

Proposed changes to existing programme manuals and interim documents on publication of the NICE HealthTech programme manual

7 February 2025

Interim documents for archiving from NICE website

- [Early value assessment interim statement](#) (PMG39)
- [Interim addendum on guidance reviews](#) (PDF only)
- [Interim addendum on scoping workshops](#) (PDF only)

Minor amendments to existing programme manuals

Table 1: Minor amendments to existing [NICE health technology evaluations: the manual](#) content

Existing wording	Section	Proposed change
<p>Health technology evaluations are developed by NICE's Centre for Health Technology Evaluation. This manual describes the methods and processes used for developing guidance in the:</p> <ul style="list-style-type: none"> • Diagnostics Assessment Programme • Medical Technologies Evaluation Programme • Highly Specialised Technologies Evaluation Programme 	<p>Introduction to health technology evaluation</p>	<p>Health technology evaluations are developed by NICE's Centre for Health Technology Evaluation. This manual describes the methods and processes used for developing guidance in the:</p> <ul style="list-style-type: none"> • HealthTech Programme • Highly Specialised Technologies Evaluation Programme • Technology Appraisal Programme.

Existing wording	Section	Proposed change
<ul style="list-style-type: none"> Technology Appraisal Programme. 		
<p>Diagnostics Assessment Programme</p> <p>The Diagnostics Assessment Programme evaluates diagnostic technologies. It is responsible for evaluating diagnostic tests and technologies when such evaluation is complex, for example, if recommendations can only be made on the basis of clinical utility and cost-effectiveness analysis or if meaningful assessment requires the consideration of multiple technologies or indications. The Diagnostics Assessment Programme evaluates diagnostic technologies that have the potential to improve health outcomes but whose introduction is likely to be associated with an overall increase in cost to the NHS. The Diagnostics Assessment Programme also evaluates diagnostic technologies that may offer similar health outcomes at less cost, or improved health outcomes at the same cost as current NHS practice.</p> <p>The programme evaluates diagnostics that are intended for use in the NHS in England and are paid for by the NHS with public funds, either in part or in whole.</p> <p>The aims of the programme are to:</p> <ul style="list-style-type: none"> promote the rapid and consistent adoption of innovative clinically and cost-effective diagnostic technologies in the NHS improve treatment choice or length and quality of life by evaluating diagnostic technologies that have the potential to improve key clinical decisions 	Introduction to health technology evaluation	Delete

Existing wording	Section	Proposed change
<ul style="list-style-type: none"> improve the efficient use of NHS resources by evaluating diagnostic technologies that have the potential to improve systems and processes for the delivery of health and social care. <p>Medical Technologies Evaluation Programme</p> <p>The Medical Technologies Evaluation Programme evaluates new or innovative medical technologies (including devices and simple diagnostics). It aims to help the NHS adopt efficient and cost-saving medical devices and simple diagnostics more rapidly and consistently. This supports innovation and transformation and improves healthcare delivery.</p> <p>The programme looks at medical technologies that:</p> <ul style="list-style-type: none"> deliver treatment – like those implanted during surgical procedures give greater independence to patients detect or monitor medical conditions. <p>The Medical Technologies Evaluation Programme uses a cost-minimisation approach to assess products. This approach considers the costs and resource consequences resulting from, or associated with, the technology under evaluation and comparator technologies. It considers clinical benefits (for example, effectiveness outcomes) alongside the cost analysis</p>		
<p>Other resources are available on the NICE website, including:</p>		<p>Other resources are available on the NICE website, including:</p>

