The NICE Medical Technologies Evaluation Programme (MTEP): An Analysis of Clinical and Economic Evidence Evaluated in Published Medical Technology Guidance

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Objective

To better understand the evidence requirements for a positive NICE Medical Technologies Guidance recommendation.

Background

- The NICE Medical Technologies Evaluation Programme (MTEP) assesses whether evidence for medical technologies supports NHS adoption, published as Medical Technologies Guidance (MTG) for medical devices.[1,2] However, there is currently limited guidance on the clinical and economic evidence requirements for a positive MTG recommendation, including the need to conduct a randomised controlled trial (RCT) and the level of evidence required to demonstrate cost savings.[3]

Methods

- This analysis builds on a previous study by Crispi *et al.*, which evaluated 31 MTGs published between 2009 and February 2017.[4]
- The decisions and clinical and economic evidence of the subsequent 42 MTGs published between March 2017 and April 2023 were reviewed. To evaluate changing requirements over time, MTGs were considered in two year intervals, and included those analysed in the previous study by Crispi *et al.*[4]

Results

- Of the 42 assessed MTGs, 13 received full support (FS, 31.0%), 14 were not supported (NS, 33.3%), and 15 received partial support (PS, 35.7%). At least one RCT was included in the majority of submissions (**Figure 1**). The mean number of RCTs per submission was 6.5 in FS (SD: 8.7), 1.9 in NS (SD: 2.0) and 1.9 in PS (SD: 1.3) MTGs.
- All 13 FS MTGs were deemed cost-saving/neutral. Of the 14 NS MTGs, 10 (71.4%) were cost-saving in at least one setting; 3 (21.4%) were deemed cost-incurring, whilst cost implications of 1 (7.1%) were "highly uncertain."
- 7/10 (70.0%) cost-saving NS MTGs also included clinical evidence from ≥1 RCT but were still not recommended due to concerns with the included RCTs, outlined in **Table 1**. As data from these RCTs provided inputs for subsequent models, the economic evaluations of these technologies were also considered uncertain.

Time Analysis

- The number of published MTGs has increased from 2017/18 to 2021/22, but the proportion of FS MTGs has reduced in that time to 23.1% and 27.3% in 2019/20 and 2021/22, respectively (**Figure 2**). Over this time period, the number of FS MTGs that did not include evidence from RCTs has decreased, with all FS MTGs presenting evidence from at least one RCT in 2021/22 (**Figure 3**). Since March 2017, only two MTGs received FS without including an RCT:
  - MTG50 included two single-arm trials. Both trials reported a significant improvement in disease measures and quality of life measures compared with baseline.
  - MTG33 included four retrospective studies, with 3/4 studies including >1,000 participants and demonstrating improved outcomes for the device versus comparators.

Conclusions

This study suggests an increasing requirement for robust evidence to ensure a positive recommendation via the NICE MTEP. These findings align with the previous analysis by Crispi *et al.*, which concluded that the main drivers for negative decisions included low evidence quality or quantity.[4] However, the importance of RCT-derived evidence appears to have increased since the publication of this study. In line with MTEP criteria, technologies must be cost-saving to achieve full support. However, merely being cost-saving may not be sufficient: it must be demonstrated that economic models are based on robust clinical evidence.

FIGURE 1

Summary of MTG recommendations published since March 2017, stratified by the inclusion of RCT evidence in the submission

