Navigating large evidence bases for MTEP submissions and for the new NICE HealthTech program

Moss E[a], Jenkins A[a], Tatman S[a], Priestman E[a]
[a]Petauri Evidence, Bicester, UK

ISPOR poster acceptance code: HTA246
Abstract ID: 7367

Introduction and Methods

The National Institute for Health and Care Excellence (NICE) makes recommendations for medical technologies based on Medical Technologies Evaluation Programme (MTEP) submissions. A systematic approach to evidence generation was recommended by MTEP; however, uncertainty remains as to whether companies were submitting adequate evidence. In July 2025, NICE and the Department of Health and Social Care (DHSC) introduced the HealthTech programme (1,2), replacing MTEP and other programmes, to ensure availability of innovative technologies by providing timely, evidence-based guidance on their value and effectiveness. To understand evidence requirements under the MTEP process, we undertook a review of the number of submissions, guidance followed, and recommendations since its inception in 2011. Additionally, we explored the structure of the new HealthTech programme to understand the implications for evidence generation.

MTEP process

Submissions and guidance

Since 2011, 66 guidance documents have been published. The publications peaked in 2021 (n=11) and 2022 (n=11), with a drop in published guidance in 2023 (n=1) and 2024 (n=2) (Figure 1). The guidelines to companies regarding clinical and economic evidence have remained the same, stating that "evidence should be systematic and transparent" (3), and recommend using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (4). For clinical evidence, a meta-analysis should be conducted where appropriate.

Figure 1: Number of MTEP submissions per year (2011–2024)

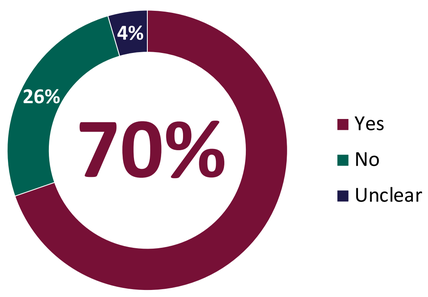
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Total	4	3	3	5	3	2	4	4	7	6	11	11	1	2

Review of recommendations

A comprehensive review of all previous MTEP submissions revealed 66 completed submissions. Of these, the majority, 46 (70%), were recommended, 17 (26%) were not recommended, and 3 (4%) had unclear recommendation status (Figure 2).

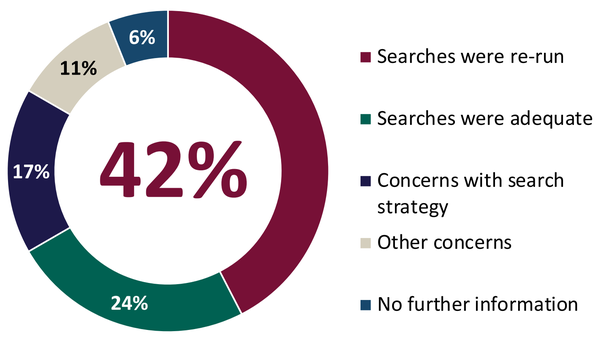
Of the 46 that were recommended, 2 submissions were noted to have limited evidence but were still recommended due to the perceived low risk of harm.

Figure 2: Recommendation status of MTEP submissions



The review revealed that 42% (n=28) had inadequate search strategies, and there were concerns with searches for a further 17%. To determine the extent of the evidence inadequacies, the External Assessment Centre (EAC) re-ran all 28 inadequate searches. Where searches were deemed adequate (24%, n=16), the EAC still re-ran searches in 4 submissions, twice to ensure absolute confidence, once to focus on company device only, and once to expand the search date limits (Figure 3).

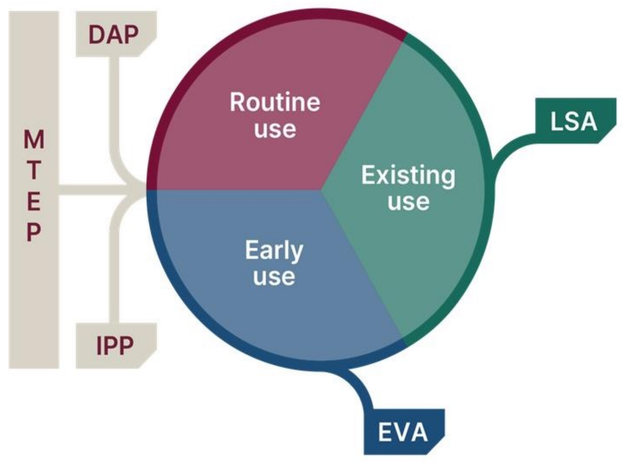
Figure 3: EAC responses to submission search strategies



HealthTech programme

In order to evaluate a broader range of technologies, the former NICE Diagnostics Assessment Programme (DAP), Interventional Procedures Programme (IPP), and MTEP have been incorporated into the HealthTech programme (1). The new programme takes a lifecycle approach, requiring companies to respond to NICE's requests for information, ideally with complete evidence dossiers and fully executable health economic models, rather than a dossier submission to NICE (1). This has implications for evidence generation, as it would need to be pre-emptively executed ahead of requests, as it is expected that the timeframe for response will range from 8–24 weeks (5). The evaluations will be conducted by external assessment groups (EAGs), and while single technology appraisals remain possible, the emphasis is now on multi-tech evaluations (3) (Figure 4).

