NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Draft manual consultation

NICE HealthTech programme manual

Introduction

This guide describes the methods and processes that NICE follows when evaluating interventional procedures and HealthTech products. The methods and processes are designed to produce robust guidance for the NHS in an open, transparent and timely way, with appropriate contribution from stakeholders. Organisations invited to contribute to health technology evaluation development should read this guide in conjunction with the NICE-wide topic prioritisation process. All documents are available on the NICE website.

The NICE HealthTech programme combines the former NICE Diagnostics Assessment programme, Interventional Procedures programme and Medical Technologies Evaluation programme.

To avoid duplication, this guide refers to the existing evaluation manual (NICE health technology evaluations: the manual) for methods and processes that remain the same. This guide sets out the new approaches in the HealthTech programme including further detail for clarity. Section 1 covers process (except for guidance that focuses on HealthTech products in existing use, which is currently set out in the late stage assessment interim methods and process statement). Section 2 covers methods (except for guidance that focuses on HealthTech products in existing use, which is currently set out in the late stage assessment interim methods and process statement, and interventional procedures guidance which can currently be found in NICE's interventional procedures programme manual).

HealthTech products and interventional procedures can offer significant benefits to patients, such as a quicker diagnosis, faster recovery, and reduced risk. They also have the potential to improve efficiency and reduce costs, such as by streamlining patient flow, tailoring treatments to an individual, and reducing hospital admissions.

The HealthTech programme provides 2 types of guidance: interventional procedures guidance and HealthTech guidance.

HealthTech guidance

HealthTech is often used interchangeably with ‘medtech’. For NICE guidance, HealthTech includes non-medicine technologies. This means diagnostics, medical devices and digital technologies including artificial intelligence. Examples include technologies, techniques, strategies and pathways that help diagnose, monitor, prognose, predict or symptomatically screen for health conditions, and technologies that treat, manage or prevent a health condition (including digital health technologies listed in tier C of NICE's evidence standards framework for digital health technologies).

Recommendations are made based on assessment of clinical and cost effectiveness of HealthTech products.

When multiple technologies with a similar purpose are available to the NHS, they will be assessed in one piece of guidance. When only one technology is available, a single technology assessment will be done. It is expected that most HealthTech assessments will be for multiple technologies.

Interventional procedures guidance

Interventional procedures involve making an incision, a puncture or entry into a body cavity, or using ionising, electromagnetic or acoustic energy.

Recommendations are made based on assessment of the efficacy and safety of new, significantly modified or established procedures. Although some interventional procedures can involve implanting or using a health technology, the guidance and recommendations are about the procedure.

Where cost is considered in guidance, interventional procedures (including those with existing NICE interventional procedures guidance) can be assessed in HealthTech guidance or other NICE guidelines (see section 8.3 in developing NICE guidelines: the manual).

Life cycle approach

The approaches taken to develop guidance, and the types of recommendation made, reflect what stage a technology or procedure is at in the lifecycle.

Early use

This approach considers HealthTech products that could address a national NHS need. It rapidly assesses products early in the lifecycle or that have limited use in the NHS, and need further evidence to support wider use. Technologies considered for early use can be conditionally recommended for use while further evidence is generated, as long as any clinical, economic or system risk can be managed. This enables early access to promising new technologies for patients. Conditional recommendations are for a fixed period of time and the technologies will be reassessed for routine use using the evidence generated.

For interventional procedures guidance, procedures such as those that are new or significantly modified can be conditionally recommended for use while more evidence is generated to check if they are safe and efficacious, as long as measures are in place to manage clinical and system risk.

For routine use

This approach considers HealthTech products that address a national NHS need and may be suitable for routine widespread use in the NHS. Recommendations are based on assessment of clinical and cost effectiveness, or cost comparison.

For interventional procedures guidance, a recommendation that the procedure can be used is made if there is enough evidence on the safety and efficacy of the procedure for healthcare professionals to consider it as an option.

For existing use

This approach considers HealthTech products that are already in widespread or established use within the NHS, to inform commissioning and procurement decisions. Process and methods for this are currently in the late stage assessment (LSA) interim process and methods statement.

1 Processes for developing guidance in the HealthTech programme

This section covers the process for developing guidance in the HealthTech programme. Links are made to sections in NICE health technology evaluations: the manual as appropriate. This guide supersedes other sections in the manual, including interim statements, for guidance produced in the HealthTech programme (excluding the late stage assessment interim methods and process statement).