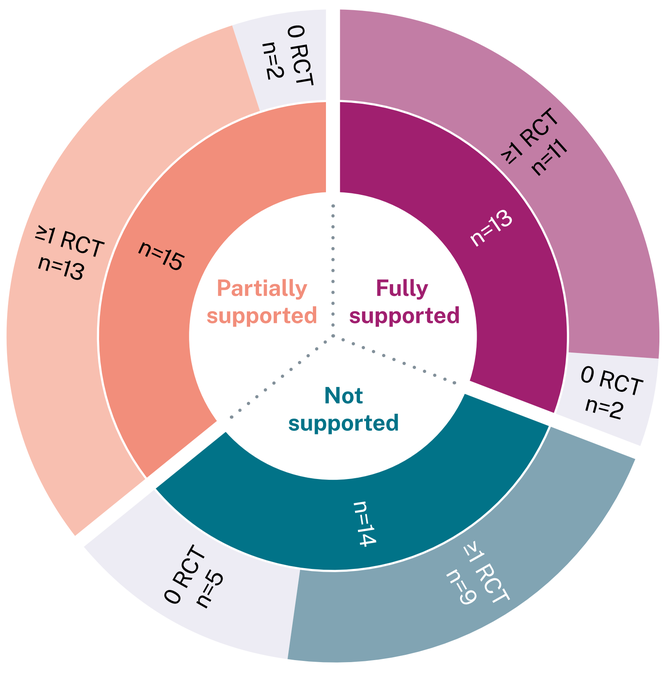


TABLE 1

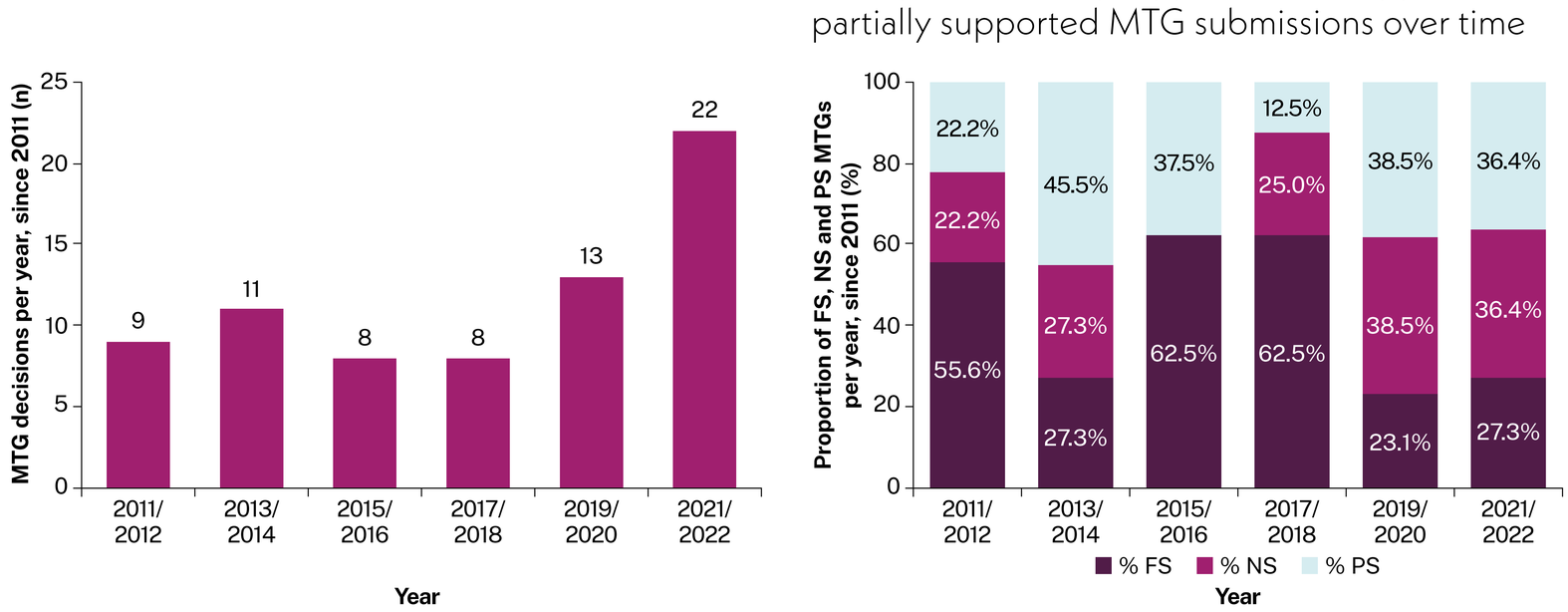
Concerns raised by the NICE Medical Technologies Advisory Committee regarding clinical RCTs included in seven cost-saving NS MTGs since March 2017

Concern with RCT	n/N (%)
Sample size	♦♦♦♦◇◇◇ (57.1%)
Clinical effectiveness of the technology unclear	♦♦♦♦◇◇◇ (57.1%)
Methodological quality	♦♦♦♦◇◇◇ (57.1%)
Generalisability to the UK or treatment population	♦♦♦◇◇◇◇ (42.9%)
Treatment or trial duration	♦♦◇◇◇◇◇ (28.6%)
Relevance to the decision problem	♦◇◇◇◇◇◇ (14.3%)
No demonstration of mechanism of action	♦◇◇◇◇◇◇ (14.3%)

