

BACKGROUND

Context: The growing interest in artificial intelligence (AI)-enabled technologies in healthcare presents novel opportunities and challenges for health technology assessment (HTA) agencies.¹

- However, the unique characteristics of AI such as algorithmic learning, data dependency, and limited clinical validation necessitate adapted or novel assessment frameworks.²
- The UK's National Institute for Health and Care Excellence (NICE) and Canada's Drug Agency (CDA) are at the forefront of evaluating such innovations.

Objective: This study aims to analyze and provide insights on HTA submitted to NICE and CDA for AI-enabled technologies.

METHODS

- Searches were conducted on the NICE and CDA websites.
- The HTA submissions evaluating the AI-enabled technologies submitted to the NICE and CDA, from data inception to May 2025, were identified.
- The relevant submissions were reviewed thoroughly, and data extraction was conducted.
- The data were extracted on disease indication, utility of AI-enabled technology, HTA decision drivers, key critiques, and final recommendations.

RESULTS

- The searches identified six HTA submissions, of which **five were submitted to the NICE**, and one was submitted to the CDA.
- All HTAs were for **AI-enabled software used for detection of diseases** (Figure 1).
- Table 1** presents the AI technologies evaluated in each of these submission.
- Majority of submissions were **early value assessments** (4/6; 68%).
- Most appraisals resulted in **conditional recommendations (5/6, 85%)** (Figure 2), if the evidence outlined in the evidence generation plan is being generated and after appropriate regulatory approval including NHS England's Digital Technology Assessment Criteria (DTAC) approval; none was fully recommended, and **one was not recommended**.
- The main HTA decision drivers affecting the HTA recommendation of technologies are presented in Figure 3.
- There were many critiques or limitations associated with the HTA recommendations, with majority being AI-related. These included **uncertainty around methods used to develop AI models, AI accuracy, uncertainty around AI algorithms**, etc.
- Other critiques included limited evidence for **different population subgroups, lack of data in routine care settings as compared to laboratory settings, underestimation of costs due to lack of real-world evidence and uncertainty around the parameters**.

