Unlocking Value Early: Insights into NICE's Early Value Assessments and Evidence Generation Plans for Medical Technologies

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Objective

To evaluate previous early value assessments (EVAs) of medical technologies to determine the evidence needs for positive recommendation.

Background

- The National Institute of Health and Care Excellence (NICE) developed an EVA pathway to facilitate rapid assessment of promising medical technologies that meet a national unmet need.
- The aim of EVA is to provide guidance on what further evidence is required for positive recommendation in a future full appraisal.
- However, specific evidence requirements and criteria for evaluation are not currently well-defined for the EVA pathway.

Methods

- EVAs and evidence generation plans (EGPs) published for medical technologies between March 2023 and May 2025 were reviewed.
- Decision parameters, existing clinical and economic evidence, and further evidence generation required were assessed and synthesised.

Results

Overall EVA Characteristics

- A total of 21 EVAs were identified; these were most commonly for digital medical technologies (n=19).
- Most EVAs were multi-technology (n=16), with psychiatry (n=5) the most common specialty.
- Seven appraisals received full support, 12 received partial support and two were not supported (**Figure 1**). The seven appraisals that received full support were within digital (n=5), diagnostic (n=2) and surgical devices (n=2).[a]

Full Support EVAs

Evidence Levels

- Only three of the EVAs that received full support included technologies that have been assessed in a published randomised controlled trial (RCT; n=3/7) (**Figure 2**).
- Six of the EVAs that received full support included economic evaluations (n=6/7); four of these were developed by an external assessment group and two were published models identified during the appraisal.
  - Of these, two EVAs included technologies that were deemed cost-effective (n=2/6), and the remaining four included technologies with the potential to be cost-effective (n=4/6; **Figure 3**).

EGPs

- In published EGPs for full support appraisals, NICE requested essential evidence for 2–7 topic areas, and desirable evidence for 0–3 topic areas for future committee decision making.
  - Data pertaining to healthcare cost and resource utilisation were most requested (n=6), followed by clinical effectiveness/efficacy, and outcomes related to clinician experience/decision-making or organisational pathways (all n=5) (**Figure 4**).

Conclusion

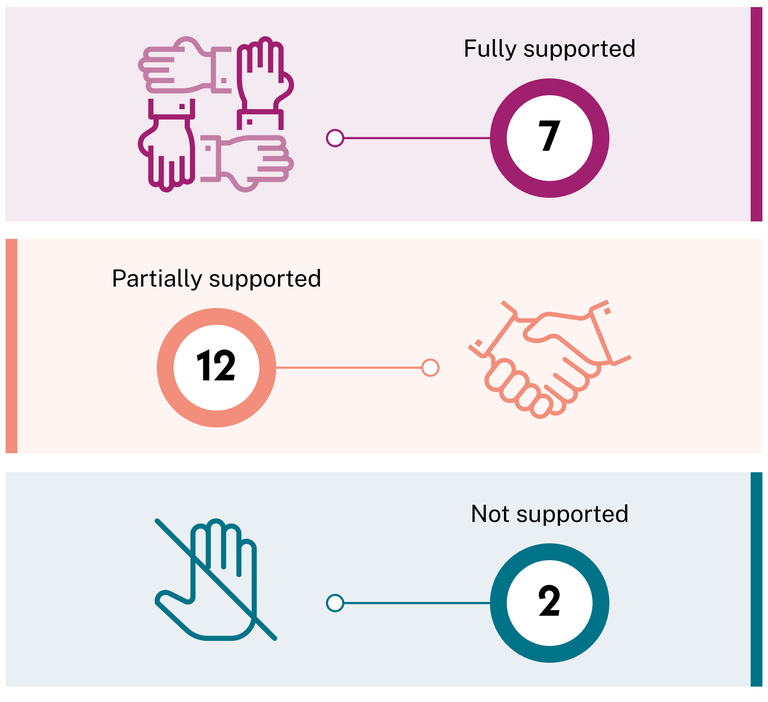
Our analysis shows that EVA represents a flexible appraisal pathway, adaptable to a variety of technologies and evidence levels. RCT evidence is not a prerequisite for positive recommendation, but potential for cost-effectiveness is important.

Topic selection for EVAs remains ambiguous; given the wealth of evidence for robotic-assisted surgery and its recent EVA, there is a need for greater clarity on eligibility criteria and evidence needs.

By highlighting areas that future evidence generation should focus on, the EVA process facilitates the development of robust evidence for new medical technologies and potentially accelerates their implementation.

FIGURE 1

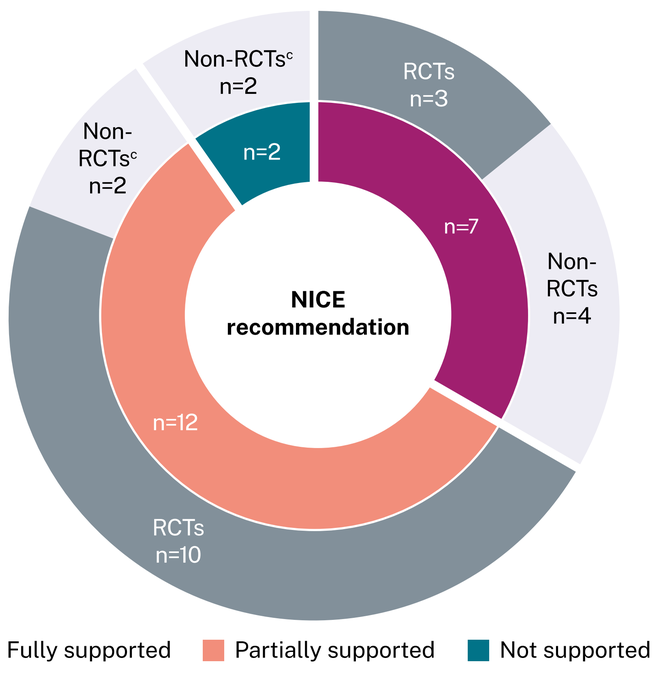
Overall recommendations[b]



[b]Recommendations were either explicitly stated in the 'why they made the recommendations' section, or if not included explicitly, the recommendation was inferred.

