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Standardising HealthTech Evidence to Meet NICE Expectations

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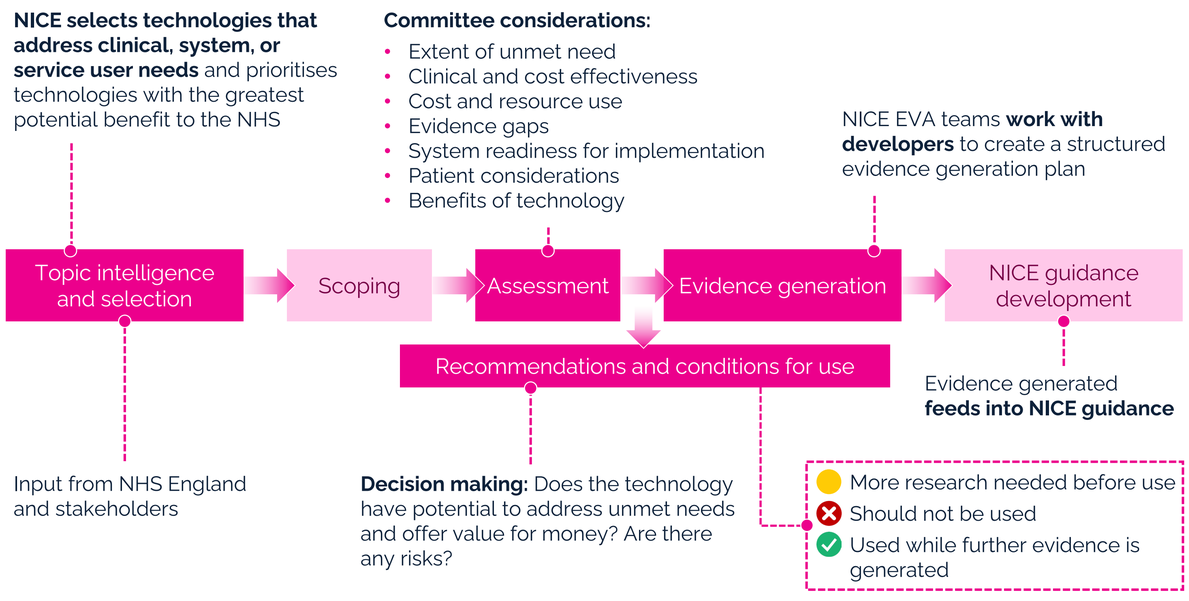
INTRODUCTION

- Technological innovation offers significant opportunities to improve patient outcomes and NHS efficiency in England. Ensuring that effective, cost-efficient technologies reach patients early remains a key priority for the NHS and NICE.[1]
- In 2022, NICE launched the Early Value Assessment (EVA) pilot to advance this goal. EVAs provide early guidance on promising non-pharmaceutical health technologies — such as digital tools, medical devices and diagnostics — with emerging evidence, enabling earlier patient access while additional data are gathered.[2]
- As shown in **Figure 1**, the EVA process includes key stages from topic selection and assessment to evidence generation and guidance development. Technologies are prioritised by unmet clinical need and potential benefit to the NHS. NICE then collaborate with developers to create evidence generation plans which will, ultimately, lead to recommendations on technology adoption.

Figure 1: Key stages in the EVA process



- As technological progress accelerates, health technology assessment and reimbursement systems must evolve to ensure innovations are identified, evaluated, and adopted for maximum population benefit.
- Accordingly, NICE is reforming its HealthTech programme, integrating its previous evaluation routes into a single, flexible framework that supports evidence generation across the lifecycle of medical and digital technologies.

BACKGROUND

- Since the EVA rollout in 2022, NICE's methods and expectations have continued to evolve.
- **An earlier review (2024) identified**[3,4]:

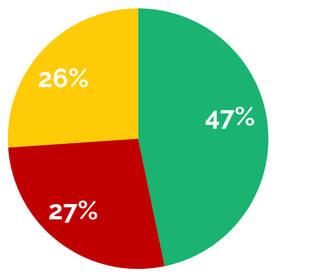
14 published EVAs

90 technologies assessed

Digital: mental health, diet, MSK, respiratory, oncology

Diagnostics: cardiology, oncology, urinary, neonatal

Outcomes

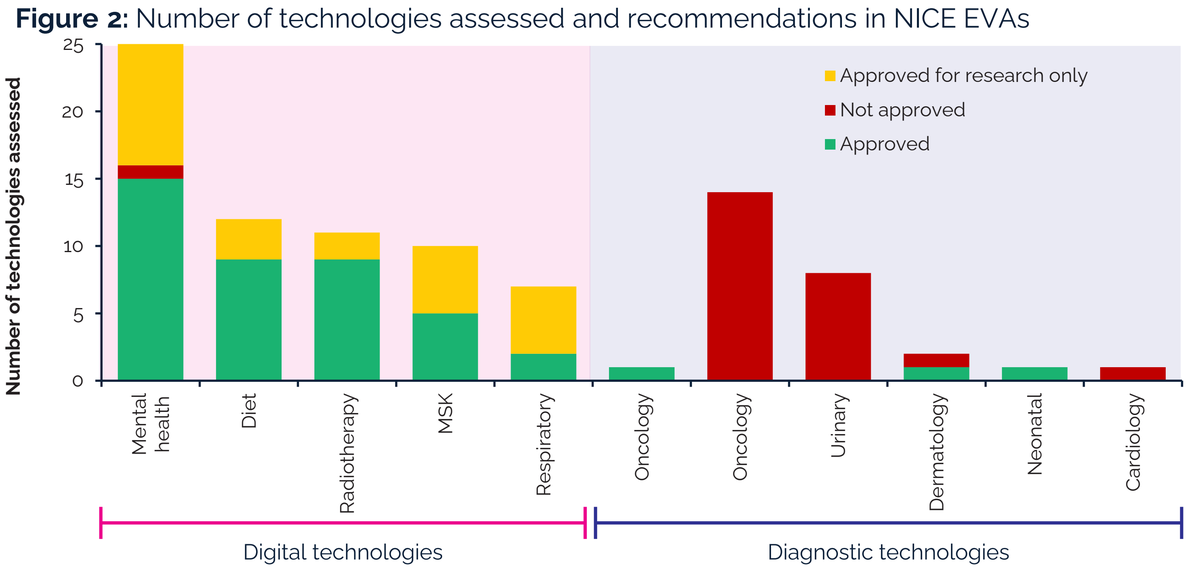


Drivers of Positive Outcomes
- Emerging benefit
- NHS-ready
- Evidence plan in place

Factors Limiting Early Use
- Weak/limited data
- Uncertain cost-effectiveness
- Safety/performance concerns

- **Figure 2** shows that digital technologies achieved a higher proportion of positive EVA recommendations than diagnostic tools.
- Digital solutions, particularly in mental health, demonstrated stronger evidence and readiness for NHS use.
- In contrast, diagnostic technologies, especially in oncology and urinary testing were often not recommended due to limited validation data, uncertain clinical impact, and safety concerns such as the risk of missed cancer diagnoses.

Figure 2: Number of technologies assessed and recommendations in NICE EVAs



OBJECTIVES

- As NICE undergoes reform of its HealthTech programme, there remains uncertainty around how EVAs are being conducted and how decision-making criteria are evolving.
- The objective of this study was to reduce this uncertainty by extending and updating the 2024 review of published EVAs, examining:
  - Changes in the types of evidence submitted and reviewed,
  - Patterns in recommendations and evidence generation plans, and
  - Insights into how NICE's evolving framework may influence future technology assessments.

METHODS

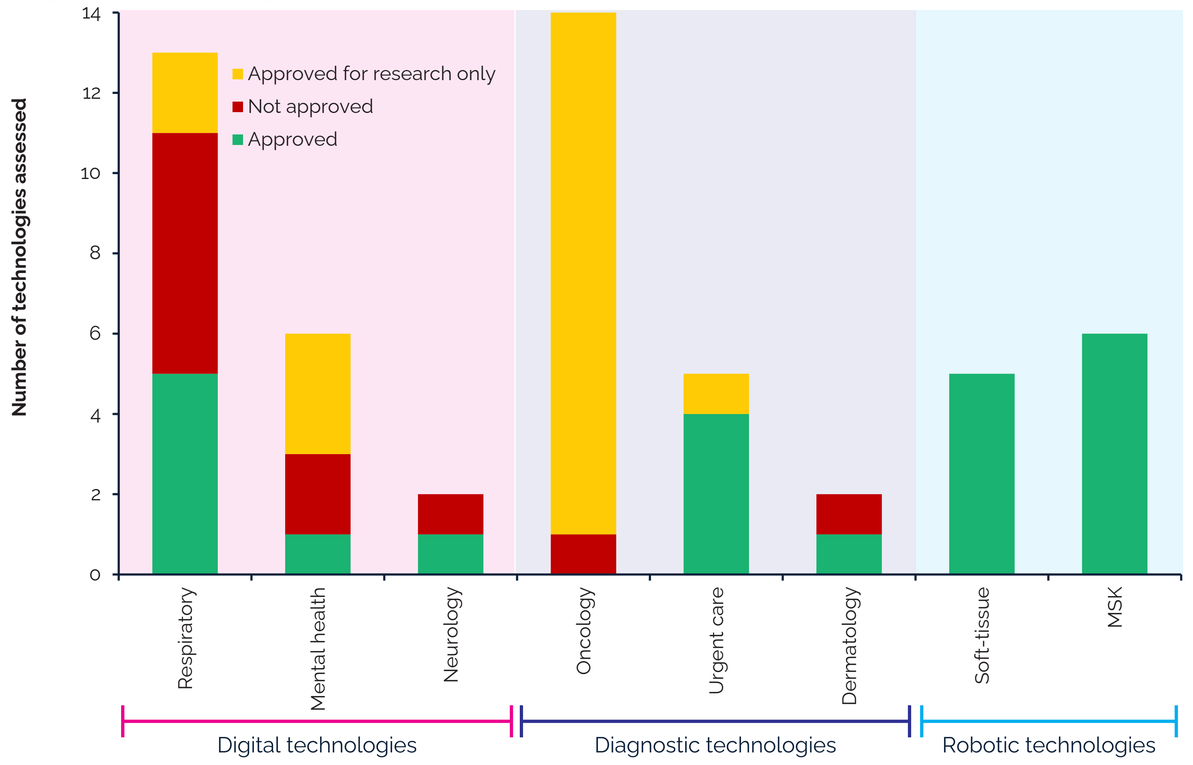
- All EVAs published between Oct 2024 and June 2025, plus updates to existing EVAs, were identified for review from the NICE website (www.nice.org.uk).
- For each EVA, the guidance document and evidence generation plan were reviewed. Data on the technologies, clinical and economic evidence, potential benefits, and evidence generation plans were extracted.
- The data were analysed qualitatively (including the identification of common patterns in evidence types/recommendations) and quantitatively (including descriptive statistics).