The process set out here will also be used for developing interventional procedures guidance, superseding any process described in the interventional procedures programme manual.

1.1 General information

1.1.1 NICE sends correspondence for an evaluation to key contacts identified by each stakeholder organisation. Stakeholders (see section 1.2.16 in NICE health technology evaluations: the manual) must notify NICE of any change in contact details, or in organisation or company name, during the evaluation. This and any other correspondence should be to the email address provided by NICE.

1.1.2 Companies with a technology being assessed must inform NICE as soon as possible of any significant new information relevant to the assessment that occurs during guidance development.

1.1.3 Technologies will not be withdrawn from a scope or guidance purely because of a company request.

Information handling

1.1.4 Details on information handling, including confidential information, is described in sections 5.3 and 5.4 of NICE health technology evaluations: the manual. Further detail is available from NICE.

Technology costs

1.1.5 The cost of a technology is important for economic evaluations. Companies can provide costs relevant to use of their technology in their response to a request for information (see section 1.3.4) and at consultation on draft guidance (see section 1.5.5). Outside of these times it may not be possible to consider new or updated prices. Because the technology price is likely to be important for decision making it should not be marked as confidential. If companies believe there are extenuating circumstances for why the technology cost cannot be disclosed in public documents, further information on these circumstances must be provided for NICE to consider whether this is acceptable. In circumstances where NICE agrees to accept a price marked as confidential, a further price that can be publicly disclosed should also be provided.

1.1.6 Guidance can include recommendations on a technology for which no price has been provided. But if this cost is needed for an economic evaluation and the cost cannot otherwise be determined, it can prevent the technology being recommended for use in the NHS, because it leads to uncertainty about the cost effectiveness and budget impact.

1.2 Guidance development process overview

1.2.1 The guidance development process starts after a topic has been selected and scheduled for NICE guidance development. It consists of 3 phases: scoping, assessment and developing recommendations. Subsequent process for finalising and publishing the guidance are described in section 7 of NICE health technology evaluations: the manual.

1.2.2 It is not possible to set absolute timelines for the phases of the process. The length of time needed for each phase can vary depending on the nature of the evaluation. Illustrative lengths are shown in table 1. A shorter process can be used for technologies assessed for early use and interventional procedures because typically the assessment phase can be shorter.

1.2.3 Stakeholders are encouraged to input at several stages. These are described in the following process details, and a summary is provided in table 1.

Table 1 Overview of the 3 phases of HealthTech guidance development

Phase	Overview	Opportunities for stakeholder input
Scoping	Developing and finalising the assessment scope. This phase typically takes about 10 weeks.	• Providing responses to any requests for information or other questions from NICE. • Providing comments on the draft scope during consultation (if held) or a scoping workshop (if held).
Assessment	Producing an assessment report. This phase typically takes between 12 and 30 weeks.	• Providing responses to any requests for information or other questions from NICE. • Submitting comments on an external assessment report and any economic model produced during a comment period for the report (if held).
Developing recommendations	Committee meeting and producing draft guidance and final draft guidance.	• Attending committee meetings. • Submitting comments on draft guidance during a consultation period.

1.2.4 Throughout guidance development, up-to-date information about timelines and progress is published on the NICE website.

1.2.5 NICE informs stakeholders about timeline changes during an evaluation and the reasons for these changes. When the reasons

are commercially sensitive, NICE works with the company to release as much information as possible to stakeholders and on the NICE website.

Stopping guidance development

1.2.6 In exceptional circumstances, NICE may need to permanently stop guidance development. This decision is made by NICE. If guidance development is stopped, registered stakeholders are informed, and the NICE website is updated. Guidance production can be stopped for several reasons. This includes if producing the guidance is no longer considered useful or a priority for the healthcare system, or if it is no longer possible to produce recommendations, for example because no technologies being considered have appropriate regulatory approval.

1.3 Scoping

1.3.1 Sections 2.3 and 2.4 of NICE health technology evaluations: the manual describe the initial steps in developing the draft scope, including identifying stakeholders.

1.3.2 During the scoping phase, NICE will speak to individuals and organisations to gather information needed to develop the draft scope. This can include healthcare professionals, committee members, patients and carers, companies with technologies that may be relevant to the assessment, and other organisations as necessary. A key activity is identifying technologies that may be relevant to the assessment, which includes asking for suggestions and input during any scoping workshop or scope consultations (see section 1.3.19).

