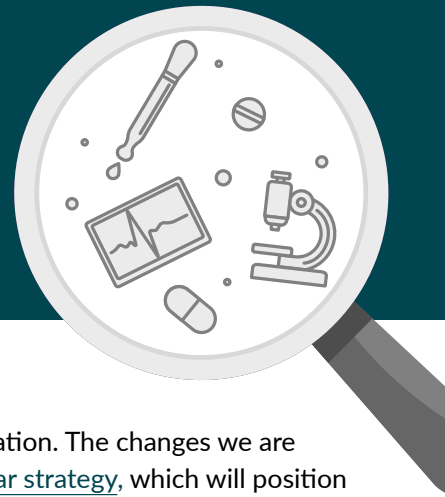


Our ambitions for the future of health technology evaluation



NICE improves health and wellbeing by putting science and evidence at the heart of health and care decision making. As health technologies advance, so too must our methods of evaluation. To remain at the forefront of providing independent, world-leading assessments of value for the health system and improve patient access to the best healthcare innovations, we are conducting a comprehensive review of our methods and processes

for health technology evaluation. The changes we are proposing support [our 5-year strategy](#), which will position NICE at the forefront of anticipating and rapidly evaluating new and existing technologies.

A public consultation on our proposals is open until 11.59pm on Wednesday 13 October 2021.

An evolutionary process

Since March 2000, [we have published more than 700 technology appraisals](#). Our latest proposals are an incremental development of our methods and processes, building on our existing rigorous approach to evaluating new health technologies.

We are already providing earlier access to innovative drugs than ever before. NICE is currently one of the fastest health technology assessment bodies in the world. During 2019/20, the average time from marketing authorisation to first NICE output was 1.3 months.¹

Improvements and benefits

Our proposals will bring many improvements. For example, within our decision making we propose giving additional weight to innovations that support the most severe diseases. This could enable some treatments to be recommended at up to £50,000 per quality adjusted life year (QALY) gained. In doing so, it will expand beyond end-of-life treatments, supporting innovation in a broader range of conditions, including technologies with indications in conditions such as heart failure and severe depression, depending on their severity.

Going forward, NICE will commission research to establish the extent to which society is willing to displace possible health gains elsewhere in the system – and therefore the amount of additional weight that should be applied

for severe diseases – in order to provide more treatment options for people with these conditions.

We also recommend enabling our committees to accept a greater degree of uncertainty and risk in some circumstances. For example, for conditions where evidence generation is complex and difficult. This could be for rare diseases or diseases that affect children.

Our proposals mean we will robustly and transparently describe, characterise and quantify uncertainty. This will ensure our independent committees can think more flexibly about accepting technologies where the evidence is usually more difficult to collect.

¹ Life Science Competitiveness Indicators 2020

Our proposals will bring a range of benefits to 3 key groups



For patients:

- Earlier access to new and innovative treatments.
- More equitable access to treatments for severe diseases.
- Greater emphasis on user experience through real-world evidence.



For the NHS:

- Increased access to cutting edge, cost effective medicines and technologies
- More opportunities for innovative commercial deals and managed access agreements to pilot promising technologies.
- Fairer and more equitable provision of care.



For the life sciences industry:

- Fast, flexible and fair evaluation of healthcare products.
- Acceptance of a more comprehensive evidence base and increased opportunities to generate and use real-world evidence.
- Supporting the UK to become a more attractive place for life sciences companies to innovate, succeed and grow.

How your feedback has informed our planned changes

Feedback from patient groups, industry and other stakeholders has informed the changes we are proposing. For example, in an effort to make our processes faster, more flexible and responsive, we proposed shorter consultation periods for draft guidance on some products. But stakeholders told us that they valued the opportunity to engage with NICE and wanted to retain existing consultation timescales. We listened to this feedback and have removed this proposal.

We want to make the topic selection routing criteria for our Highly Specialised Technologies (HST) Programme clearer and more precise. The aim of our HST Programme



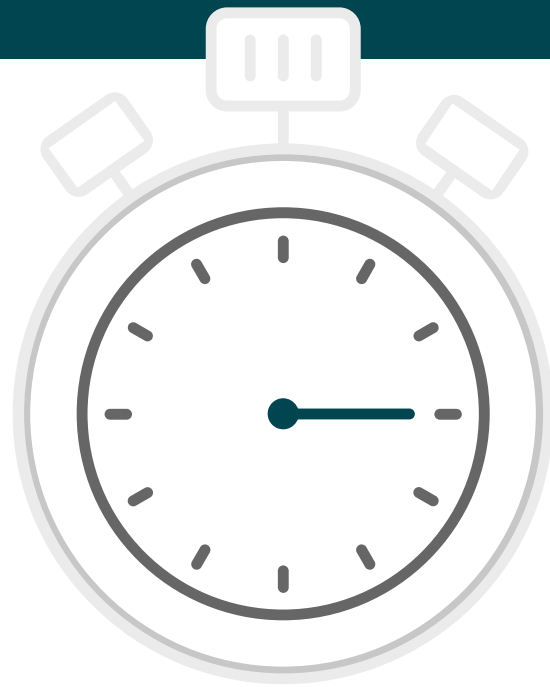
is to encourage research and facilitate fair and equitable access to treatments for patients with serious and very-rare conditions.

During a previous consultation, stakeholders told us that our vision and principles for selecting which topics are routed to the HST Programme were unclear. In response, we have amended the wording of the topic selection routing criteria to reflect the specific requirement that the condition is very rare with a prevalence of 1:50,000 or less in England. We've made all of the criteria for the HST programme more specific, and each one is now supported by an explanation of how it will be applied.

Accelerating access to the best innovations

The government's [Life Sciences Vision](#) outlines an ambition to make the NHS the country's most powerful driver of innovation – through the development, testing and adoption of new technologies at a population scale. We are already working collaboratively with regulators and other system partners to develop a world-leading regulatory and access system that will bring life-changing innovations to patients faster than ever before.

We are closely involved in the [Innovation Licensing and Access Pathway](#), [Project Orbis](#), the [NHS Accelerated Access Collaborative](#) and the [multi-agency advisory service for artificial intelligence and data-driven technologies](#). Each of these initiatives aims to bring efficiencies to regulatory processes and provide greater clarity and comprehensive support to life sciences companies throughout approval and access pathways. The changes we are proposing to our methods and processes support NICE's broader work in the innovation landscape.



In addition, NICE is a key partner in the forthcoming [Innovative Medicines Fund](#). This new managed access scheme is intended to give patients early access to the most promising health technologies which have received regulatory approval but lack the evidence base to secure a NICE recommendation for routine NHS funding.

Next steps

We will publish our new programme manual in January 2022, implementing the new processes and methods from February 2022 onwards.

Following this review, we will move to a dynamic modular methods update approach. This will combine improved horizon scanning with seamless adoption to benefit patients. We are already mapping several modular updates such as health inequalities, digital technologies, including artificial intelligence, genomics and antimicrobials.

Our view

Meindert Boysen, NICE's deputy chief executive and Centre for Health Technology Evaluation director, said:



“Our proposed changes will build on NICE's world-leading reputation, demonstrating how we will remain at the cutting edge of health technology assessment. Optimising our methods and processes will enhance our ability to support rapid transformation in healthcare and the changing needs of society and the health and life sciences ecosystems.”