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Early Value Assessments (EVAs) for MedTech by NICE. What can we learn so far?

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INTRODUCTION

- Technological advances offer significant opportunities to improve patient care within the NHS. To optimise these opportunities, the NHS must identify which technologies provide the best value for money and ensure early access for patients.
- In 2022, NICE launched their Early Value Assessments (EVA) programme to facilitate this process.
- The EVA approach enables a rapid, and early, evaluation of digital products, devices and diagnostics in terms of their clinical effectiveness and value for money.

Table 1. Overview of the EVA programme

TOPIC	OVERVIEW
Eligibility criteria	Technologies must: • be appropriately CE/UKCA marked, and have DTAC approval (digital technologies). • have the potential for patient and system benefit in an area of unmet need. • be supported by healthcare professionals and the healthcare system. • need further data collection or evidence generation.
Value assessment	Technologies are reviewed by a committee who consider: • the extent of an unmet need; clinical effectiveness; costs and resource use; evidence gaps; system readiness for implementation; patient considerations; benefits of the technology.
EVA outcomes	• A recommendation for early use/no recommendation for early use in the NHS is made. • The conditions of the recommendation are reported and may include the key outcomes to be collected in evidence generation along with the timeframe for collection. • Companies are given the opportunity, and facilitation, to work with stakeholders who can help with further data collection and analysis. • Following evidence generation NICE will re-review and develop full NICE guidance.

OBJECTIVES

- This research provides an overview of the technologies selected for the EVA programme to date, along with a summary of the key learnings from the submissions, including insights into the evidence reviewed and recommendations made.

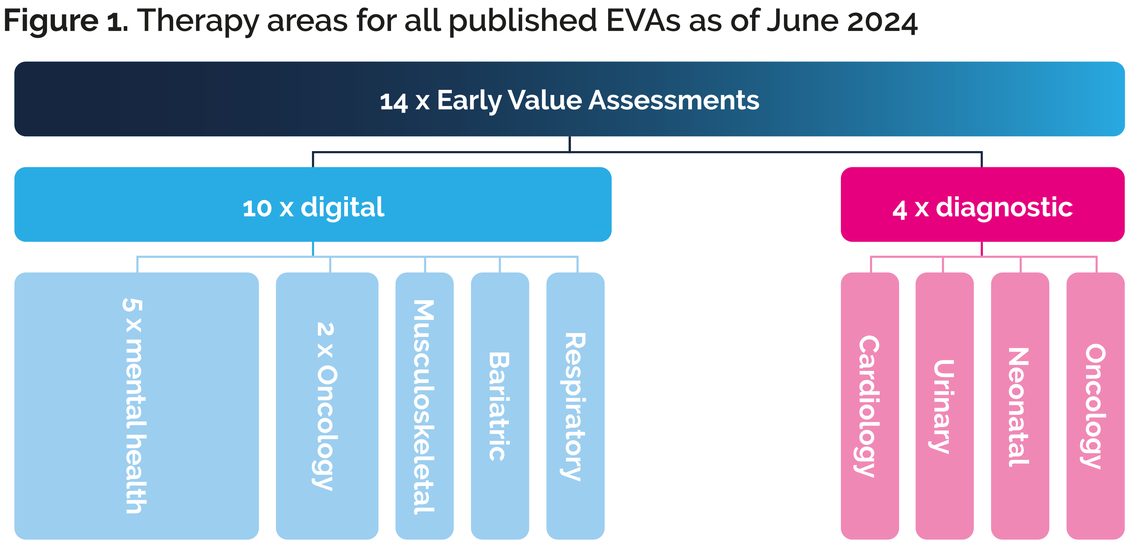
METHODS

- All EVA's published at the time of the review (October 21st, 2024) were included.
- For each EVA, the guidance document and evidence generation plan were reviewed.
- Data were extracted on the technology (type, number of technologies assessed/recommended), clinical evidence (evidence submitted, clinical-effectiveness, safety), economic evidence (evidence submitted/reviewed, findings), potential benefits and evidence generation plan.
- The data were analysed qualitatively and quantitatively.

RESULTS

- Fourteen EVAs were identified: 10 included digital technologies and four included diagnostics. Of the digital technologies, 5 were for mental health indications, and 5 for bariatric, respiratory, musculoskeletal and oncology indications. Indications for the diagnostics were cardiology, oncology, urinary and neonatal. An overview of therapy areas for all published EVAs is provided in **Figure 1.**