1.3.3 Requests for information may be sent to companies during scoping if they have technologies that could be included in the assessment or otherwise be relevant to it (for example, for interventional procedures guidance, requests can be sent to companies

producing devices that may be used to do the procedure). Being asked for, and providing, a request for information does not mean that a technology will be included in the scope for the assessment. Information provided is often used to determine if a technology is suitable to include in the scope.

Requests for information

1.3.4 Company evidence submissions are not made for HealthTech programme guidance. Instead, companies can be asked to provide responses to requests for information from NICE. Requests for information may be made as needed throughout the guidance development process.

1.3.5 Unpublished evidence can be provided with a request for information. See section 1.1.4 for information on how to provide confidential information to NICE.

1.3.6 A completed checklist of confidential information must be provided with a returned request for information.

1.3.7 Economic models can be submitted as part of the response to a request for information. But economic models may not be considered in the assessment period if they are not fully executable and using standard software, that is, Excel, DATA/Treeage, R or WinBUGs. When the company submits a fully executable electronic copy of the model, it must give NICE full access to the programming code and provide instructions on how to run the model.

1.3.8 It is not essential to provide a response to a request for information. Technology will not be withdrawn from a scope or guidance because a response has not been received. But not providing information needed by NICE may affect the assessment of a technology and consequently the recommendation.

1.3.9 Completed requests for information provided by a company can be shared with the committee, experts (see section 1.3.11) and an external assessment group (EAG; see section 1.4.5).

Information provided by non-company stakeholders or other organisations

1.3.10 NICE can also invite non-company stakeholders or other organisations to provide evidence to inform scoping and the assessment. This is to reflect the experience of patients, healthcare professionals and commissioners of current care in the NHS. It can also help understand the potential impact of using the new technology. Information on implementation issues, such as staffing and training needs, could also be provided.

Experts

1.3.11 The following experts can provide evidence, their views and experience throughout the evaluation:

- clinical experts
- relevant non-clinical experts (such as scientists, software specialists, data analysts, engineers or people with procurement or other technical experience, as needed)
- people with a condition and their carers, who can provide information about the impact of both the condition and the technology being assessed
- commissioning experts.

Experts will typically be selected during the scoping period but can also be selected later in the process if needed, for example if gaps are identified in the knowledge and expertise needed by a committee.

Identifying experts

1.3.12 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.

1.3.13 Relevant NHS commissioners of the technology can be invited to nominate NHS commissioning experts if commissioning expertise is specifically needed or if the population is covered by an NHS England specialised commissioning group.

Expert eligibility and selection

1.3.14 Sections 1.3.17 and 1.3.18 of NICE health technology evaluations: the manual describe the process of selecting experts and requirements that must be met.

1.3.15 The number of experts appointed will vary between guidance topics and will be informed by the knowledge and expertise needed by the committee. Typically, this would be between 3 and 10 experts.

Expert participation

1.3.16 Experts help clarify issues that NICE has identified throughout guidance development (including during scoping) and can also provide further input as needed. Experts can attend committee meetings, and they may submit written evidence such as completed questionnaires.

1.3.17 In committee meetings experts are expected to interact fully in the discussions with the committee, including responding to questions. Section 1.3.24 of NICE health technology evaluations: the manual further explains the role of experts in committee meetings.

1.3.18 Experts are asked to leave the meeting before the committee makes its decision and finalises the recommendations in the guidance in the private session (part 2) of the meeting, which is closed to the public. The chair may ask experts to remain for part of the private session (part 2A) of the committee meeting to respond

to any questions from the committee about information that cannot be discussed in part 1.

Draft scope: scoping workshops and scope consultations

1.3.19 After a draft scope is produced, NICE may hold a scoping workshop, have a consultation on the draft scope, or both.

1.3.20 A scoping workshop or draft scope consultation will not be held if NICE judges that there are no substantive uncertainties related to scope to resolve.

1.3.21 Section 2.5 of NICE health technology evaluations: the manual describes the process for consultation on the draft scope. The consultation will be 7 to 14 calendar days, but can be extended to 28 calendar days if there is a higher level of uncertainty about elements of the draft scope.

