Assessment criteria supporting implementation and reimbursement of responsible AI systems (incl. HTA Labs)

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ESC European Society of Cardiology

About NICE

NICE helps practitioners and commissioners get the best care to people, fast, while ensuring value for the taxpayer.

We do this by:

Producing useful and usable guidance for health and care practitioners.

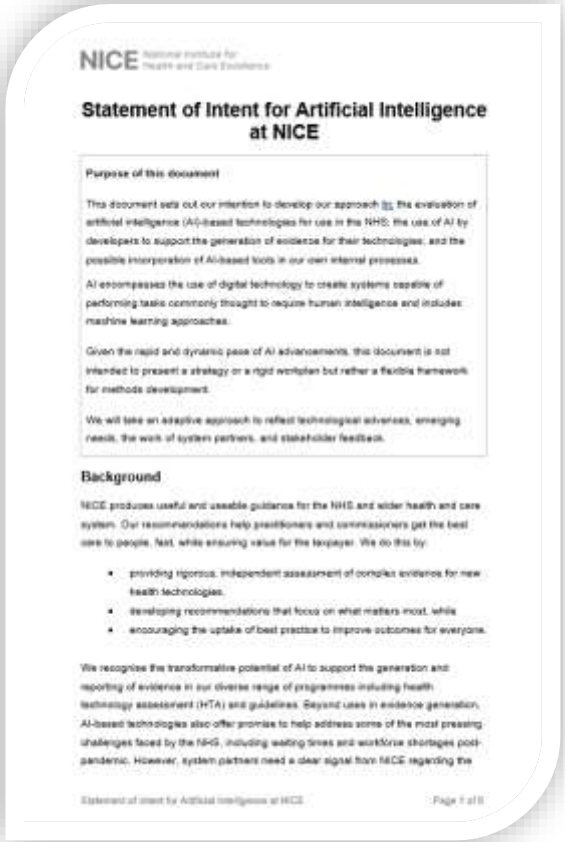
Focusing on what matters most by prioritising topics that are most important to the health and care system or address an unmet need.

Providing rigorous, independent assessment of complex evidence for new health technologies.

Encouraging the uptake of best practice to improve outcomes for everyone.

NICE's Statement of Intent for AI

- **Outlines NICE's intent within the 3 priority areas: AI in evidence, HTA of AI tech, and use of AI internally**
- **Signals NICE's approach to:**
  - adopt an agile approach to a fast-moving field,
  - safely balance opportunities and risks,
  - adhere to best practice and government standards, and
  - maintain our core principles that underpin NICE's work.
- **Highlights the need to collaborate with key experts and stakeholders to develop evidence requirements and pilot new tools**
- **Published on a dedicated AI-space on NICE's website**



NICE

Statement of Intent for Artificial Intelligence at NICE

Purpose of this document

This document sets out our intention to develop our approach to the evaluation of artificial intelligence (AI)-based technologies for use in the NHS; the use of AI by developers to support the generation of evidence for their technologies; and the possible incorporation of AI-based tools in our own internal processes.

AI encompasses the use of digital technology to create systems capable of performing tasks commonly thought to require human intelligence and includes machine learning approaches.

Given the rapid and dynamic pace of AI advancements, this document is not intended to present a strategy or a rigid workplan but rather a flexible framework for methods development.

We will take an adaptive approach to reflect technological advances, emerging needs, the work of system partners, and stakeholder feedback.

Background

NICE produces useful and useable guidance for the NHS and wider health and care system. Our recommendations help practitioners and commissioners get the best care to people, fast, while ensuring value for the taxpayer. We do this by:

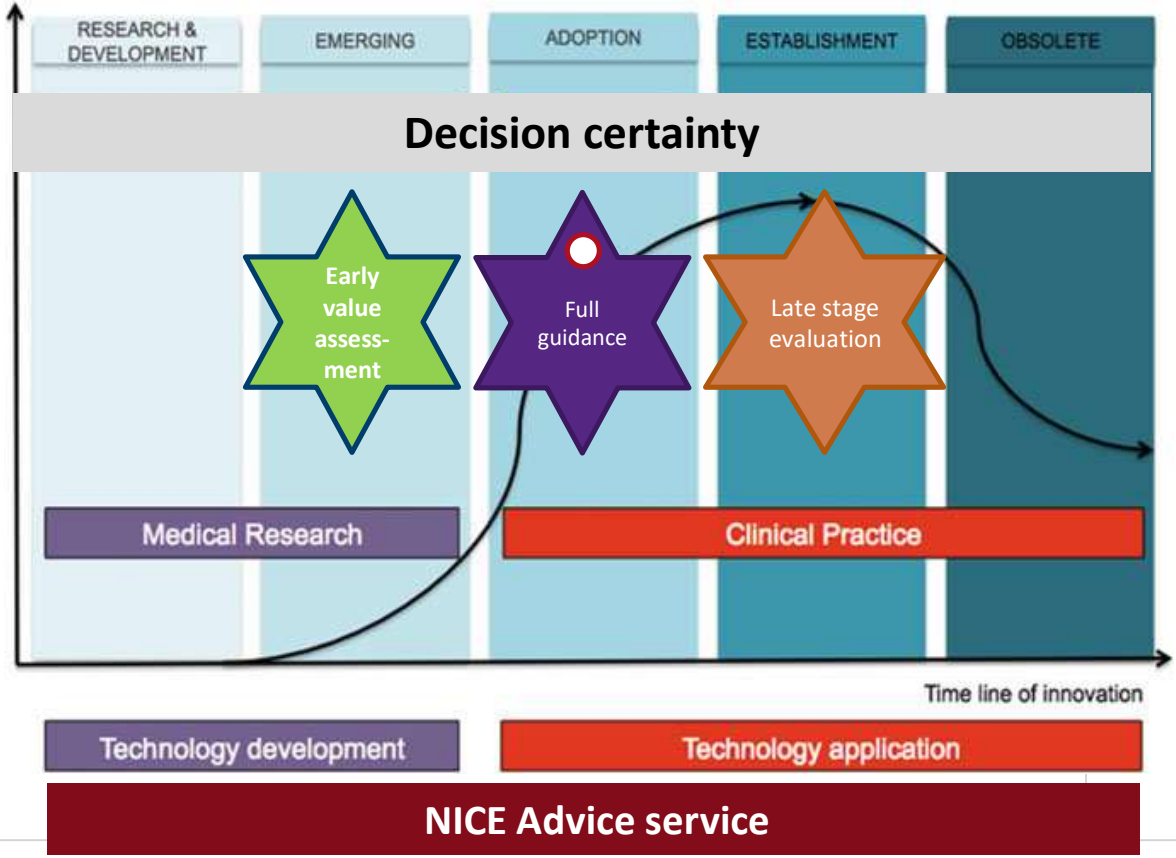
- providing rigorous, independent assessment of complex evidence for new health technologies
- developing recommendations that focus on what matters most, while
- encouraging the uptake of best practice to improve outcomes for everyone.

We recognise the transformative potential of AI to support the generation and reporting of evidence in our diverse range of programmes including health technology assessment (HTA) and guidelines. Beyond uses in evidence generation, AI-based technologies also offer promise to help address some of the most pressing challenges faced by the NHS, including waiting times and workforce shortages post-pandemic. However, system partners need a clear signal from NICE regarding the

Statement of intent for Artificial Intelligence at NICE Page 1 of 8

NICE HealthTech Programme

- Has moved to taking a **life cycle approach**
- Early value assessments:
  - **identify available evidence**,
  - explore if the technologies have the **potential to address the identified unmet need and offer value for money**,
  - help **direct further evidence generation for future evaluations**, and
  - determine if **any clinical, economic and system risk posed by early use can be managed** and, consequently, if the technologies should be used while further evidence is generated.



What's different about EVA

ESC Cardiovascular Round Table

Previously

Topic selection → Scoping → Evaluation → Full guidance development → Evidence generation

New approach

Topic intelligence and selection → Scoping → Early value assessment → Evidence generation → Evaluation → Full guidance development

- Conditional recommendations – use while collecting further evidence, including RWE
- Evidence generation plan
  - Describes evidence gaps identified in the EVA
  - Outlines the approach that could be taken to address the evidence gaps, including suggested real-world evidence study designs

NICE has assessed a number of digital and AI technologies

- CaRi-Heart for predicting cardiac risk in suspected coronary artery disease (HTE4)
- AI for autocontouring (HTE11)
- AI for chest X-rays for suspected lung cancer (HTE12)
- AI technologies to help detect fractures on X-rays in urgent care: early value assessment (HTE20)
- AI-derived computer-aided detection (CAD) software for detecting and measuring lung nodules in CT scan images (DG55)
- AI for clinical decision making in stroke (DG57)
- Heart failure algorithms for remote monitoring in people with cardiac implantable electronic devices (DG61)
- Zio XT for detecting Cardiac arrythmias (MTG52)
- KardiaMobile for atrial fibrillation (MTG64)

Case study

Artificial intelligence technologies to help detect fractures on X-rays in urgent care: early value assessment

Health technology evaluation | HTE20 | Published: 14 January 2025

- **Use case:** Fracture assessment and diagnosis in urgent care typically involves triage in which a nurse, advanced clinical practitioner or doctor will do an initial assessment before requesting imaging.
- NICE's guideline on non-complex fractures recommends that a radiologist, radiographer or other trained reporter should review X-rays and provide a definitive report before the injured person is discharged (hot reporting). Clinical experts explained that in practice this is not always possible and reporting delays can occur ranging from days to weeks.
- **Missed fractures are reported to be the most common diagnostic error in the emergency department**. Hussain et al. (2019) found that 44% of diagnostic errors in fractures resulted from inappropriate response to imaging. Missed or delayed diagnosis of fractures on radiographs is reported to occur in around 3% to 10% of cases (Kuo et al. 2022).
- **Role of AI:** AI technologies that can help healthcare professionals detect fractures on X-ray images could improve the accuracy of fracture diagnoses in urgent care.