Figure 1. Number of HTA submissions used for different disease detection

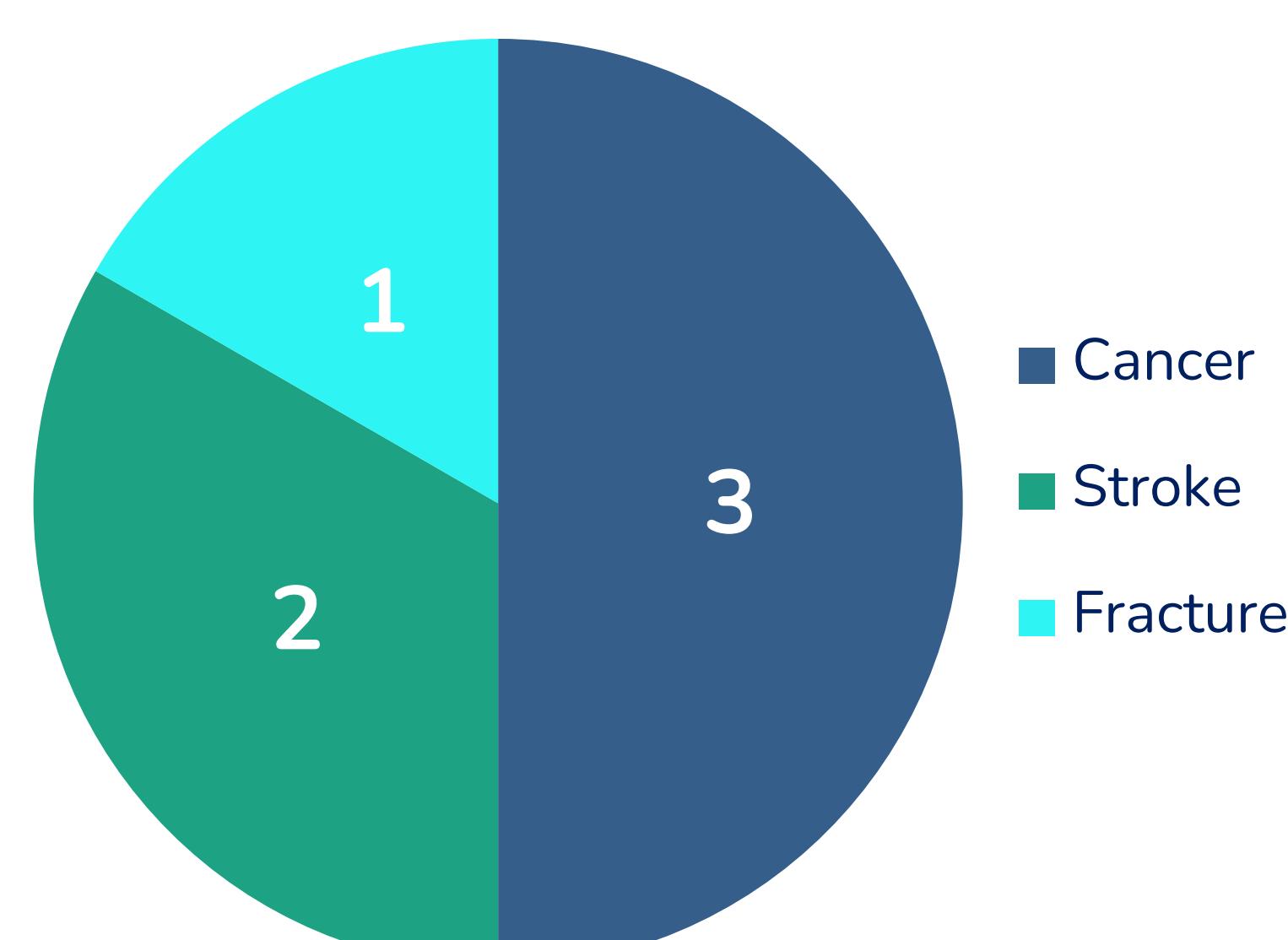


Figure 2. HTA recommendations by agencies



Figure 3. Key HTA decision drivers in the submissions

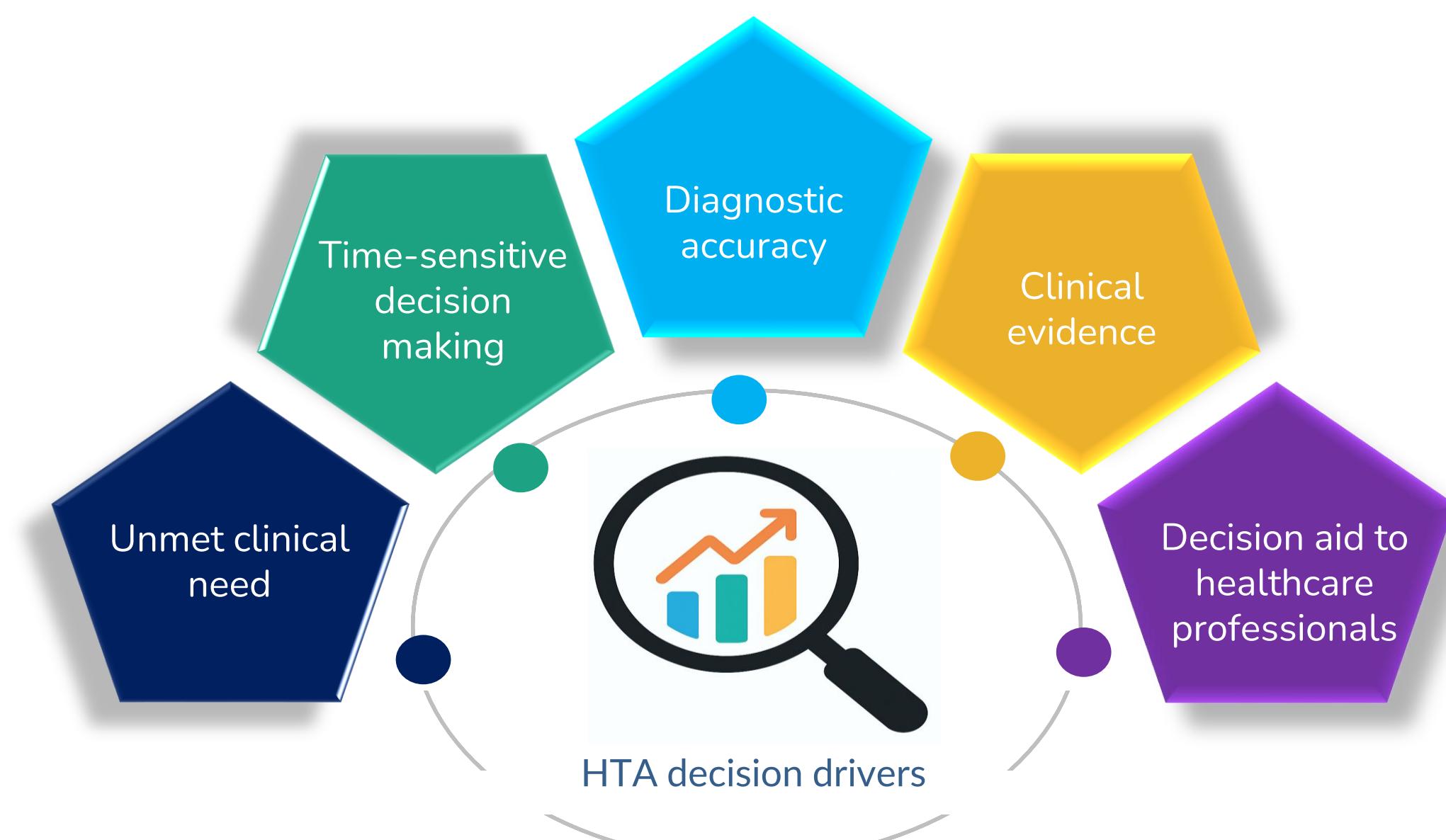


Table 1. AI health technologies evaluated in HTA submissions

HTA body	Title	Name of AI health technology
NICE ³	AI technologies for assessing and triaging skin lesions referred to the urgent suspected skin cancer pathway: early value assessment	DERM (Deep Ensemble for Recognition of Malignancy)
NICE ⁴	AI-derived software to analyse chest X-rays for suspected lung cancer in primary care referrals: early value assessment	<ul style="list-style-type: none"> AI-Rad Companion Chest X-ray (Siemens Healthineers) Annalise CXR (Annalise ai) Auto Lung Nodule Detection (Samsung) ChestLink (Oxipit) ChestView (Gleamer) Chest X-ray (Rayscape) ClearRead Xray (Riveraintech) InferRead DR Chest (Infervision) Lunit INSIGHT CXR (Lunit)\ Milvue Suite (Milvue) qXR (Qure.ai) SenseCare-Chest DR PRO (SenseTime) VUNO Med-Chest X-Ray (VUNO)
NICE ⁵	AI technologies to help detect fractures on X-rays in urgent care: early value assessment	<ul style="list-style-type: none"> Rayvolve TechCare Alert BoneView RBfracture.
