Accelerating Access to Medical Technologies: An Overview of the NICE Early Value Assessment Pilot Project in the UK

Poster # HTA186

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Background

- In June 2022, the National Institute for Health and Care Excellence (NICE) in the UK began its Early Value Assessment (EVA) pilot project to accelerate the assessment of medical technologies (MedTech; **Figure 1**).[1]
- MedTech include all digital health technologies, such as therapies and systems, that can improve patient health or increase healthcare capacity.[2]
- The objective of EVA is to enable patients and the National Health Service (NHS) to benefit from using promising MedTech while further research is conducted.[2]

Figure 1. EVA processes for Health Technology Evaluations[2]

Eligibility criteria

Products are eligible for EVA, if:

- They have a European Conformity or UK Conformity Assessment mark (and Digital Technology Assessment Criteria approval for digital technologies), and
- They address an unmet need in a priority area and are currently being used in the NHS or are planned for use within the next six months, and
- They are in need of further data collection or evidence generation before they can be recommended for use

NICE assessments

- EVAs assess the benefits and harms of a single digital product or a group of similar digital products in the absence of a complete evidence base and determine whether it is acceptable for the product to be used within the NHS while further research is conducted.
- Companies can provide comments and additional information during the public consultation of the draft guidance, which will be considered by the committee and NICE before final guidance is published.

NICE recommendations

NICE can make the following recommendations based on EVA:

- **Conditionally recommended for use while further evidence is generated:** For products that are likely to address an unmet need.
- **Recommended in research only:** For products where there is too much uncertainty over whether the unmet need would be addressed or about the balance between the benefits and risk.
- **Not recommended for use:** For products that do not address an unmet need or may be harmful in research.

Next steps

- Following a conditional recommendation, evidence generation plans are developed to highlight evidence gaps and suggest methods to address them. Once the evidence is generated, NICE will re-appraise the technology and make a full recommendation.
- There is currently no option for MedTech that are recommended in research only or not recommended to appeal or re-apply.

Abbreviations: EVA = Early Value Assessment; MedTech = medical technologies; NHS = National Health Service; NICE = National Institute for Health and Care Excellence

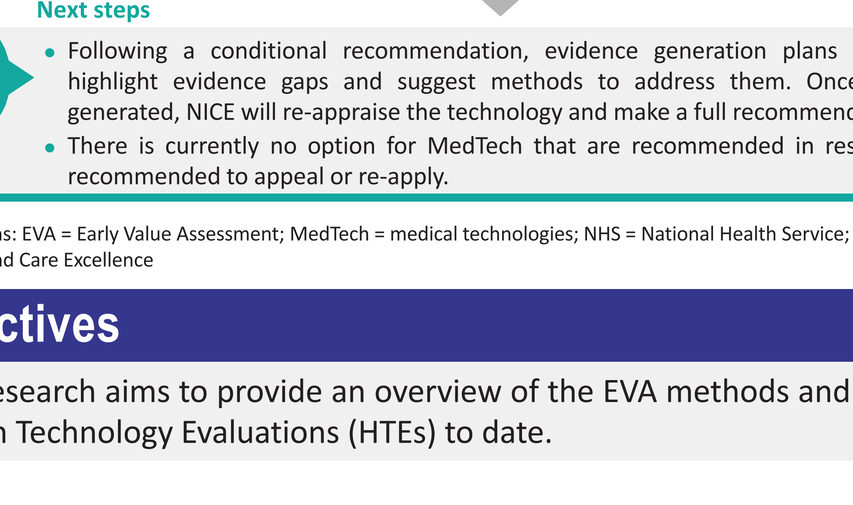
Objectives

- Our research aims to provide an overview of the EVA methods and published EVA Health Technology Evaluations (HTEs) to date.

Methods

- We conducted a targeted search for published materials on NICE EVAs, including the interim process/methods statement, HTEs, upcoming assessments, and evidence generation plans.
  - There are currently no published submission templates.
- Key details from published HTEs (uncertainties, benefits, recommendations) and evidence generation plans (evidence gaps, recommended approaches to evidence generation) were extracted into a Microsoft Excel® sheet and analyzed quantitatively and qualitatively.