Scoping for guidance updates

1.3.22 For updates of existing guidance, NICE will update the original scope. This is to make sure that the guidance update considers the care pathway and use of the technology at the time the guidance update starts. NICE can review any element in the scope, including whether to expand the scope of the guidance update to include additional technologies.

1.3.23 When changes to the original scope are made, NICE may consult on a draft scope or hold a scoping workshop.

1.3.24 Guidance updates include any procedures or technologies recommended for use while more evidence is generated that are re-evaluated once this evidence is generated. This will be done according to the NICE HealthTech programme process and methods, and in the context of the healthcare system at the time of the guidance update, rather than at the time the original recommendation was made.

Final scope

1.3.25 After any scoping workshop or consultation held has completed, NICE agrees the final scope. Section 2.9 of NICE health technology evaluations: the manual describes the process for finalising and issuing a scope.

1.3.26 If the scope for an evaluation is too large for the available resources, NICE may revise it in collaboration with experts and members of the committee.

1.3.27 NICE will publish the final scope on its website at the start of an evaluation.

1.3.28 A decision will be made at the end of the scoping process if a topic is suitable for early use assessment. This decision will be communicated in the final scope. Topics likely to be suitable for early use assessment are those that:

- address a significant unmet need
- have a lower level of evidence available to support using the technologies and
- have system support for using the technologies while further evidence is generated.

Assessment protocol

1.3.29 For topics with an EAG appointed (see section 1.4.5), this group develops an assessment protocol, derived from the final scope of the evaluation. This will be published at the same time as or soon after the scope is published. The protocol will not be consulted on.

Amending the final scope after publication on the NICE website

1.3.30 There can be circumstances when the final scope may need amending after it has been published on the NICE website. NICE decides whether to amend the scope.

1.3.31 If a final scope is amended after publication, registered stakeholders are informed. The revised scope and revised assessment protocol, if needed, are published on the NICE website. Further consultation on the scope would not usually be done.

1.4 Assessment period

1.4.1 After the scoping process completes, at the start of or during the assessment period, the assessment may need to be paused. This may be because of external factors such as ongoing studies that will generate relevant evidence. NICE decides whether to pause the assessment period. Registered stakeholders are informed if the assessment period is paused.

1.4.2 An assessment report is generated to support guidance development. This report can either be produced by NICE or an EAG (see section 1.4.5). When produced by an EAG, this is an external assessment report, and the EAG is responsible for the content and quality of the report.

1.4.3 The length of the assessment period will be based on the expected amount or complexity of evidence and the extent of any economic evaluation needed. If this is more extensive than expected, the assessment period may need to be extended and the scope may be updated (see section 1.3.30).

1.4.4 Information provided during the assessment period that is not in response to a request for information from NICE or agreed in advance with NICE, may not be able to be considered in the assessment report.

EAGs

1.4.5 EAGs can be commissioned to produce an external assessment report to support guidance production (see section 1.3.28 in NICE health technology evaluations: the manual for further description of

EAGs). They can be used when there is a larger volume or complexity of evidence, or if more complex statistical analysis or an economic evaluation is needed.

1.4.6 Experts selected by NICE may also support the EAG during the evaluation. But they cannot be appointed as advisers to the EAG. This is so they can maintain sufficient independence from the evidence and contribute to a committee's discussions on the quality of the external assessment report.

Comment period for an external assessment report

1.4.7 NICE can share a copy of the external assessment report with companies that have a named technology in the assessment (that is, the technology name is specified in the assessment scope as an intervention) for comment in advance of committee meetings. The focus of comments should be issues of factual accuracy in the assessment report, and model if produced.

1.4.8 If an economic model is produced as part of the assessment, NICE offers to send the economic model (in its executable form) to stakeholders with the external assessment report. If the model contains confidential material that the data owner is unwilling to share with stakeholders, despite the assurances provided through the signed confidentiality agreements, NICE will ask the group who have generated the model to replace this with dummy data or redact it if this can be done without severely limiting the model's function. Stakeholders must make requests for a copy of the model in writing. NICE provides the model on the basis that the stakeholder agrees, in writing, to the conditions of use set out in section 5.5.18 of NICE health technology evaluations: the manual.

1.4.9 In exceptional circumstances it may not be possible to provide the economic model to stakeholders. For example, if it is not possible to do so without revealing confidential information.

1.4.10 Stakeholders have 14 calendar days to submit comments.

1.4.11 If comments need an EAG response, NICE sends them to the EAG. Its responses will be tabled at the next committee discussion.

