Pilot to Practice: Insights from the NICE Early Value Assessment for Digital Health Technologies

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Introduction

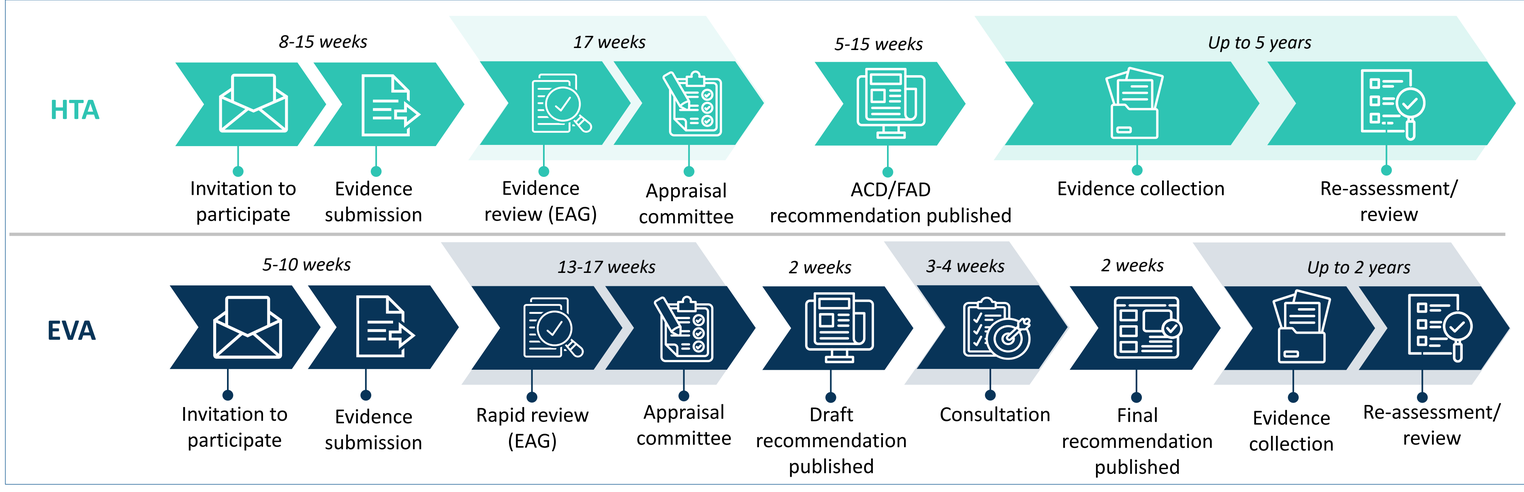
- The National Institute for Health and Care Excellence (NICE) launched the Early Value Assessment (EVA) process in June 2022 to integrate digital health advancements into the National Health Service (NHS) more expeditiously than current processes **(Figure 1)**.
- By conditionally recommending new digital health technologies (DHTs) for use within the NHS, NICE helps address unmet clinical needs and enhances patient care, while allowing time for additional evidence to be gathered on the effectiveness of these technologies.

Methods

- A targeted literature review of published NICE EVAs up to May 2024 was undertaken, and data were extracted from the identified appraisals across several domains: types of technology, therapeutic area, uncertainties identified and recommendations for future research.
- **Figure 2** presents the sample selection process whereby published appraisals were evaluated for relevance and therefore inclusion for review.

Objective: This study aims to evaluate the assessment process of DHTs by NICE through the EVA and to explore their potential early impact on patient care and clinical practice.

Figure 1. NICE HTA and EVA process diagram[1,2]



Abbreviations: ACD, Appraisal consultation document; DHT, digital health technology; EAG evidence assessment group; EVA, early value assessments; FAD, final appraisal document; HTA, health technology assessment; NICE, National Institute for Care and Health Excellence.