FIGURE 2

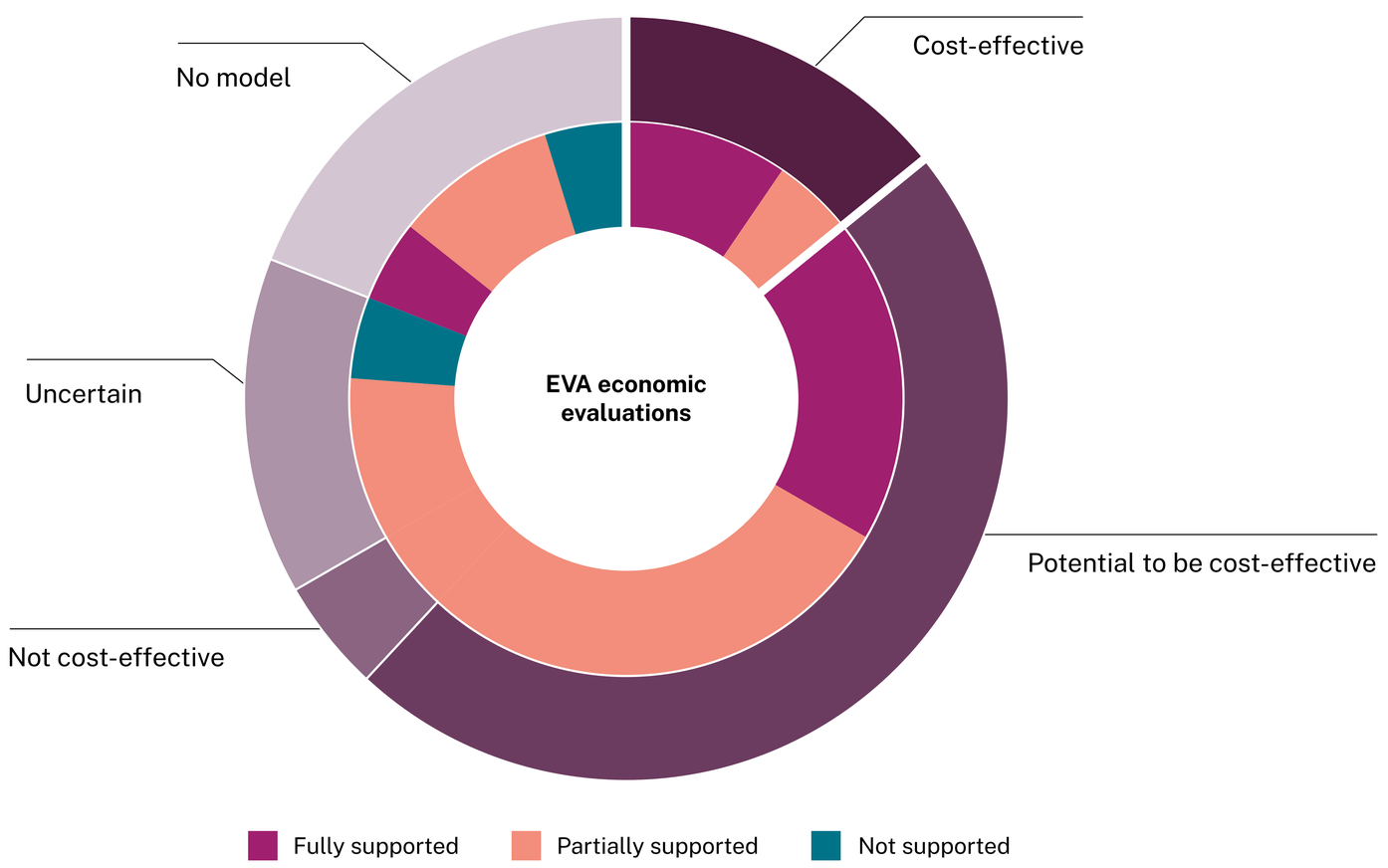
Association of RCT evidence with NICE recommendations



[c]n=1 no study design reported.

FIGURE 3

Association of cost-effectiveness modelling results with NICE recommendations



[d]These six EVAs were partially supported as only part of the original appraisal request was supported, with other parts rejected. Specifically, five EVAs were partially supported due to some of the technologies in the submission being rejected, and in one EVA, the technology was supported for use in adults but not children.

FIGURE 4

NICE requests for evidence for future committee decision making

Requested topic areas in EGPs for appraisals with full support:

[a]n numbers equal more than seven as technologies could fall within more than one type of MedTech.

Abbreviations: EVA: early value assessments; **EGP:** evidence generation plan; **NICE:** National Institute of Health and Care Excellence; **RCT:** randomised controlled trial.

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