FIGURE 2

A. Number of MTG decisions over time

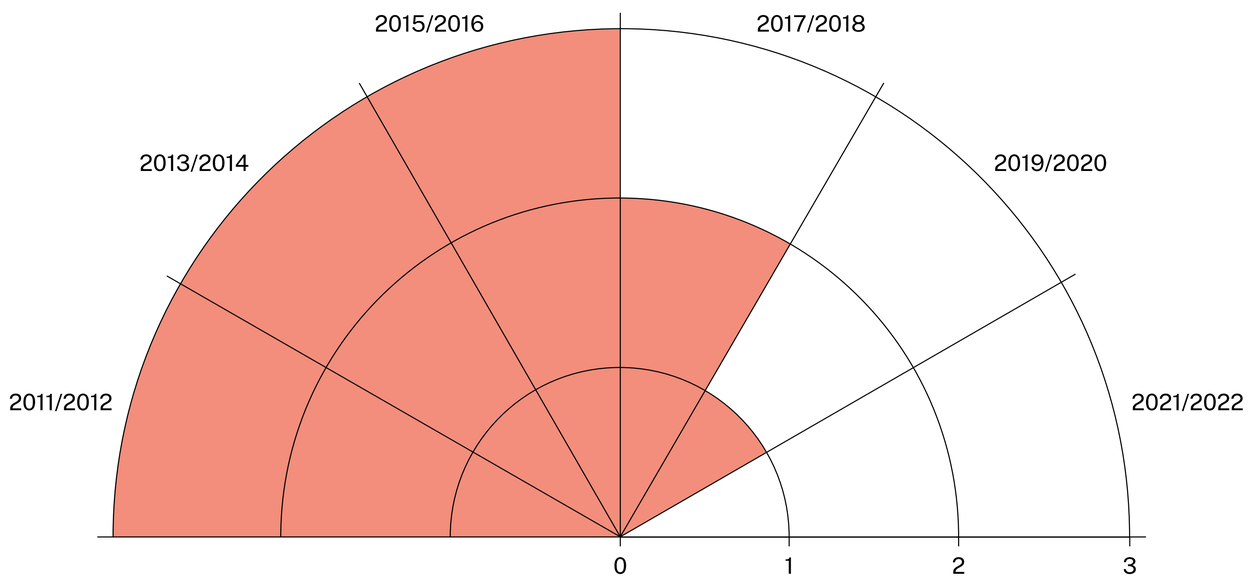
B. Proportion of fully supported, not supported and partially supported MTG submissions over time



Data from MTGs published prior to March 2017 were obtained from Crispi *et al.*, 2019.[4]

FIGURE 3

Number of fully supported MTGs that did not present an RCT over time



Data from MTGs published prior to March 2017 were obtained from Crispi *et al.*, 2019.[4]

Abbreviations: FS: fully supported; **MTEP:** Medical Technologies Evaluation Programme; **MTG:** Medical Technologies Guidance; **NHS:** National Health Service; **NICE:** National Institute for Health and Care Excellence; **NS:** not supported; **PS:** partially supported; **RCT:** randomised controlled trial; **SD:** standard deviation; **UK:** United Kingdom.

References: [1]National Institute for Health and Care Excellence. Medical Technologies Evaluation Programme. Available at: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-evaluation-programme [Last accessed: 07.09.23]; [2]National Institute for Health and Care Excellence. Medical Technologies Guidance. Available at: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-guidance [Last acccessed: 07.09.23]; [3]National Institute for Health and Care Excellence. Medical Technologies Guidance User Guide for Evidence Submission Template. https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-medical-technologies/mt-user-guide-company-evidence-submission.pdf [Last accessed: 12.09.23]; [4]Crispi F *et al.* Appl. Health Econ. Health Policy 2019;17:189–211. **Acknowledgements:** The authors thank Emma White, Costello Medical, for graphic design assistance, and the Costello Medical MedTech team for data extraction support.

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