermined the credibility and applicability of the models

DISCUSSION

This review identifies common issues in MTG submissions, including poor data quality, unrealistic assumptions, and limited transparency. While similar issues are seen in drug evaluations, medical devices pose distinct challenges. Improving data sources, clarifying assumptions, and increasing model transparency can strengthen future submissions.

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