Existing wording	Section	Proposed change
<p>the following webpages, which provide more information about each programme, including submission templates:</p> <ul style="list-style-type: none"> • Technology Appraisals Programme • Medical Technologies Evaluation Programme • Diagnostics Assessment Programme • Highly Specialised Technologies Programme 		<p>the following webpages, which provide more information about each programme, including submission templates:</p> <ul style="list-style-type: none"> • Technology Appraisals Programme • Highly Specialised Technologies Programme
<p>1.2.3</p> <p>The diagnostics advisory committee recruits several specialist committee members alongside the standing committee members for each individual evaluation. They are committee members for that topic only. They typically include clinicians or researchers using the diagnostic technology or practising in the care pathway, as well as lay people with a perspective on the condition being diagnosed. Specialist committee members have the same decision-making role as standing members of the committee. Any reference to committee includes the specialist committee members.</p>	<p>1 Involvement and participation</p>	<p>Delete</p>
<p>1.2.11</p> <p>Clinical experts and patient experts are selected from those nominated by consultee organisations or by NICE, taking into account the NICE policy on declaring and managing interests for NICE advisory committees. Experts are invited to provide written evidence, clarify issues about the evidence base and participate in committee meetings. They may be asked to provide advice before, during and after committee meetings. References to clinical and</p>	<p>1 Involvement and participation</p>	<p>1.2.11</p> <p>Clinical experts and patient experts are selected from those nominated by consultee organisations or by NICE, taking into account the NICE policy on declaring and managing interests for NICE advisory committees. Experts are invited to provide written evidence, clarify issues about the evidence base and participate in committee meetings. They may be asked to</p>

Existing wording	Section	Proposed change
patient experts means the specialist committee members for diagnostics evaluations.		provide advice before, during and after committee meetings.
1.3.2 For evaluations to develop diagnostics guidance, companies are not formally invited to make an evidence submission but provide information requested on the evidence base and their technology to enable the EAG to develop the external assessment report.	1 Involvement and participation	Delete
1.3.15 For diagnostics and medical technologies guidance, relevant NHS commissioners of the technology are invited to nominate NHS commissioning experts only if commissioning expertise is specifically needed or if the population is covered by an NHS England specialised commissioning group.	1 Involvement and participation	Delete
1.3.20 For diagnostic evaluations clinical and lay specialist committee members are recruited at the beginning of the evaluation process. Additional specialist committee members may be appointed after the final scope is published if gaps are identified in the knowledge and expertise needed by the committee. They may support the EAG on behalf of the committee during the evaluation. However, they cannot be appointed as advisers to the EAG so they can maintain sufficient independence from the evidence and contribute to the committee's	1 Involvement and participation	Delete

Existing wording	Section	Proposed change
discussions on the quality of the external assessment report and the development of guidance recommendations.		
<p>1.3.30</p> <p>For a multiple technology evaluation (including all diagnostic evaluations), the EAG creates a report that independently synthesises the evidence from published information and any evidence submissions about the clinical effectiveness and value for money of the technologies. In addition to a systematic review of the clinical and cost evidence, the external assessment report normally includes an economic evaluation and an economic model informed by a review of the evidence. Evidence requirements are explained in section 3.</p>	1 Involvement and participation	<p>1.3.30</p> <p>For a multiple technology evaluation, the EAG creates a report that independently synthesises the evidence from published information and any evidence submissions about the clinical effectiveness and value for money of the technologies. In addition to a systematic review of the clinical and cost evidence, the external assessment report normally includes an economic evaluation and an economic model informed by a review of the evidence. Evidence requirements are explained in section 3.</p>
<p>Table 2.1 Consultation lengths</p> <p>First column, second row: 7 calendar day consultation (short)</p> <p>Second column, second row: For medical technologies – information for the scope has already been gathered during the development of the medtech innovation briefing. Technology appraisals and highly specialised technologies will not use this approach.</p>	2 The scope	Delete
<p>Table 2.1 Consultation lengths</p> <p>Second column, fourth row:</p> <p>If there is a reasonable degree of uncertainty about elements of the draft scope, or whether the technology</p>	2 The scope	If there is a reasonable degree of uncertainty about elements of the draft scope, or whether the technology should be evaluated. Technology