RESULTS

2025 Update*

- Eight EVAs were identified that were published between October 2024 and June 2025[4]
- These involved 53 technologies, of which 23 (~43%) were recommended, **Figure 3**.
- Indications included respiratory, mental health, neurology, oncology, urgent care, dermatology, soft-tissue and musculoskeletal. Technologies included digital, diagnostic, artificial intelligence (AI), and robot assistance.

Figure 3: Technologies assessed and recommendations in NICE EVAs this year



- EVA activity has accelerated, with 53 technologies assessed in just eight months (Oct 2024–Jun 2025) compared with 90 over 2022–2024, showing growing developer engagement and a more efficient process.
- EVA technologies span several key areas, with many focused on mental health, oncology, respiratory, and musculoskeletal conditions — broadly reflecting the NHS 10-Year Plan priorities around digital mental health support, early cancer diagnosis, and improved management of long-term conditions.
- Assessment patterns are evolving, compared with the 2024 review, diagnostic approvals have increased — particularly in oncology where more technologies are approved for research use; digital tools now face greater scrutiny on evidence and cost-effectiveness, 2025 saw the first EVA assessments of AI-assisted robotic surgery.

Evolving Considerations and Limitations

- The latest EVA assessments show growing focus on AI and robotics, stronger governance and equity safeguards, and clearer evidence-generation plans across digital and diagnostic tools (**Table 1**)

Table 1: Summary of findings from the NICE assessments

Topic	Considerations and limitations for 2024-2025 EVAs
Clinical & safety evidence	Newer EVAs include defined real world evidence (RWE) outcomes but continue to highlight challenges with AI safety, deskilling risks, and the need for ongoing performance monitoring
Economic & implementation	Efficiency gains are reported for digital tools, but robotic platforms face high setup costs and uncertain cost-effectiveness
Patient considerations	Evaluations now embed equity measures, from digital inclusion in chronic obstructive pulmonary disease (COPD) tools to skin-tone and subgroup safeguards in AI and robotics
Technology considerations	DTAC compliance and structured evidence plans are standard, though issues persist around data security, ethics, and product continuity

CONCLUSIONS

- Recent EVAs highlight NICE's growing emphasis on robust, standardised, and transparent evidence generation.
- While digital, AI, and robotic technologies continue to expand the scope of evaluations, persistent uncertainty remains around long-term clinical outcomes, cost-effectiveness, and data quality.
- To align with NICE's evolving HealthTech framework, developers should prioritise consistent methodologies, validated outcome measures, and high-quality real-world and economic evidence to support early but reliable adoption within the NHS.

REFERENCES

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2. Early Value Assessment (EVA) for medtech, accessed at https://www.nice.org.uk/what-nice-does/our-guidance/about-medical-technologies-guidance/early-value-assessment-eva-for-medtech;
3. Brennan et al (2024) Early Value Assessments (EVAs) for MedTech by NICE. What can we learn so far? Poster presented at ISPOR EU.
4. NICE EVAs published from 2022 to June 2025: HTE3-9, HTE11-12, HTE14-22, HTE24-25. Available at: https://www.nice.org.uk/guidance/published?ngt=Health+technology+evaluations

ABBREVIATIONS:

AI, Artificial Intelligence; EVA, Early Value Assessments; MSK, Musculoskeletal; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; RWE, real world evidence

* The number of technologies included in the poster differs slightly from the abstract, as technologies were initially omitted if they were no longer commercially available within the UK. However, for completeness we have now included all assessed technologies, recognising that even withdrawn technologies can provide valuable insights

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