Adoption and Evidence Generation in NICE Early Value Assessments (EVA) for Medtech: Trends Across 2023–2025

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01 BACKGROUND

- The Early Value Assessment (EVA) programme was introduced by England's National Institute for Health and Care Excellence (NICE) in 2022 to enable faster access to promising health technologies in areas of unmet need, while real-world evidence is generated.[1]
- By recommending conditional National Health Service (NHS) use of digital, diagnostic, and artificial intelligence (AI)-driven interventions with limited clinical evidence, EVA supports innovation uptake ahead of standard appraisal timelines[1].
- Unlike technologies assessed through NICE's established Technology Appraisal (TA) programme,[2] EVA outputs are published as Heath Technology Evaluations (HTEs) under a separate process. While TAs provide recommendations following full assessments, HTEs use streamlined and pragmatic HTA methodology (adaptive HTA) to allow conditional NHS access.[1,2] EVAs provide a recommendation alongside an evidence generation plan with three-year evidence cycles,[1] making EVA an important complementary route for technologies that require earlier access pathways.
- However, the economic modelling within EVAs is often constrained by time, data gaps, and structural uncertainty, resulting in reliance on conceptual frameworks rather than full cost-effectiveness models[3].
- Understanding how NICE navigates adoption decisions and evidence requirements can inform future policy and methodological refinement.[4,5]
- EVA reflects the broader international trend toward adaptive HTA, seen in models such as coverage with evidence development (CED) in France and the Netherlands, or conditional reimbursement pathways in Canada and Germany.[4,5]

02 OBJECTIVES

- This study aimed to evaluate trends in recommendations, evidence generation plans, and post-assessment changes to availability across all NICE Early Value Assessments Health Technology Evaluations (HTEs) published from February 2023 to May 2025.

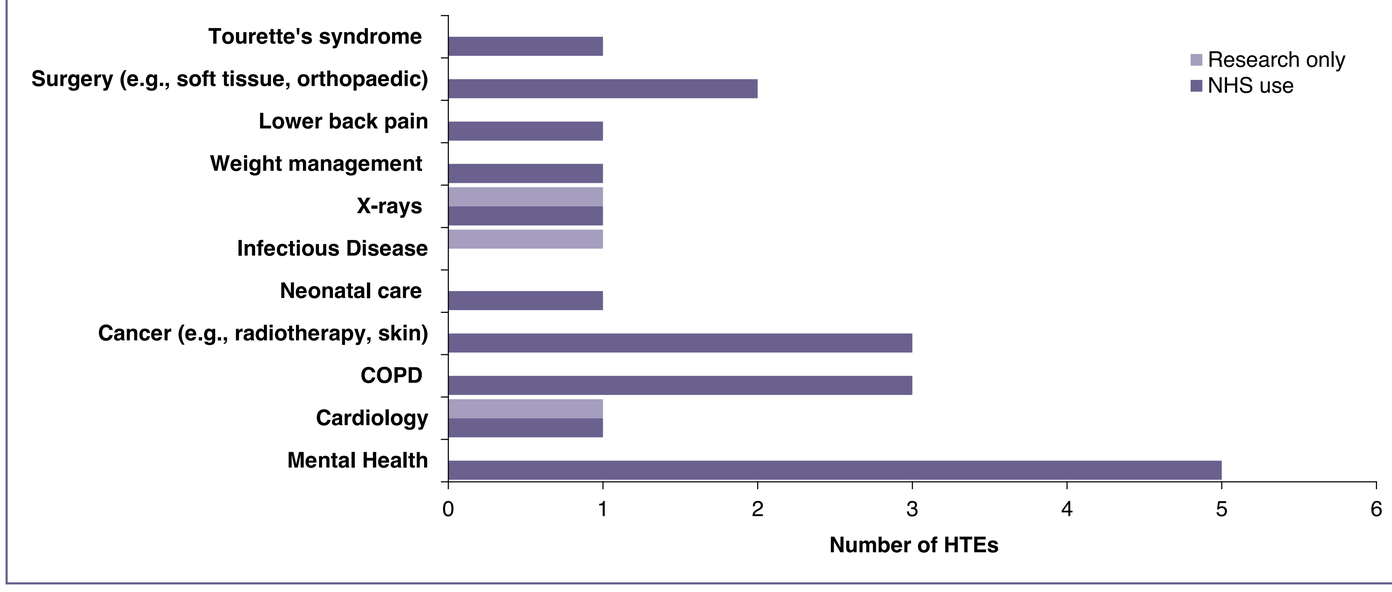
03 METHODS

- All 22 NICE HTEs published between 01.02.2023 and 31.05.2025 were reviewed.
- Key data fields extracted included: initial recommendation, disease area, technology type, recommendation outcome, evidence generation plans, and post-publication changes (e.g., withdrawal).
- Thematic analysis was used to group common evidence gaps and classify access type (NHS with conditions, research only, withdrawn).
- Frequencies and percentages were calculated for adoption trends, and references to common study designs and evidence priorities were coded.

04 RESULTS

Figure 1 shows the range of clinical areas covered in the HTEs. Mental health was the most frequently included area (23% of HTEs), followed by cancer and chronic obstructive pulmonary disease (COPD) (14% of HTEs each).

Figure 1: Clinical areas in HTEs



- **86% (19/22) of technologies were conditionally approved for NHS use while further evidence was generated, with the remaining two restricted to research-only access.** 41% of HTEs then underwent post-evaluation changes to availability, as outlined in **Table 1**.
- Three-year evidence cycles were required for conditional adoption under the EVA framework, and before-after or parallel cohort study designs were commonly recommended by NICE, with emphasis on diverse population representation and standardised outcome tracking.

