Navigating Evidence Constraints: Modelling Approaches for Digital Health Technology in NICE's Early Value Assessment

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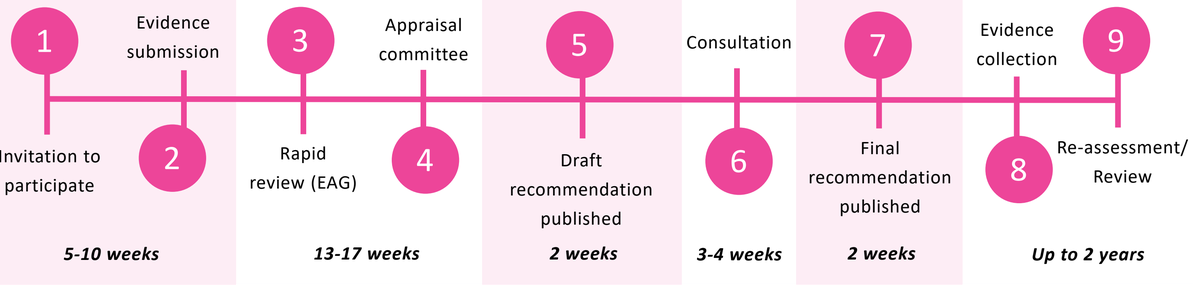
Introduction

- In June 2022, NICE launched the Early Value Assessment (EVA) programme, aiming to conditionally recommend digital health technologies (DHTs) for use in the National Health Service (NHS) while additional evidence is generated. The EVA process is shown in **Figure 1.**
- Due to the limitations in evidence surrounding DHTs, robust economic analysis is essential for EVAs to support informed decision-making.

Objective: This research aims to investigate the modelling approaches used, including model and analysis type, and subsequently explore the logical frameworks and discussion underpinning the justification of such choices.

Figure 1. EVA process diagram[1]



Abbreviations: EAG, external assessment group; EVA, early value assessment.

Methods

- A targeted literature review of all NICE EVA appraisals was undertaken up to May 2024, and data was extracted to facilitate the review of the data gaps present and modelling approaches used by the Evidence Assessment Group (EAG) to evaluate the cost-effectiveness of the appraised technologies.
- **Figure 2** presents the sample selection process whereby published appraisals were evaluated for relevance and therefore inclusion for review.
- On the included appraisals, a thematic analysis was performed, focusing on identifying evidence gaps that were discussed in the evaluation.
- Modelling frameworks and foundational discussion were collated and synthesised, specifically examining model choice, assumptions used, and the handling of uncertainty.

Figure 2. Sample selection process

Results

Review process

- 17 EVAs had been published at the time of review and were assessed for eligibility. Two appraisals were excluded as the asset being appraised was not a DHT (**Figure 2**).

Thematic analysis of evidence gaps

- Of the 103 technologies evaluated, 57 were conditionally recommended (55%). The remaining 46 (45%) were not recommended for use in the NHS primarily due to lack of evidence.
- The thematic analysis of evidence gaps covered five key evidence areas: clinical trial data, long-term effectiveness, safety data, real-world data, and economic evaluation over four key aspects—frequency, impact, breadth, and urgency (**Figure 3**).
- The impact of data limitations and the urgency to resolve them were strongly highlighted across all five domains. Breadth demonstrated the lowest score over all the domains suggesting that the evidence gaps identified detailed specific items of data.

Modelling characteristics

- Of the appraisals included, seven EAG groups were involved, and the following approaches were adopted: cost-utility (47%), cost-effectiveness (27%), cost-comparison (13%), cost-minimisation (7%), and 7% did not report the approach used (**Figure 4**).
- Five of the 15 appraisals (33%) adopted a decision tree, two (13%) used a Markov structure, and three (20%) took a hybrid approach using a decision tree to model short-term events followed by a Markov afterwards. Five (33%) did not clearly report the modelling structure (**Figure 5**).
- Six of the appraisals conducted modelling with a full range of sensitivity analyses including probabilistic sensitivity analysis (40%), four were considered early models and completed some sensitivity analysis such as one-way sensitivity and scenario analyses (27%), four were conceptual models only (27%), and one did not report modelling activity (7%) (**Figure 6**).