Existing wording	Section	Proposed change
should be evaluated. Diagnostics, technology appraisals and highly specialised technologies will normally use this approach.		appraisals and highly specialised technologies will normally use this approach.
2.1.3 For new technology appraisals and highly specialised technologies guidance, scoping normally takes place during (and is used in) topic selection. For new medical technologies and diagnostics guidance, scoping takes place after topic prioritisation and the evaluation follows immediately after.	2 The scope	2.1.3 For new technology appraisals and highly specialised technologies guidance, scoping normally takes place during (and is used in) topic selection.
2.5.6 For diagnostics evaluations, NICE normally holds a scoping workshop and does not have a consultation on the draft scope.	2 The scope	Delete
2.7.5 For diagnostic technologies, after the scoping workshop, NICE meets with the assessment subgroup (committee chair, specialist committee members, committee lead and the external assessment group) to agree the final scope and protocol for the evaluation.	2 The scope	Delete
2.9.3 If the scope for a diagnostic evaluation is too large for the available resources, NICE may revise it in collaboration with the assessment subgroup and the external assessment group.	2 The scope	Delete
4.2.18	4 Economic evaluation	4.2.18

Existing wording	Section	Proposed change
<p>A cost-comparison analysis comprises an analysis of the costs and resource use associated with the technology compared with that of the comparator(s). This type of analysis is usually used when developing medical technologies guidance or a cost-comparison technology appraisal.</p>		<p>A cost-comparison analysis comprises an analysis of the costs and resource use associated with the technology compared with that of the comparator(s).</p>
<p>5.5.11 For medical technologies evaluations, the evidence submission is provided 42 days from the publication of the final scope.</p>	5 Developing the guidance	Delete
<p>5.5.12 For diagnostic technologies, the company is not asked to provide a formal evidence submission, but the company is asked to provide information on its technology and evidence base to allow the EAG to prepare its report accurately.</p>	5 Developing the guidance	Delete
<p>5.6.14 The EAG prepares a report on the clinical and cost effectiveness or cost savings of the technology. The report is usually based on a review of the company's evidence submission (except for diagnostics guidance and multiple technology evaluations in technology appraisals and highly specialised technologies) and advice from the EAG's clinical experts. The EAG prepares the report using a template agreed with the NICE team. The EAG is responsible for the content and quality of the report for all guidance types.</p>	5 Developing the guidance	<p>5.6.14 The EAG prepares a report on the clinical and cost effectiveness or cost savings of the technology. The report is usually based on a review of the company's evidence submission (except for multiple technology evaluations in technology appraisals and highly specialised technologies) and advice from the EAG's clinical experts. The EAG prepares the report using a template agreed with the NICE team. The EAG is</p>

Existing wording	Section	Proposed change
		responsible for the content and quality of the report for all guidance types.
<p>5.6.16</p> <p>For diagnostic guidance, companies do not normally provide an evidence submission. For multiple technology evaluations in technology appraisals and highly specialised technologies, the companies are invited to provide an evidence submission but are not formally required to do so. The EAG does an assessment of the clinical outcomes and cost effectiveness of the technologies, and diagnostic test accuracy where relevant. The assessment is based on systematic reviews of the literature, data provided by the companies, information from the experts or specialist committee members, and modelling of patient outcomes, costs and cost effectiveness. The EAG's assessment highlights the uncertainties in the evidence and may include an analysis of the value of reducing those uncertainties.</p>	5 Developing the guidance	<p>5.6.16</p> <p>For multiple technology evaluations in technology appraisals and highly specialised technologies, the companies are invited to provide an evidence submission but are not formally required to do so. The EAG does an assessment of the clinical outcomes and cost effectiveness of the technologies, and diagnostic test accuracy where relevant. The assessment is based on systematic reviews of the literature, data provided by the companies, information from the experts or specialist committee members, and modelling of patient outcomes, costs and cost effectiveness. The EAG's assessment highlights the uncertainties in the evidence and may include an analysis of the value of reducing those uncertainties.</p>
<p>5.6.17</p> <p>After receiving the external assessment report, NICE will share a copy with the company for fact checking. This will allow the company time to prepare for any technical engagement. NICE may seek advice from experts at this stage if additional clarification on the submitted individual expert statement is needed. There is no fact checking stage in diagnostics evaluations.</p>	5 Developing the guidance	<p>5.6.17</p> <p>After receiving the external assessment report, NICE will share a copy with the company for fact checking. This will allow the company time to prepare for any technical engagement. NICE may seek advice from experts at this stage if additional clarification on the submitted individual expert statement is needed.</p>
5.7.7	5 Developing the guidance	5.7.7