Table 1: Post-evaluation outcomes of NICE HTEs

Post-evaluation changes	Number of HTEs	% of total
No change	13	59
Updated recommendation	6	27
Withdrawn due to (CE/DTAC)*	3	14

*CE: Conformité Européenne — the manufacturer's declaration that products meet EU safety, health, and environmental protection standards.
*DTAC: Digital Technology Assessment Criteria — a UK framework used to assess digital health technologies for usability, interoperability, clinical safety, and data protection.[3]

Figure 2: Technology types in HTEs

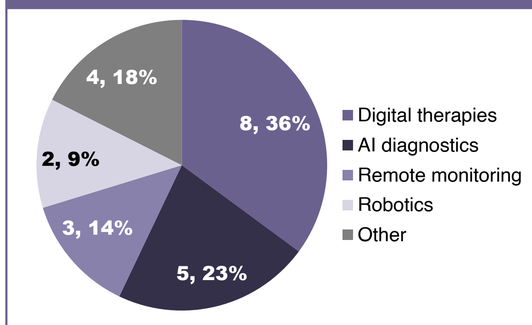
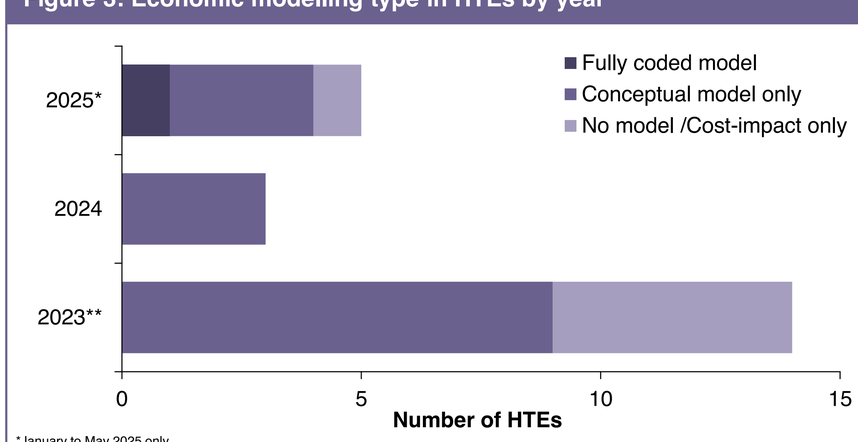


Figure 2 shows the evaluated technology types in HTEs. The most common technology was digital therapies (36%), followed by AI/diagnostics (23%), remote monitoring (14%) and robotics (9%).

Figure 3 shows how the number of evaluations and the economic evaluation types have changed over time. Conceptual modelling has been the most common model type over the three years of the EVA programme.

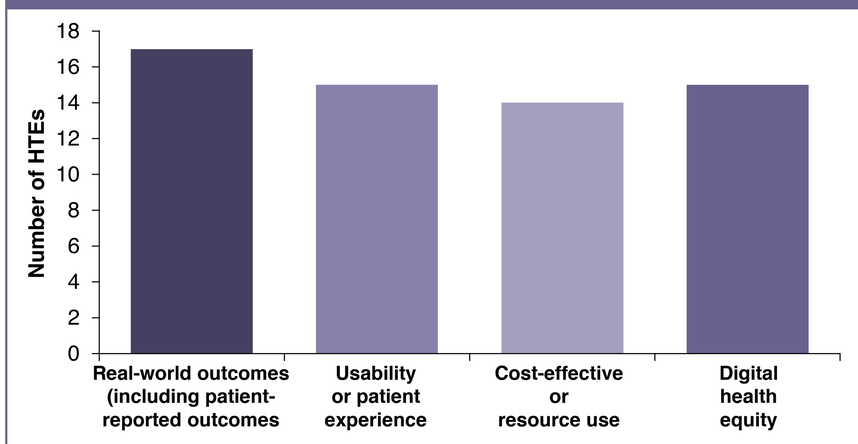
Figure 3: Economic modelling type in HTEs by year



*January to May 2025 only.
**February to December 2023 only.

- Evidence gaps were commonly observed in HTEs (**Figure 4**). The most observed evidence gap was real-world outcomes (77% of HTEs), followed by usability or patient experience and digital health equity (68% of HTEs each), and cost-effectiveness or resource use (64% of HTEs).

Figure 4: Most common evidence gaps in HTEs



05 DISCUSSION AND CONCLUSIONS

- The NICE EVA programme has made considerable progress in helping to accelerate access to promising MedTech and digital health solutions.
- 86% of technologies assessed since 2023 were recommended for use with ongoing evidence generation, signalling NICE's willingness to manage uncertainty in favour of early access. This also reflects policy priorities around supporting innovation, particularly in under-served clinical areas.
- However, several barriers continue to limit the long-term success of this approach:
  - Economic modelling remains inconsistent: 68% of 2025 assessments still rely on conceptual frameworks or cost-impact analyses rather than fully coded cost-effectiveness models due to short timelines, limited data, and uncertainty in care pathways. Strengthened pre-submission guidance for developers with clear expectations for minimum modelling standards tailored to each technology type and improvement to open-source adaptable cost-effective models that support consistent method across similar technologies are required.
  - Key evidence gaps including real-world outcomes (77%), usability or patient experience (68%), digital health equity (68%), and cost-effectiveness or resource use (64%) are frequently cited, yet often weakly addressed in submitted evidence generation plans.
  - Nearly half of the technologies experienced post-evaluation changes in availability, with some withdrawn due to failure to meet regulatory requirements such as CE marking or DTAC approval. This highlights the need for more coordinated pre-assessment alignment between developers, regulators, and evaluators to further streamline the process.

References

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