Developers guidance

Understanding routes to NICE health technology assessment

This is best practice guidance

Although not legally required, it's an essential activity.

This Guide covers:

- United Kingdom

From:

- National Institute for Health and Care Excellence (NICE)

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Understand how NICE does health technology assessments.

Planning for a NICE evaluation

NICE evaluates and produces guidance on many new products for the health and social care services in England. This includes digital health interventions, medical devices and diagnostics.

Your digital technology could be eligible for a NICE evaluation. Planning for a NICE evaluation in your evidence generation plans may:

- increase the likelihood of a positive recommendation by NICE. This will increase the likelihood of adoption of your technology across the NHS
- reduce delays in adoption of your technology
- help you create evidence generation plans that support your value proposition.

A key step in early planning is finding out about NICE's topic selection process and how guidance topics are prioritised.

Adopters may use NICE evidence standards when deciding whether to buy your digital technology. They may particularly use NICE's evidence standards framework for digital health technologies.

So it is important to consider these, even if your technology is not evaluated by NICE. For more details, see generating evidence for health technology assessment.

NICE evaluation: how does it work?

NICE carries out evaluations through a range of programmes, which require different evidence. The HealthTech programme is responsible for evaluating digital technologies and AI technologies, as well as traditional medical technologies, diagnostics and interventional procedures. The type of assessment that is done by NICE depends on the type of technology and the stage of development. The HealthTech programme has a methods and processes manual that explains how guidance is developed.

The HealthTech programme assessments are:

- interventional procedure guidance (IPG) which recommends whether an interventional procedures, such as laser treatments for eye problems or deep brain stimulation for chronic pain, are effective and safe enough for use in the NHS.

- early use assessment, which is a quick assessment of technologies for clinical effectiveness and value for money. It assesses technologies at an early stage in evidence generation and recommends promising technologies for use in the NHS, while further evidence is being collected.
- Routine use guidance, which assesses products that have not been adopted widely but have substantial evidence to produce guidance in favour or against.
- late-stage assessment for categories of technologies that are already being widely used within the NHS.

The HealthTech programme has independent committees that review the evidence for each technology and make recommendations about using them in health and social care.

Topics are selected by NICE's prioritisation board to ensure they reflect national priorities for health and care. Typically, any technologies within these topics that are eligible for a NICE evaluation will need to:

- have a CE or UKCA mark
- be a tier C intervention within NICE's evidence standards framework for digital health technologies, and
- have enough evidence to support the value proposition

Get your digital technology a NICE evaluation

Register with the NHS Innovation Service to find out if your technology could be eligible for a NICE evaluation.

Generate your evidence in line with NICE's evidence standards and methods guides, such as:

- NICE's HealthTech programme manual (in development)
- NICE's evidence standards framework for digital health technologies
- NICE's real-world evidence framework

Consider using NICE Advice.

NICE Advice service helps you optimise your approach at any point in product innovation and development, especially in the early stages. We can support you to:

- understand your product route to market
- review your development and evidence generation plans
- identify what matters most to patients, as well as the health and care system
- engage with the system during product development to support adoption and use.