1.5 Developing recommendations

1.5.1 The developing recommendations phase of the process has 4 possible stages:

- consideration of the evidence at a committee meeting to discuss the content of the draft guidance
- development of, and consultation on, the draft guidance
- review of the draft guidance after comments from consultation
- development of the final draft guidance.

Initial committee meeting

Preparing for the committee meeting

1.5.2 The committee is described in sections 1.2.1 to 1.2.6 of NICE health technology evaluations: the manual.

Committee meetings

1.5.3 Detail on committee meetings are in sections 5.8.4 to 5.8.21 of NICE health technology evaluations: the manual. Agendas and minutes of committee meetings are published on NICE's website.

1.5.4 Detail on the participation of company representatives at the committee meeting are in sections 1.3.6 and 1.3.7 of NICE health technology evaluations: the manual.

Consultation on the draft guidance

1.5.5 The draft guidance and committee papers are sent to stakeholders for consultation. These documents are confidential until NICE publishes them on its website. Information designated as confidential will be redacted from the documents.

1.5.6 The committee papers and the draft guidance document are made available during consultation on draft guidance. Section 5.8.45 of NICE health technology evaluations: the manual describes draft guidance, and section 5.8.48 describes the purpose of consultation.

1.5.7 Stakeholders have 21 calendar days from the date of sending to submit comments on the draft guidance.

1.5.8 NICE publishes the draft guidance and any additional committee papers not already shared on its website with an electronic comment facility within 7 days of circulation to stakeholders. The deadline for comments to be received is the same as for stakeholders.

1.5.9 The committee may be unable to develop recommendations without further scrutiny or further analyses. If this is the case, the evaluation can be paused. NICE may request that a company or EAG submits specific information, further analyses or an updated economic model.

After draft guidance consultation

1.5.10 The committee 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.

1.5.11 The chair's decision will be shared with stakeholders. This will be a brief statement of the decision.

1.5.12 If needed the committee can meet again to consider the preliminary recommendations in the draft guidance with comments received. Before the meeting, NICE sends the committee members the full text of the comments from stakeholders. Sections 5.8.57 and

5.8.58 of NICE health technology evaluations: the manual describe the process of a further committee meeting.

1.5.13 When consultation comments are received that lead to a substantial revision of the committee's previous decision, involving a significant change in the recommendations, discussions or the evidence base, NICE and the committee chair will decide whether it is necessary to have a further draft guidance consultation. The decision to hold another consultation will extend the timelines for the evaluation. NICE will distribute any further committee papers with the second draft guidance, together with initial consultation comments. The process of a further consultation is the same as for the initial consultation.

Developing final draft guidance

1.5.14 Sections 5.8.64 to 5.8.69 of NICE health technology evaluations: the manual describe the process of developing final draft guidance.

1.5.15 For comments received on the draft guidance, NICE reserves the right to summarise and edit comments received during consultations. It can also decide to not publish them at all when, in the reasonable opinion of NICE, the comments are voluminous, or publication would be unlawful or otherwise inappropriate.

Resolution

1.5.16 Section 7.2 of NICE health technology evaluations: the manual describes the resolution process. Definitions for ‘stakeholders’ and ‘consultees’, as mentioned in this section, can be found in sections 1.2.17 and 1.2.18 of NICE health technology evaluations: the manual.

Tools and resources

1.5.17 Section 5.12 of NICE health technology evaluations: the manual describes the production of tools and resources to support guidance. This includes resource impact tools or statements.

NICE's assessing resource impact process manual has further details.

1.5.18 During guidance development for interventional procedures, appropriate OPCS codes for the procedure are identified and reviewed by the committee. These codes are published with guidance on the NICE website. NICE liaises with relevant partners to identify when a new code is needed for a procedure because no appropriate codes currently exist. New codes are published on the NICE website when they become available.

1.5.19 For interventional procedures guidance, an audit tool template for procedures is available on the NICE interventional procedures guidance webpage.

Evidence generation plans

1.5.20 For technologies recommended for use while further evidence is generated in early use HealthTech guidance, an evidence generation plan can be produced (see section 1.7).

1.6 Guidance surveillance

1.6.1 After guidance publication, the process of guidance surveillance is described in section 8 of NICE health technology evaluations: the manual.

