A review of NICE submissions for medical technologies in the United Kingdom: Key trends over the last 2 years

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Introduction

The Medical Technologies Evaluation Programme (MTEP) at the National Institute for Health and Care Excellence (NICE) was introduced in December 2009 to promote and produce guidance for the evidence-based adoption of innovative diagnostic and therapeutic technologies into National Health Service (NHS) clinical practice (1,2).

Health Technology Assessment (HTA) approach to medical devices is often challenging due to the known limited amount and poor quality of the evidence base. This is due to several factors such as less regulatory demand for evidence compared with pharmaceuticals, large proportion of small-to-medium sized manufacturers with limited experience and the rapid advancement in product development (1).

MTEP considers all levels of evidence and aims to foster collaborative research between medical device manufacturers and the healthcare sector to fill the evidence gaps. The MTEP process considers whether the evidence supports the case for adoption in the full population or in subgroups, together with the overall cost to the NHS relative to standard of care. If a technology is not recommended, the reasons are outlined with the need for further research often emphasised (3).

Objectives

To review submissions to the Medical Technologies Evaluation Programme (MTEP) of NICE over the last 2 years and identify:

- The proportion of medical devices receiving a positive, partial or negative recommendation
- Key factors leading to a negative recommendation or partial recommendation

Methodology

A search for published medical technologies guidance over the past 2 years (June 2021–June 2023) was conducted using the NICE database (3). Each identified submission and the resulting recommendations were reviewed, and key data were extracted in Excel. These included device name and characteristics, indication, recommendation, and key criticisms from the NICE committee meeting. Key criticisms were mainly extracted from sections 3 and 4 of the recommendation document, which focused on evidence description and committee discussion. Data were extracted by one HTA Consultant, with spot checks from the HTA Director. Following review, themes for the main limitations emerged and were grouped in three broad categories:

- Clinical efficacy
- Economic case
- Device-specific

Each of the broad categories were then further divided into several sub-categories to better understand the emerging themes (Table 1).
As recommendation decisions are primarily based on the clinical and economic evidence base, detailed results were presented for each of the decision categories. The prevalence of issues was numerically compared between the submissions for not recommended/partially recommended, and the fully recommended medical devices. Comparisons using statistical methods were not possible due to the small sample of published MTEP guidance. Results for category 3 were presented descriptively, irrespective of committee decision.

Table 1: Limitation categories and subcategories

1	Clinical case	1	Population: Small sample size
		2	Population: Heterogenous population
		3	Population: Only subgroup data available
		4	Outcomes Inconsistent definition, measurement or reporting
		5	Outcomes: Surrogate outcomes
		6	Outcomes: Insufficient evidence for all relevant outcomes
		7	Limited comparative evidence
		8	Study design: Mostly observational/retrospective studies
		9	Limited long-term clinical efficacy data
		10	Clinical evidence potentially not generalisable to the UK context
2	Economic case	1	Uncertainties in cost savings
		2	Not cost saving in full population or subgroup(s)
3	Device-specific	1	Requires training of clinicians/patients/carers
		2	Environmental impact
		3	May be unsuitable for certain patient groups

Results

Over the past 2 years, guidance was published associated with 26 NICE MTEP submissions, with a 69% approval rate. Of those, 28% received partial recommendation with additional research required (Figure 1). Most medical devices were therapeutic (73%), including two digital apps, with only two diagnostic and five associated with prevention (Figure 2). The majority (65%) were new guidance documents, with the rest being updated following a review process.
The HTAs, which were not recommended or partially recommended, had a higher prevalence of issues with the clinical evidence base in most subcategories (Figure 3). The prevalence of limited comparative data and mostly observational and/or retrospective studies were universal across submissions, but slightly higher in the recommended technologies.
The clinical evidence base of medical devices, which were not recommended, had a higher prevalence of issues with study population in terms of sample size, heterogeneity and relevance (Figure 4). Similarly, more of the clinical studies used surrogate primary outcomes and/or did not include all relevant outcomes.
The issue of outcome inconsistencies in studies was universal across submissions, irrespective of committee decision (Figure 5).
Half of the not-recommended technologies were found to be cost-incurring, with the rest having uncertain cost-savings due to the limitations of the clinical evidence base or variability in clinical practice. There were uncertainties in the economic case in approximately 30% of the recommended medical devices but all of them were considered likely cost-saving (Figure 6).
In terms of device-specific considerations, the implementation of 38% required some form of training and 23% were considered unsuitable for certain patient groups. The environmental impact was considered in only one submission.
It should be noted that recommendation decisions were made based on the totality of evidence. Where limitations with the clinical evidence were noted, their impact was thoroughly discussed. Additionally, clinical expert opinion and patient experiences were considered. However, cost-incurring technologies, when compared with standard of care, were never recommended.

