Board meeting

20 May 2025

HealthTech Manual post consultation

Purpose of paper

For decision

Board action required

The Board is asked to:

* + Approve publication of the HealthTech manual
  + Approve publication of NICE’s thematic responses to comments on the consultation
  + Approve minor updates to [NICE health technology evaluations: the manual](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation) and the [Interventional procedures programme manual](https://www.nice.org.uk/process/pmg28/chapter/introduction)
  + Approve implementation of the HealthTech manual for July 2025

Brief summary

This paper provides an update on a public consultation held earlier this year on the first section of the HealthTech manual, and proposed minor updates to [NICE health technology evaluations: the manual](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation) and the [Interventional procedures programme manual](https://www.nice.org.uk/process/pmg28/chapter/introduction). It provides an overview of the consultation comments, responses and next steps.

Board sponsor

Mark Chapman, Director of Medical Technology

Introduction

HealthTech is vital to delivering the 3 big shifts needed in the NHS, as outlined by government: from hospital to community; from analogue to digital; and from treating sickness to prevention. In light of advances in life sciences and technology, and the different demands on the health and care system, NICE has simplified its approach to HealthTech assessment and strengthened its partnership working to enable greater flexibility in assessment and increase its ability to respond to the needs of patients and the health and care system.

The manual text that was developed, and has been consulted on, describes the methods and processes for NICE when evaluating interventional procedures and HealthTech products. The methods and processes were designed to produce robust guidance for the NHS in an open, transparent and timely way, with appropriate contribution from stakeholders.

The manual text also sets out the life cycle approach for guidance now taken by the HealthTech programme.

Background

In December 2024 the Board approved the first section of a HealthTech manual for public consultation, which was held between 7th February and 6th March 2025. We received 650 responses from 37 organisations and individuals. An overview is provided in table 1.

Table 1 Consultation responses by organisation type

|  |  |  |
| --- | --- | --- |
| Respondent | Number of organisations (or individuals) | Percentage of comments |
| Industry/consultancies | 24 | 65% |
| Trade bodies/associations | 1 | 3% |
| External Assessment Groups (EAGs) and academic institutions | 6 | 16% |
| Voluntary and community sector organisations | 2 | 5% |
| NHS England | 1 | 3% |
| NHS trusts, NHS network groups | 3 | 8% |

We have addressed the comments received, revised the manual text and written responses to comments. The updated manual text and a document setting out NICE’s responses to comments received have been approved by Guidance Executive (GE).

Consultation themes

General

Respondents welcomed a greater focus on the assessment of non-pharmaceutical technologies. But they cautioned that further work is required to make sure the manual reflects the needs of assessing HealthTech. And that it is important that the aim of the work is to be fit for purpose rather than being a version of methods and process for assessing pharmaceuticals. The need for ongoing consultation with patients and industry throughout the process of changes was highlighted, as was the challenge for a sector made up of many small and medium-sized enterprises.

### Overview of NICE response and changes to manual text

This new manual sets out the foundations for the HealthTech programme and is the first step in an ongoing iterative process to set out in greater detail the process and methods to be used by the NICE HealthTech programme. Further work to add clarity to methods approaches will be developed in the coming year and form part of an update to the manual following consultation. While we are keen to make sure there is consistency with approaches to how pharmaceuticals are assessed by NICE, the focus will be on health technologies and making sure the approaches that NICE takes are appropriate for such assessments. Further updates will be subject to consultation, giving the opportunity for comment on the proposed text.

Involvement of people with lived experience in committee meetings

Respondents raised concern about the proposal to use patient experts (people with lived experience of a condition) across all HealthTech guidance, rather than appointing as a specialist committee member, as happens for some HealthTech guidance topics at present.

### Overview of NICE response and changes to manual text

1. The key rationale for this proposal was for greater transparency in guidance production by ensuring that input from healthcare professionals and patient experts, and discussion of this, is in the public part of a committee meeting. This means that public observers, including people from patient, voluntary and community sector organisations and members of the public with lived experience relevant to the guidance, can observe input from experts in committee, understand how this has contributed to committee decision making and make any consultation comments on draft guidance in light of this. The advisory committees in the HealthTech programme include standing patient members (lay members) who advocate for patient points of view and can work closely with patient experts to make sure the issues that are important to them are understood and represented to the committee in meetings. Patient experts will still present to committee the patient and carer perspective and considerations so patient input will remain a critical part of the guidance development process. Information from patient, voluntary and community sector organisations will also continue to be used to inform decision-making. Working closely with the People and Communities Involvement and Engagement (PCIEP) team at NICE, we will continue to explore and drive further improvements to ensure we are engaging with patients and carers in the most effective way for them to contribute to NICE guidance and ensure our guidance is relevant for the people most directly affected by our recommendations.

## Assessment of multiple technologies using cost utility analysis

Respondents welcomed the requirement that medical devices would no longer have to be cost saving to be recommended. They stated that this would enhance innovation and the development of devices to contribute to better outcomes for patients. Benefits of moving to a multiple technology approach in guidance were acknowledged, but respondents cautioned this should not cause delays to assessment, and access to novel technologies, if only a single technology is available. Respondents also asked for greater detail on the process of assessing multiple technologies in one piece of guidance, including how technologies are identified for inclusion in a single guidance.

### Overview of NICE response and changes to manual text

Responses to these comments explained that decisions about what technologies to include in guidance are made during the scoping phase, including opportunities for companies and other stakeholders to provide input at scoping workshops or consultations. People who will use the technology in practice, typically healthcare professionals and people with lived experience of a condition, are important contributors to these discussions.

Recommendation wording

At the meeting in December, the Board asked for greater clarity to be added to the manual to clarify the meaning of recommendations, particularly for research recommendations. Further text was added to the manual, and we included a question with the consultation asking for comments on the clarity of the meaning of the different recommendations and how they would be interpreted. No concerns were raised in the consultation about the meaning of research recommendations. We received some specific comments about the recommendation wording which we have addressed in the updated manual text.

Proposed minor changes to existing manuals

Few comments were received on proposed minor amendments to [NICE health technology evaluations: the manual](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation) and the [Interventional procedures programme manual](https://www.nice.org.uk/process/pmg28/chapter/introduction). Minor changes were suggested which have been made to the proposed text changes.

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