NICE National Institute for Health and Care Excellence

NICE statement of intent for artificial intelligence (AI)

Corporate document

Published: 14 November 2024

www.nice.org.uk/corporate/ecd12

Contents

This corporate should be read in conjunction with ECD11.

Purpose of this document

This document sets out our intention to develop our approach to:

- **providing guidance** for technology developers on best practice for artificial intelligence (AI)-based methods to support the evidence generation for their technologies
- **evaluating** AI-based technologies for use in the NHS
- **exploring the use** 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. This 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

We recognise the transformative potential of artificial intelligence (AI) to support the generation and reporting of evidence for our diverse range of programmes including health technology assessment and guidelines. 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 after the COVID-19 pandemic. However, system partners need a clear signal from NICE about the effectiveness and value of these technologies. Finally, AI may potentially increase the efficiency of NICE's internal processes, enabling our guidance to be more timely and responsive to system needs.

The careful assessment and incorporation of AI, when appropriate, could help NICE better achieve its core aim of helping the NHS and wider health and care system get the best care to people, fast, while ensuring value for the taxpayer.

We are committed to continuously monitoring progress in the field of AI and adapting our approach to harness new capabilities in an appropriate and proportionate way as they emerge.

Objectives

This statement of intent outlines our approach to develop and test methods to support the use and evaluation of artificial intelligence (AI) at NICE. The work falls into 3 main priority areas:

- providing guidance for technology developers on best practice for AI-based methods to support evidence generation
- evaluating technologies that incorporate AI, such as clinical prediction models, decision support systems, diagnostics, or digital health technologies
- exploring the use of AI to support and improve the efficiency of NICE's internal processes.

Developing evidence requirements and piloting new tools in these priority areas will require close collaboration with key experts and stakeholders, including healthcare professionals, patients, researchers and life sciences industry representatives.

Approach

In our work we will aim to:

- adopt a flexible approach to a fast-moving field
- safely balance opportunities and risks
- adhere to best practice and government standards
- maintain our core principles that underpin NICE's work, including:
  - describing our approach in methods manuals
  - using evidence that is relevant, reliable and robust
  - supporting innovation in the provision and organisation of health and social care services.

NICE's priority areas

Guidance on best practice for AI-based methods to support evidence generation

We aim to establish guidance on the use of innovative AI methodologies that are starting to be, or are likely to be, impactful for evidence generation. This will build on and supersede NICE's position statement on the use of AI in the generation and reporting of evidence considered by NICE. We will outline best practice principles that enable scientific rigour and consider ethical use, as well as transparency. When possible, we will work with national and international system partners to reduce duplication of effort and increase harmonisation.

What this means in practice

We will:

- **Gather insights** on current practices, challenges and expectations regarding the use of AI in evidence generation, drawing input from expert advisers.
- **Prioritisetopic areas** for development, such as guidance for assessing the quality and reliability of AI-generated evidence, and considerations for bias, transparency, reproducibility and ethical use.
- **Lead exploratory and applied researchactivities** to develop relevant case studies applying AI in evidence generation and to understand the implications for NICE's methods and processes, including in systematic reviews of evidence and economic modelling.
- **Consider aligning** with existing literature and guidelines on AI methodologies, and frameworks from other regulatory bodies and relevant organisations.
- **Supportcompanies and evidence developers** through the NICE Advice service.

Our approach will help ensure good practice in evidence generation, and foster appropriate trust in and reliability of evidence generated with AI.

Evaluating AI-based technologies

NICE has already evaluated various technologies that incorporate AI. To date, these have included the use of AI for predictive purposes, diagnostic uses (for example, in imaging) and in digital therapeutics. As the use of AI increases in the NHS, it is critical that we ensure our evaluation programmes are considering challenges for AI-based technologies, for example, additional elements of bias and ethical considerations, societal harms, misuse and autonomy risks.

What this means in practice

We will:

- **Work with system partners** to prioritise topics for standards development, covering issues inherent to AI technologies. This may include additional considerations in: the validation of algorithms; evaluation of adaptive algorithms; assessment of real-world impact; and bias, acceptability, transparency of evidence generation, algorithmic explainability and cyber security. If needed, we will consider developing tools and templates to support implementation of new standards.
- **Consider aligning** with existing guidelines and frameworks from other regulatory bodies and relevant organisations.
- **Train** our staff and committees to develop the skills required to evaluate AI-based technologies, including aspects that differ from traditional medical technologies and how to recognise associated risks.
- **Supportcompanies and evidence developers** through the NICE Advice service, the AI and digital regulations service (AIDRS), and other engagement work.

We will engage with regulatory bodies to ensure that our evaluation processes are aligned with the latest regulatory standards and best practices, allowing us to assess new AI technologies quickly and effectively as they emerge.

Using AI to streamline our processes and increase efficiency and effectiveness

We will explore how AI can help us improve internal processes, particularly in enhancing

efficiency, accuracy and quality. We will do this in collaboration with suppliers and system partners, ensuring we guard against risks and prioritise cybersecurity.

What this means in practice

We will:

- **Learn** from successful and unsuccessful implementation of AI projects and gather case studies to demonstrate potential value.
- **Explore AI tools** to automate tasks, speed up guidance production, enhance data analytics and support decision making, while assessing risks.
- **Adhere to ethical guidelines**, ensuring transparency, accountability, and compliance with relevant regulations, standards, licences and copyright frameworks.
- **Establish processes** for performance monitoring, cybersecurity and risk mitigation, ensuring safety, responsibility and fairness.
- **Train our staff** to ensure effective use of these tools and to build AI literacy within the organisation.

Leadership in international collaboration

Our approach will require collaboration with system partners, experts and key stakeholders, and international organisations that can help to reduce duplication of effort. We will:

- **Further develop partnerships** with health technology assessment and professional organisations, research institutions and regulatory bodies internationally to agree best practices, research findings and evaluation methodologies.
- **Align or co-develop** evaluation criteria with international standards to promote consistency and interoperability in the assessment of AI technologies.
- **Participate in joint research initiatives** that advance the development and evaluation of AI in healthcare, where possible, on a global scale.
- **Support other countries** who want to advance their AI-related workstreams by providing advice, sharing best practice and expertise from NICE.

Conclusion

NICE is committed to embracing artificial intelligence (AI) responsibly, through

- developing guidance on the appropriate use of AI methods to support evidence generation
- doing thorough and robust evaluation of technologies incorporating AI for use in the NHS
- exploring the use of AI to enhance our internal capabilities.

We will strive for responsible and effective use of AI in the context of health technology assessment and guideline development, safely balancing opportunities and risks to ensure that our efforts translate into tangible benefits for patients, healthcare providers, and the broader healthcare system.

ISBN: 978-1-4731-6651-6