Figure 3: Limitations of clinical evidence

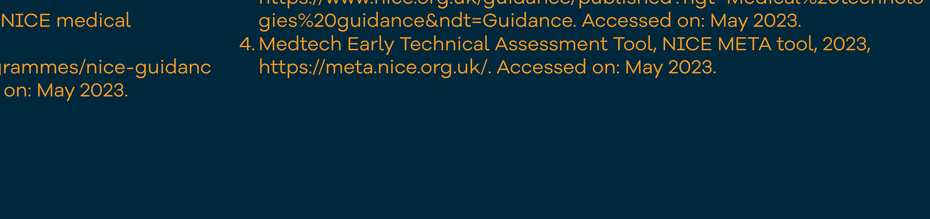


Figure 1: NICE committee decision

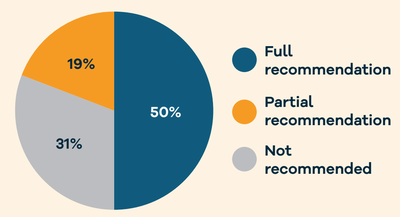


Figure 2: Treatment/Prevention/Diagnosis

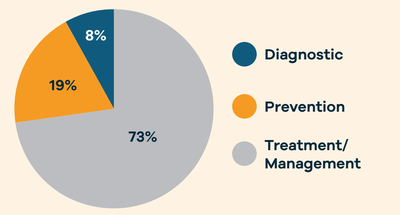


Figure 4: Issues with population

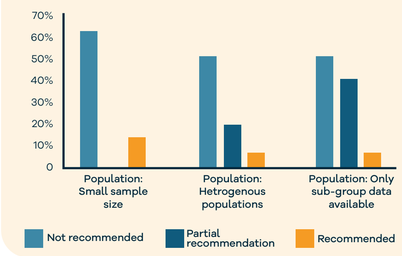


Figure 5: Issues with clinical outcomes

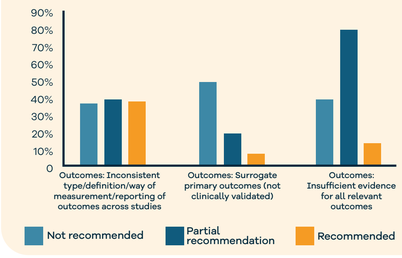
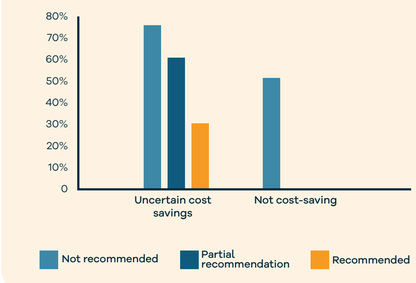


Figure 6: Limitations of economic case



Conclusion

Half of the MTEP submissions to NICE in the past 2 years were not recommended or were only recommended in a subgroup of patients. The main issues in those submissions included limitations of the clinical evidence with regards to study populations, outcomes, long-term data, relevance to UK clinical practice, but also weak economic case, with half of the not-recommended technologies found to be cost-incurring compared with standard of care.

To increase the chances of a positive recommendation following MTEP, medical device manufacturers need to carefully consider the level of evidence available for their medical device ahead of submission. An evidence review gap analysis, which can be facilitated via the MedTech Early Assessment tool (META), is recommended (4). Additionally, the price point of the medical device needs to be such that a roll-out across the UK will lead to cost savings to the NHS, when compared with current standard of care.

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Abbreviations

HTA: Health Technology Assessment
NHS: National Health Service
NICE: National Institute for Health and Care Excellence
MTEP: Medical Technologies Evaluation Programme