Figure 4: HealthTech programme assessment process



Early use

The early use assessment pathway (previously called early value assessment [EVA]) offers a pragmatic route into the National Health Service (NHS) for digital tools, diagnostics, and devices in the early stages of evidence generation (1). It acknowledges that not every promising technology arrives with a portfolio of randomised controlled trials (1), reducing the costs and complexities associated with traditional NICE submissions (2).

The process, adapted from the DAP model (2), includes topic selection, scoping, EAG review, and conditional recommendations. Crucially, NICE may provide an evidence generation plan, giving companies a period of 3 years or more to plug gaps before re-evaluation (1).

Routine use

Technologies deemed ready for routine use face a more rigorous comparative process. NICE and DHSC select categories, and evaluations focus on relative cost effectiveness (1). For suppliers, the reintroduction of price negotiations and discounting marks a shift from selling features to defending value (1).

Existing use

The existing use assessment pathway (previously called late-stage assessment [LSA]) targets technologies already embedded in NHS procurement (2). With NICE prioritising value for money over novelty, categories include high-cost items with price variation and incremental innovation. User preference assessments are a notable addition to this pathway; these allow the capturing of user-specific value components that may not be covered in the clinical evidence or economic modelling (1).

HealthTech programme evidence requirements

The updated NICE HealthTech programme manual was published on 23rd October 2025 (6), providing more clarity on the evidence requirements. For both early use and existing use assessments, pragmatic or rapid review (7) methodology is acceptable; however, justification for this approach must be included in the protocol. For routine-use, reference to the standard NICE health technology manual (1) is made.

Conclusion and considerations

This research shows that a systematic approach to evidence generation was not a necessity for recommendation under MTEP. The guidance for the new HealthTech programme is more permissive for early use and existing use assessments, providing the rationale for a pragmatic or rapid review is stated in the protocol. However, it appears a more rigorous approach is needed for routine-use assessments, due to the HealthTech manual (6) referring to the standard NICE manual (1), which indicates a systematic review would be required.

The early use pathway will be beneficial for early-stage innovators, but new multi-tech evaluations may pose strategic challenges for suppliers of routine and existing technologies. A new emphasis on user preference assessments for existing use technologies marks an interesting shift; by capturing user experience and value beyond what can be captured in clinical or economic evaluations, NICE appears to be acknowledging the subtler forms of innovation in mature technologies.

Taken together, the reforms hint at a tougher stance ahead. Beyond the early use track, NICE is signalling that unsubstantiated claims and weak evidence will no longer pass unchallenged.

Scan for a video walkthrough

ISPOR Europe 2025
9–12 November
Glasgow, Scotland

Booth no. 608

References

1. NICE. NICE HealthTech programme manual (PMG48). 2025. Available from: https://www.nice.org.uk/process/pmg48/resources/nice-healthtech-programme-manual-pdf-72286843070149. Accessed: October 2025.
2. Varghese, A; YHEC. Digital Health Technologies and the Challenges in Evaluation. 2025;53-86.
3. NICE. Medical Technologies Evaluation Programme: Sponsor submission template (version 1.1). 2011. Available from: https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-medical-technologies/mtep-sponsor-submission-template-1.pdf. Accessed: October 2025.
4. Page MJ, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ. 2021;372:n71.
5. Owens R, et al. NICE Advice HealthTech Masterclass. September 2025. (Training course).
6. NICE. NICE health technology evaluations: the manual PMG36. 2025. Available from: https://www.nice.org.uk/process/pmg36/resources/nice-health-technology-evaluations-the-manual-pdf-72286779244741 Accessed: October 2025.
7. Garritty C, et al. Updated recommendations for the Cochrane rapid review methods guidance for rapid reviews of effectiveness BMJ 2024; 384 :e076335 doi:10.1136/bmj-2023-076335

Abbreviations

DAP, Diagnostics Assessment Programme

DHSC, Department of Health and Social Care

EAC, External Assessment Centre

EAG, external assessment group

EVA, Early Value Assessment

HTA, health technology assessment

IPP, Interventional Procedures Programme

LSA, late-stage assessment

MTEP, Medical Technologies Evaluation Programme

NHS, National Health Service

NICE, National Institute for Health and Care Excellence