Figure 3. Results of thematic analysis

Figure 4. Model approach

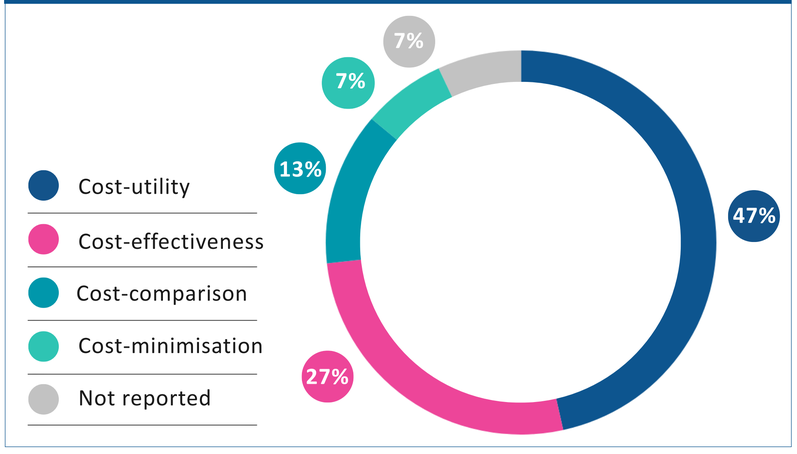


Figure 5. Model structure

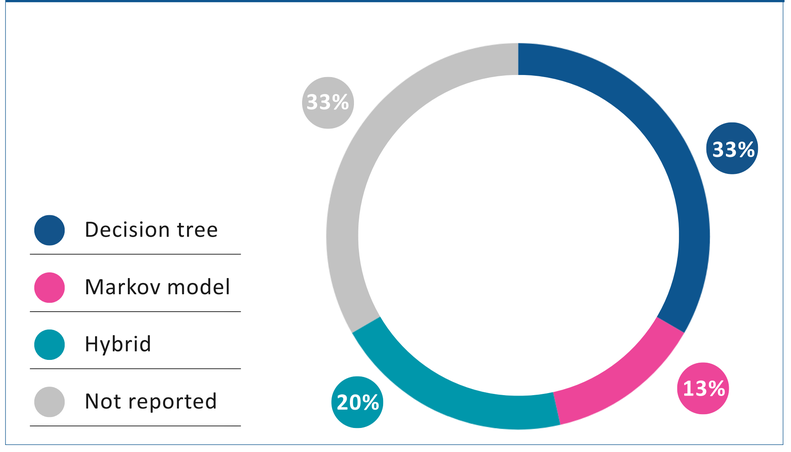
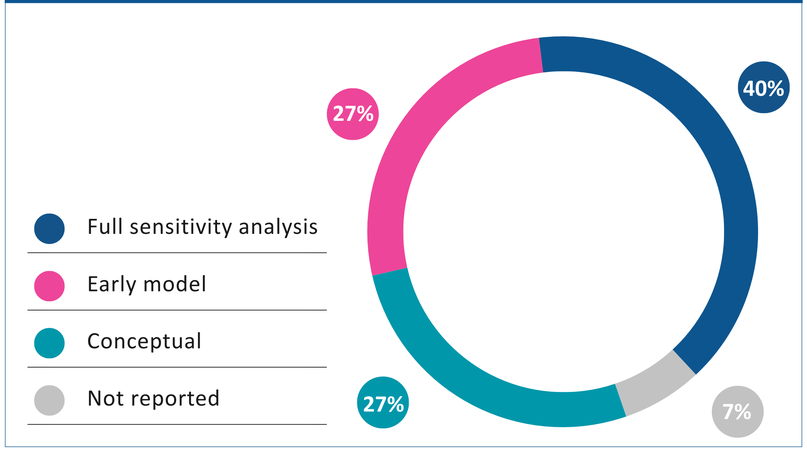


Figure 6. Scope of analysis



Conclusions

Insights

- Comparative evidence was often noted as missing; in the absence of direct data, assumptions of a class effect between DHTs being appraised were frequently made.
- Additionally, discussions around utility values often featured whether the available data aligned with the NICE reference case and subsequently assessed if EQ-5D-3L adequately captures health benefits specific to relevant sub-populations of interest, such as children, or conditions, such as hearing loss and pain.
- The EAGs also highlighted a lack of definition regarding care pathways and stressed the need for clarity regarding the anticipated impact on care/downstream sequelae by the appraised DHTs. This was discussed both in terms of general themes and recommendations by the EAG for future model iterations to undertake more complex discrete event simulation modelling.

References: *1. NICE. Early value assessment interim statement [PMG39]. 2022.*
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Implications

- This research highlights the variety of approaches used in EVAs to produce suitable models despite reported evidence gaps.
- Due to insufficient data, simplification of complex disease and care pathways potentially overlooks impactful costs and outcomes. However, early collaboration with economic experts to identify parameters that are key drivers and signal the value of technologies could guide evidence generation to facilitate faster adoption of innovative technologies through processes like EVA.

Study limitations

- The EVA process has completed a limited number of appraisals to date; however, due to the range of DHTs being appraised through EVA, there was limited generalisability i.e. not all items assessed against were relevant in all appraisals.
- The involvement of different EAGs in the appraisal processes led to inconsistency of reporting when discussing key critiques and future evidence-generation recommendations, making it challenging to compare findings accurately or draw broader conclusions.