Figure 1. Therapy areas for all published EVAs as of June 2024



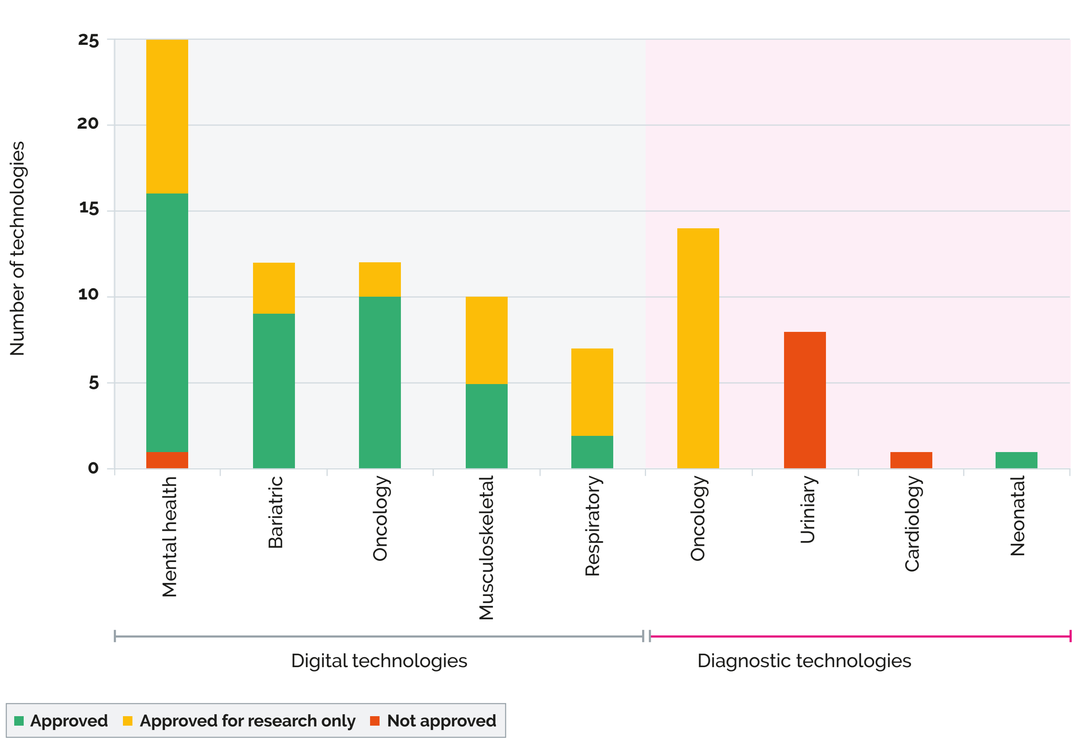
- From the 14 EVAs, a total of 90 technologies were assessed, some within multiple indications.
- Forty-two technologies were recommended for use alongside data collection. Where a technology was not recommended, and had UKCA approval, NICE stipulated it should only be accessed through company, research or non-core NHS funding.
- NICE reviewed the available evidence for each technology to assess potential benefits of its use to the NHS. An overview of the strengths, identified in EVAs resulting in positive recommendations, and limitations, reported as reasons for non-approval, are presented in **Table 2.**

RESULTS (CONT)

Table 2. Summary of findings from the NICE assessments

TOPIC	STRENGTHS	LIMITATIONS
Clinical evidence	• RCTs are essential for demonstrating non-inferiority or superiority compared to face-to-face or usual care. • RWE is sought to show benefits in clinical outcomes such as symptom reduction, QoL and adherence.	• Limited or no clear evidence of clinical outcomes compared to existing treatments and lack of long-term data especially for chronic conditions. • Lack of sufficient RWE to support widespread routine use in an NHS setting. • Lack of UK specific data - leading to uncertainty in the generalisability of results.
Safety data	• Detailed documentation of AEs with recommendations on addressing any patient safety concerns.	• Inconclusive safety data – insufficient safety data or potential risks associated with the use of digital or AI-driven solutions over conventional methods.
Economic evidence	• Demonstration of cost-effectiveness or cost-savings in an NHS setting. • Resource use – evidence of improvement in efficiency, e.g. reduced waiting times, increased patient access.	• Uncertain cost implications or cost-effectiveness and impact on healthcare resources – inconclusive cost models or lack of ability to demonstrate cost-effectiveness over standard of care. • Uncertainty of costs related to resource use, implementation and maintenance.
Patient considerations	• Addressing potential access issues such as digital literacy, culture considerations, patient preference and adherence.	• Patient barriers – issues with accessibility such as internet access or socio-economic barriers.
Technology considerations	• Ensuring data security and data privacy.	• Technology issues - concerns around data security, privacy or ethical issues related to patient data collection and/or use.

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



- **Figure 2** provides an overview of the technologies which have gone through the EVA programme and preliminary outcomes. It shows that low levels of diagnostic technologies have received early recommendation alongside data collection compared with other digital technologies. Reasons for this include concerns that the use of software to facilitate diagnostic imaging reviews could lead to missed cancer diagnoses; concerns that the technical performance and accuracy of tests are unsubstantiated; and uncertainty on the impact of some diagnostic tests on subsequent treatments.

CONCLUSIONS

- The EVA approach enables a rapid, early, evaluation of a technology's clinical effectiveness and value for money.
- Although selected technologies have a limited evidence base, approval alongside an evidence generation plan still requires sufficient evidence to show potential clinical or cost benefits.

REFERENCES

1. NICE Early Value Assessment (EVA) for medtech. Available at: https://www.nice.org.uk/about/what-we-do/eva-for-medtech Accessed on 30th May 2024.

2. NICE Published: Guidance, quality standards and advice. Available at: https://www.nice.org.uk/guidance/published?q=early%20value&ndt=Guidance&ngt=Health%20technology%20evaluations Accessed 21 October 2024.

Abbreviations: AEs, adverse events; CE, Conformité Européene; DTAC, digital technology assessment criteria; EVA, early value assessment; NHS, NHS; NICE, National Institute for Health and Care Excellence; QoL, quality of life; RCT, randomised controlled trial; RWE, real world evidence; UKCA, United Kingdom Conformity Assessment; UK, United Kingdom.

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