Existing wording	Section	Proposed change
<p>The purpose of the technical engagement is to note and consider any evidence gaps and potential resolution ahead of the committee meeting and to consider any commercial or managed access proposals. Technical engagement is not normally needed in medical technologies evaluations.</p>		<p>The purpose of the technical engagement is to note and consider any evidence gaps and potential resolution ahead of the committee meeting and to consider any commercial or managed access proposals.</p>
<p>5.7.10 Stakeholders have 28 days to submit comments on the external assessment report for technology appraisals and highly specialised technologies or 14 days for diagnostics or medical technologies evaluations. Comments must be submitted electronically. During the engagement period, NICE may meet with any company who has made an evidence submission and with selected experts when the technical team thinks this is necessary.</p>	<p>5 Developing the guidance</p>	<p>5.7.10 Stakeholders have 28 days to submit comments on the external assessment report for technology appraisals and highly specialised technologies. Comments must be submitted electronically. During the engagement period, NICE may meet with any company who has made an evidence submission and with selected experts when the technical team thinks this is necessary.</p>
<p>5.8.62 For medical technologies and diagnostics guidance, the chair will review the consultation comments received. When the comments will not change the recommendations, the chair can decide that another committee meeting is not needed. Factual changes and corrections to the guidance are made and final draft guidance and recommendations are agreed by the committee electronically.</p>	<p>5 Developing the guidance</p>	<p>Delete</p>
<p>7.1.1 For technology appraisals and highly specialised technologies guidance, consultees can appeal the final</p>	<p>7 Finalising and publishing the guidance</p>	<p>7.1.1 For technology appraisals and highly specialised technologies guidance, consultees can appeal</p>

Existing wording	Section	Proposed change
draft guidance, or the process followed using the appeal process . For medical technologies and diagnostics guidance, stakeholders can use the resolution process on the final draft guidance and the process followed.		the final draft guidance, or the process followed using the appeal process . For Interventional Procedures and HealthTech guidance, stakeholders can use the resolution process on the final draft guidance and the process followed.
7.2 Resolution for medical technologies and diagnostic guidance	7 Finalising and publishing the guidance	7.2 Resolution for Interventional Procedures and HealthTech guidance

Table 2. Minor amendments to existing [Interventional procedures programme manual](#) content

Existing wording	Section	Proposed change
Entire section	3 Timings for developing interventional procedures guidance	Delete
When consultation begins, NICE publishes the consultation document for comment on its website for 4 weeks. It also informs, by email, everyone who registered an interest that consultation has begun. During consultation, anyone may submit comments via NICE's website using a structured web form, or by email, fax or post. NICE only accepts comments submitted as part of the consultation process. It does not accept comments that are posted by third parties on other organisations' websites as consultation responses. No person or organisation may submit comments of more than 20 pages, although this may be waived in exceptional	13 The consultation process	Delete