Figure 2. Review process

Results

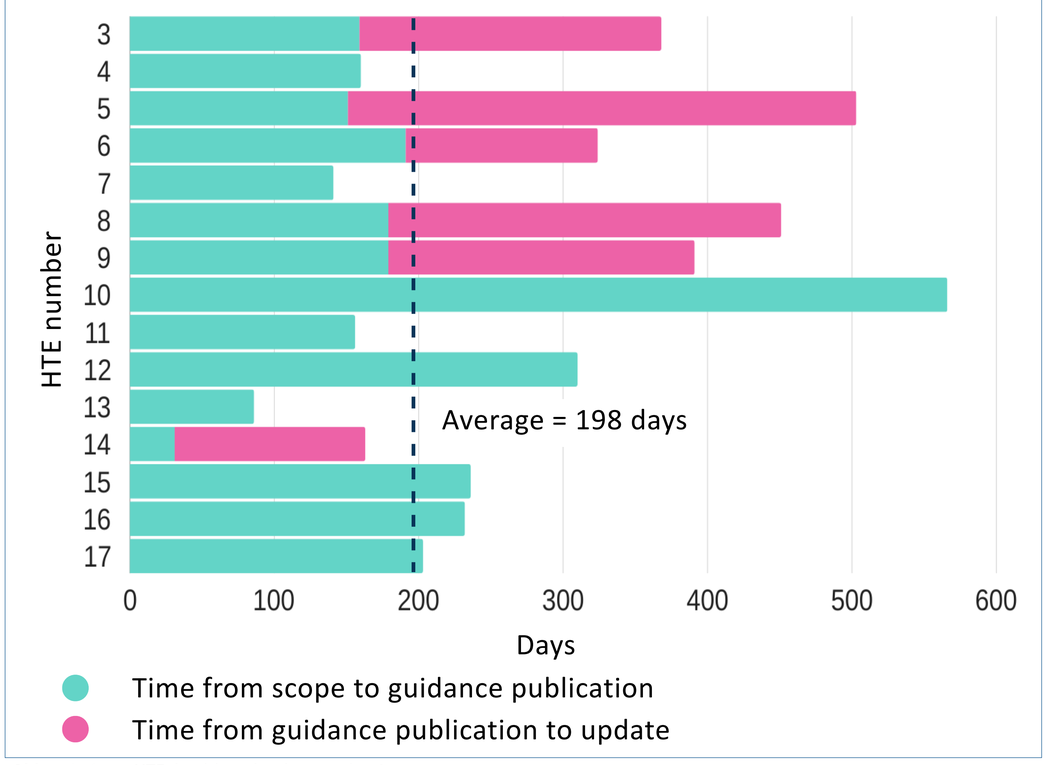
Review process

- Seventeen 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**).

Figure 3. Therapeutic areas

Figure 4. Types of DHT

Figure 5. Time from scope to guidance publication



Abbreviations: HTE, health technology evaluation

General characteristics

- Of the 103 technologies evaluated, 57 were conditionally recommended (55%) for use in the NHS.
- The most frequent therapeutic area reported was mental health (6/15, 40%), followed by oncology (3/15, 20%) as shown in **Figure 3**.
- Technologies that facilitated care from a distance, i.e. patient facing apps or platforms, were the most common type of technology reviewed, (8/15, 53%). Diagnostic tools providing clinical decision support were appraised in six HTEs (6/15, 40%), and only one reviewed a technology concerned with the storing, management or transmission of data **(Figure 4)**.
- On average, it took 199 days from the scope being published to the publication of guidance. Six appraisals have since been updated; on average approximately 218 days later (**Figure 5)**.
- No temporal trend was identified with respect to therapeutic area, as it appears that, to date, NICE consistently appraises a wide range **(Table 1 – colour coded by therapeutic area)**. However, the last five EVAs conducted (HTE 13-17) have all considered technologies that facilitate care from a distance.

Table 1. Overview of key themes discussed in the published guidance

Theme	NICE HTE number														
	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Unmet need	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Equality considerations	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
Information governance and safeguarding			✓			✓	✓	✓	✓				✓	✓	✓
Antibiotic resistance				✓											
Risk management		✓										✓			
Implementation into NHS											✓			✓	
Patient engagement												✓		✓	
Patient/ carer considerations				✓	✓						✓		✓	✓	

Abbreviations: HTE, health technology evaluation; NHS, National Health Service; NICE, National Institute for Care and Health Excellence.

Thematic analysis of published guidance

- The committee primarily focused on themes such as unmet need, equality considerations, and information governance (**Table 1)**. This aligns with broader perspectives on DHTs, which have been slower to adopt, largely due to concerns with information governance, data protection and equity of access.
- Addressing an unmet need was discussed in all but two HTEs, due to the technologies being appraised aiming to innovate testing that was already available.
- **Table 1** also highlights the committee's flexibility in addressing various key themes relevant to the technologies under review. This is particularly evident in the 'Other' therapeutic area, where four themes were discussed in two or fewer appraisals.
- It was also noted that in the later HTEs (13-16) discussions considering the patient engagement and impact on carers and ease of implementation into the NHS were facilitated more frequently.

Conclusions

Access implications

- By evaluating the value of technologies early in their lifecycle through EVA, NICE promotes the rapid adoption of solutions that are both effective and efficient within the NHS.
- This process not only provides guidance to companies on how best to align their innovations given NICE standards, therefore facilitating the faster implementation of technologies that could positively impact patient care, but it also highlights areas for future improvement and focus, ensuring the development of robust evidence for new digital technologies.

Study limitations

- Our results should be interpreted with caution due to the small sample size; as the process is relatively newly established, there have been a limited number of appraisals through EVA. As such, it is worth noting that this research was conducted using only data that were available publicly from NICE within the published guidance and associated documentation.
- As the review was conducted in May 2024, any subsequent updates in guidance, regulations, or specific digital health technology are not reflected in this study.

References: 1: *NICE. Early value assessment interim statement [PMG39]. 2022,* ***2****: NICE. Early Value Assessment (EVA) for MedTech. 2024.*
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