NICE ⁶	AI-derived software to help clinical decision making in stroke	<ul style="list-style-type: none"> AI based software e-Stroke RapidAI Viz.
NICE ⁷	AI technologies to aid contouring for radiotherapy treatment planning: early value assessment	<ul style="list-style-type: none"> AI-Rad Companion Organs RT (Siemens Healthineers) ART-Plan (TheraPanacea, Oncology Systems; Brainlab) DLCExpert (Mirada Medical) INTContour (Carina Medical) Limbus Contour (Limbus AI, AMG Medtech) MIM Contour ProtégéAI (MIM Software) MRCAT Prostate plus Auto-contouring (Philips) MVision Segmentation Service (MVision AI Oy, Xiel) RayStation (RaySearch).
CDA ⁸	RapidAI for Stroke Detection ⁶	RapidAI (AI software)

There are limited number of HTA submissions for AI-enabled technologies. With increasing significance of innovative AI based health technologies, there is a need to develop novel methodological guidelines/ frameworks to assist the decision makers.

DISCUSSION

- A tailored HTA framework for AI-based medical devices can assess their effectiveness, cost-efficiency, and societal impact to guide responsible implementation and maximize healthcare benefits.
- Defining key expertise within the framework will help building a skilled workforce capable of performing rigorous and reliable HTAs for AI-based medical technologies.²

REFERENCES

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