Case study

Artificial intelligence technologies to help detect fractures on X-rays in urgent care: early value assessment

Health technology evaluation | HTE20 | Published: 14 January 2025

Evidence suggested that AI technologies when used with humans **increased sensitivity and did not reduce specificity**. However, there were **remaining uncertainties**

Diagnostic accuracy: retrospective and case control designs, notes interpreted in isolation rather than with clinical history	**Subpops:** age, sex, ethnicity, socioeconomic status, fracture types conditions affecting bone health	**Clinical impact:** time saved, number of onward referrals, inappropriate and otherwise
Imperfect reference standard: radiologist vs emergency physician, heterogeneity across staff/setting	**Change in decisions:** actual impact on decisions, over-reliance and automation bias	**Implementation costs:** across different urgent care centres
Setting: non-UK	**AI software failure rates**	**Costs/cons** associated with false-positives and false-negatives

Four AI technologies can be used in the NHS during the evidence generation period as options to help healthcare professionals detect fractures on X-rays in urgent care.

Case study

- NICE supports effective decision making by **providing useful and usable advice**
- The EvGen plan:
  - **prioritizes the uncertainties** highlighted by the committee
  - is **not a study protocol.** It provides some **suggestions** for how these evidence gaps may be filled
  - includes **minimum evidence requirements**
  - references the **NICE RWE framework** - this outlines **best practice principles** for planning and conducting and reporting RWE studies.

Evidence generation plan for artificial intelligence technologies to help detect fractures on X-rays in urgent care

1 Purpose of this document

NICE's early value assessment of artificial intelligence (AI) technologies to help detect fractures on X-rays in urgent care recommends that BoneView, Rayvolve, RBfracture and TechCare Alert can be used in the NHS while more evidence is generated. The other AI technology considered in the guidance can only be used in research and is not covered in this plan.

This plan outlines the evidence gaps and what data needs to be collected for a NICE review of the technologies again in the future. It is not a study protocol but suggests an approach to generating the information needed to address the evidence gaps. For assessing comparative treatment effects, well-conducted randomised controlled trials are the preferred source of evidence if these are able to address the research gaps.

The companies are responsible for ensuring that data collection and analysis takes place.

Guidance on commissioning and procurement of the technologies will be provided by NHS England.

Observations from evaluating AI technologies

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- AI technologies have largely presented the **same challenges as many diagnostic technologies**.
- There is often a **paucity of evidence** so can be difficult to assess whether they will provide value for money, and the value proposition for the tech may not match how the NHS will use the technology.
- Developers and clinicians need to provide evidence to demonstrate the impact that a technology has on the **entire pathway of care**, efficiencies in one step of a pathway may not lead to efficiencies downstream. Changes in the pathway may be needed to realise the benefits of the AI tech.
- Evaluating efficiency claims can enable a simpler analysis to be done, but to date **not seen robust data to truly allow the impact of efficiency savings to be quantified and understood**.
- There **can be a higher risk of unintended consequences** from using AI technologies which is an important consideration.

Relevant resources

NICE evidence standards framework: Evidence standards framework for digital health technologies – this has been updated to include AI health technologies

NICE AI hub: Artificial intelligence (AI) at NICE hub

- statement of intent for artificial intelligence at NICE
- use of AI in evidence generation: NICE position statement

NICE webinar: Navigating the future: AI at NICE virtual event

NICE HTA lab: Health Technology Assessment Innovation Laboratory (HTA Lab)

NICE Advice service: NICE Advice service | Life sciences: how to get your product to market

NICE HTA lab projects

www.nice.org.uk/about/what-we-do/our-research-work/hta-lab

- Generative AI to support economic modelling
  - testing generative AI tools' capability to support model adaptation, development, updates and validation
  - leading on a series of technically focused stakeholder engagement activities to identify the key potential benefits and barriers
- Adoption of AI technologies in the context of health and care guidance development
  - ensuring alignment with regulatory frameworks and ethical considerations
- New project with a focus on the future of AI in HTA, and whether it can support new concepts such as continuous health technology assessment of interventions

AI and Digital Regulations Service (AIDRS) for health and social care

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www.digitalregulations.innovation.nhs.uk

1 

Clarity– providing advice that is clear, specific and meaningful.

2 

Navigation – one access point for advice, to foster timely access to new and promising technologies.

3 

Compliance – demystifying regulatory requirements with clear signposting to necessary approvals and best practice.

4 

Trust – transparent regulation in line with ethical, legal and best practice principles.

The AIDRS website, developed by CQC, HRA, MHRA and NICE, offers an essential resource for developers and adopters of AI and digital health technologies, serving as the **go-to platform for regulatory guidance**.

Thank you

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