Existing wording	Section	Proposed change
<p>circumstances at NICE's discretion. If a submission is longer than 10 pages, it should contain an executive summary of no more than 1 side of A4.</p> <p>NICE is committed to promoting the values of equality and diversity through its guidance, and to eliminating discrimination. NICE encourages comments on its draft guidance from all sections of the community. Consultees are asked to highlight any ways in which draft guidance fails to promote equality or avoid discrimination, and how it might be improved.</p> <p>Late comments received after the 4-week deadline are shown to the Committee only at the discretion of the Chair, on the advice of the programme team. Late comments are usually considered if they highlight substantial new information or are sent by ratified specialist advisers or professional organisations directly involved in patient care. The programme is not obliged to accept or note comments unless they are formally made during the consultation period.</p> <p>It is up to consultees what they include in their response to consultation. However, the Committee particularly welcomes the following:</p> <ul style="list-style-type: none"> comments on the draft recommendation(s) the identification of possible factual inaccuracies additional relevant evidence, with bibliographic references where possible. <p>All consultation responses are potentially important to, and potentially influence, the development of the guidance,</p>		

Existing wording	Section	Proposed change
<p>including those that are entirely supportive of the proposed guidance.</p> <p>During consultation, stakeholders submitting consultation comments are invited to complete a confidentiality statement enabling them to be involved in the programme's resolution process (see section 15).</p>		
Entire section	14 The production of guidance	Delete
Entire section	15 The resolution process	Delete
<p>During guidance development, appropriate OPCS codes for the procedure are identified and reviewed by the committee. These codes are published with guidance on the NICE website. The programme also liaises with the Health and Social Care Information Centre Clinical Classifications Service to identify when a new code is needed for a procedure because no appropriate codes currently exist. New codes are also published on the NICE website when they become available.</p> <p>Also, new guidance is considered in terms of appropriate inclusion and presentation in NICE Pathways. Pathways are an online tool accessed through the NICE website that provide access, topic by topic, to the range of guidance from NICE (including interventional procedures guidance) and NICE implementation tools.</p> <p>When the Committee recommends that special arrangements be in place for audit, and there is no existing register or data collection facility in place, NICE also develops an audit tool for the procedure, to help and</p>	16 Publication, dissemination and surveillance of guidance	Delete

Existing wording	Section	Proposed change
<p>encourage good auditing practice for the procedure. The tool is developed with advice from specialist advisers and Committee members, as appropriate.</p>		
<p>Arranging attendance at a Committee meeting NICE publishes a notice on its website announcing each Committee meeting, at least 20 working days in advance of the meeting. The notice includes:</p> <ul style="list-style-type: none"> • the date, time and place of the meeting • a list of agenda items, showing whether each will be discussed in the open or closed session of the meeting • the name, address and telephone number of the administrator responsible for providing administrative support to the meeting. <p>Members of the public may apply to observe a meeting via the NICE website. NICE also accepts enquiries by post or fax. Up to 20 places are available for each meeting.</p> <p>If attendance at any meeting is oversubscribed, attendees are selected according to NICE's allocation procedure. To allow wide public access, NICE reserves the right to limit attendees to 1 representative per organisation.</p> <p>When the meeting agenda has been finalised, NICE contacts applicants to let them know whether a place is available to them. The invitation includes information on Committee procedures and admission to the building where the meeting is to be held. All efforts are made to follow the meeting agenda, but all agendas can be subject</p>	<p>17 Transparency</p>	<p>Delete</p>

Existing wording	Section	Proposed change
<p>to change because of availability of Committee members and specialist advisers. Attendees should allow for this.</p> <p>If a meeting is cancelled, NICE will try to provide as much notice as possible.</p> <p>How meetings are conducted</p> <p>Scheduled meetings of the Committee are typically held in London, at venues for which access to members of the public is available.</p> <p>As per NICE policy, each item on the agenda may either be held entirely in public or split into a part 1 session for which the public, companies and additional experts are present and a part 2 session from which the public, companies and additional experts are excluded. The reasons for holding a part 2 session include when:</p> <ul style="list-style-type: none"> • the decisions made by the Committee are commercially sensitive. • the Committee is considering commercial- or academic-in-confidence information • the Committee is considering patient commentator submissions when these have been submitted under conditions of confidentiality. <p>The decision not to hold a part 2 session is at the discretion of the Chair in consultation with the Centre Director or their nominated deputy and is taken when no confidential or personal data or information are being considered, and when the matters under consideration are not commercially sensitive.</p>		