Figure 2. Topics across all published and ongoing EVAs as of 20 October 2023[3,4]



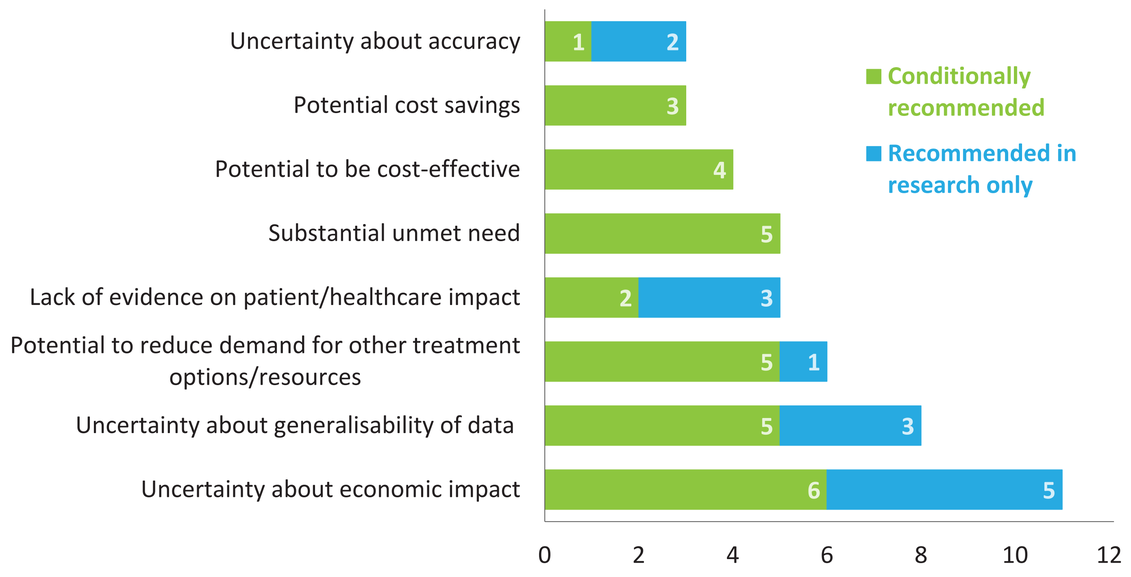
[a] includes diagnostics for genetic variants and urinary tract infections
[b] includes digital therapies for weight management, chronic obstructive pulmonary disease and back pain

Results

Overview of published EVA HTEs

- As of 20 October 2023, 11 EVA HTEs were published (three digital therapies for mental health, five diagnostics, three medical technologies that improve healthcare capacity) and seven EVAs were in or awaiting development (**Figure 2**).[3,4]
  - The median duration from publication of the final scope to guidance publication was 22.9 weeks (range: 12.3, 80.9).[3]
- Potential to be cost-effective or cost-saving and potential to reduce demand for other treatment options/resources were frequently highlighted as benefits of MedTech in published appraisals with recommended outcomes (**Figure 3**).[3]
- Over half of published appraisals commented on uncertainties regarding generalisability of data and economic impact, which did not always result in not being conditionally recommended (**Figure 3**).[3]

Figure 3. Common benefits and uncertainties discussed across 11 published EVAs[3]



Recommendations among published EVAs

- Across 10 HTEs of 63 MedTech (reference numbers HTE3 through HTE12)[3]:
  - Twenty-five of 63 MedTech (**39.7%**) were **conditionally recommended** for use while further evidence is being generated and 25 technologies (**39.7%**) were **recommended for use in research only**
  - Seven MedTech (**11.1%**) were **not recommended** because they were not expected to improve patient care or to address an unmet need.
  - The remaining six technologies did not have regulatory approval at the time of assessment and did not receive a recommendation.
- Virtual ward platforms were conditionally recommended for use in HTE13.[5]
  - The NICE scoping and consultation process identified 21 MedTech, but the final recommendation did not distinguish between individual products.

Evidence generation plans

- As of 20 October 2023, two evidence generation plans have been published.[3]
  - The median duration from publication of the HTE guidance publication to evidence generation plan publication was 24.4 weeks (range: 19.0, 29.9).
  - Evidence generation plans included recommendations on endpoints for data collection, study design and data sources.

Conclusions

- Eleven EVA HTEs have been successfully published by NICE to date, facilitating quicker patient and healthcare provider access to new MedTech.[3] The median duration between final scope to guidance publication (22.9 weeks) is considerably shorter than the median time to guidance for Single Technology Appraisals (48.0 weeks) and Multiple Technology Appraisals (74.0 weeks).[6]
- Our research has identified the key appraisal topics and benefits/uncertainties of interest to NICE in the EVA process.
- Use of digital technologies in healthcare is becoming more common, and the number of MedTech HTAs is expected to increase accordingly. Future research activity will continue to monitor newly published HTEs and evidence generation plans for insights into predictors of positive recommendation for use.

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