Existing wording	Section	Proposed change
<p>17.4 Using confidential data</p> <p>Normally, the assessment of procedures by the programme is based on published evidence. However, occasionally it may be necessary for the Committee to review confidential data to assess a procedure. This may happen at any stage in the process. When a data owner considers that unpublished data should be marked as either 'commercial in confidence' or 'academic in confidence', the rationale for doing so should be clearly stated and should be consistent with the following principles:</p> <ul style="list-style-type: none"> • Information and data that are in the public domain anywhere in the world may not be marked as confidential. • When confidential results from a research study are used during preparation of an overview, publication of NICE documentation quoting these results will be delayed until the study has been accepted for publication. <p>NICE asks data owners to reconsider restrictions on release of data, either when there appears to be no obvious reason for the restrictions or when such restrictions would make it difficult or impossible for NICE to show the evidential basis for its guidance.</p>	<p>17 Transparency</p>	<p>17.4 Using confidential data</p> <p>Normally, the assessment of procedures by the programme is based on published evidence. However, occasionally it may be necessary for the Committee to review confidential data to assess a procedure. This may happen at any stage in the process. When a data owner considers that unpublished data should be marked as either 'commercial in confidence' or 'academic in confidence', the rationale for doing so should be clearly stated and should be consistent with the following principles:</p> <ul style="list-style-type: none"> • Information and data that are in the public domain anywhere in the world may not be marked as confidential. <p>NICE asks data owners to reconsider restrictions on release of data, either when there appears to be no obvious reason for the restrictions or when such restrictions would make it difficult or impossible for NICE to show the evidential basis for its guidance.</p>
<p>NICE does not proactively review standard arrangements guidance. It is therefore not updated unless a stakeholder or organisation alerts NICE to significant new evidence that casts doubt on the validity of the original</p>	<p>19 Reviewing and updating interventional procedures guidance</p>	<p>Delete</p>

Existing wording	Section	Proposed change
<p>recommendations, for example, because of emerging new safety concerns. The relevance of safety alerts issued by national or international regulators (for example, the Medicines and Healthcare products Regulatory Agency or the US Food and Drug Administration) or any other serious safety concerns brought to NICE's attention are considered, and may trigger an update of guidance.</p> <p>Guidance on procedures with 'special' or 'research only' arrangements is proactively reviewed after 3 years, and the guidance is updated if important new evidence is available. This may be done sooner if there is significant new evidence or emerging new safety concerns. If the programme is made aware of a trial that is due to be published, this may also influence the timing of guidance production.</p> <p>Guidance with a 'do not use' recommendation is not proactively reviewed, and so would not be updated unless there is a significant change in the evidence base.</p>		
<p>19.2 Key steps in proactive guidance review</p> <p>In proactive reviews of guidance, the guidance information services team carries out a literature search to identify new evidence published since the literature searches were done for the original guidance. The search strategies developed for the original guidance are updated (if necessary) and rerun. Specialist advisers' opinions are obtained on the validity and relevance of any new evidence identified in this way, and they are asked if any</p>	<p>19 Reviewing and updating interventional procedures guidance</p>	<p>Delete</p>

Existing wording	Section	Proposed change
<p>new issues have emerged around use of the procedure. A new brief is produced for the procedure.</p> <p>If it is deemed that there is sufficient new published evidence and that the opinions of specialist advisers support the reassessment of the procedure, a proposal to update the guidance is submitted to the NICE Guidance Executive for approval.</p> <p>19.3 Guidance update</p> <p>Once the NICE Guidance Executive has approved the proposal to update the guidance, the update is scheduled into the programme's work processes, and follows the standard timelines and process for guidance development.</p>		
Entire section	23 Overall process for development of guidance	Delete