1.7 Evidence generation process for early use HealthTech guidance

Overview

1.7.1 The evidence generation process is designed to help companies work with NHS sites, data custodians and analytical partners to generate evidence needed to support future NICE guidance. This process will start from the point of the decision to take a topic through early use assessment and will support the development of guidance.

1.7.2 The evidence generation process will aim to deliver proportionate and pragmatic approaches to evidence generation. The evidence generated during the period of use in the NHS should provide the information needed for NICE to make a recommendation about routine use in the future.

Stakeholder roles for the evidence generation process

1.7.3 NICE:

- identifies uncertainties that are essential to resolve for future decision making and that should be prioritised for further evidence generation
- assesses the feasibility of evidence generation while the technologies are used in the NHS
- engages with stakeholders about ongoing or planned studies and considers if and how they could address the uncertainties
- highlights NHS real-world data sources that could support or contribute to evidence generation
- suggests an approach to evidence generation that could address the uncertainties
- highlights potential sources of funding when NICE is aware of these
- highlights potential partners that could support evidence generation, such as research groups, clinical networks or implementation specialists when NICE is aware of these
- monitors progress of evidence generation.

1.7.4 Companies:

- are responsible for delivering evidence generation
- are responsible for organising funding to support evidence generation
- engage with and support the NICE evaluation and monitoring process
- engage with partners to implement evidence generation, by:

  - choosing appropriate NHS sites to develop the evidence
  - using robust approaches to evidence generation, considering aspects such as data quality, study design, analysis, and reporting and partnering with experts in research and analysis when necessary to ensure key uncertainties are addressed
  - ensuring new evidence is generated in accordance with all applicable data protection legislation
- ensure that safety is monitored, and signals of concern are discussed with clinical leads and reported to the Medicines and Healthcare products Regulatory Agency and NICE as appropriate
- lead response to safety signals as necessary
- minimise burden of data collection whenever possible, for example, by using real-world data collections that build on existing clinical information flows
- consider advice laid out in NICE's health technology evaluation manual, real-world evidence framework and evidence standards framework for digital health technologies to inform evidence generation
- make the evidence generated available to NICE in a form that can be used for decision making.

The evidence generation process

Feasibility assessment

1.7.5 The feasibility assessment considers barriers and facilitators to addressing the likely uncertainties during a standard evidence generation period. It will be finalised shortly before the first committee meeting and will use information from the EAG report as well as information already gathered from topic selection and scoping stages.

1.7.6 The feasibility assessment considers the following aspects:

- if key uncertainties could be resolved in a fixed period of 3 years from the point of guidance publication (4 years will be allowed in exceptional circumstances)
- the likely number and complexity of new studies needed
- facilitators that increase the likelihood that evidence generation will be successful (based on knowledge of relevant data sources, previously completed research, or known funding opportunities).

1.7.7 The feasibility assessment will be informed by:

- uncertainties highlighted in the EAG report
- consideration of the evidence landscape, including:
  - ongoing or planned studies
  - real-world data sources
- consideration of methodological approaches to address the evidence gaps, for example those outlined in NICE's real-world evidence framework
- knowledge of existing funding sources
- knowledge of potentially suitable implementation partners.

1.7.8 Key conclusions from the feasibility assessment can be presented to the committee.

Evidence generation plan

1.7.9 The committee will identify the uncertainties that need to be addressed to support future NICE guidance of a technology. This will inform the development of an evidence generation plan. The plan describes the uncertainties and what evidence should be generated for a NICE evaluation of the technologies again in the future. It is not a study protocol but suggests an approach to generating the information needed to address the evidence gaps. The evidence generation plan will sit alongside the guidance.

Evidence generation monitoring

1.7.10 Once guidance is published, NICE will monitor the companies evidence generation activities. The monitoring process is designed to support companies to deliver the evidence that NICE needs and to support NICE planning for a future evaluation.

1.7.11 NICE has the right to withdraw or change individual technology recommendations at any stage. Information collected through the monitoring process will inform decision making about withdrawal. Reasons a recommendation to use a technology while further evidence is generated may be withdrawn include:

- the technology is not available to the NHS
- NICE is unable to contact the company
- the company volunteers to withdraw
- there are significant safety concerns about the technology
- the company is not engaging in evidence generation, or evidence generation will not address the essential uncertainties.

1.7.12 The monitoring period will begin at the date of publication of the guidance and evidence generation plan. The monitoring process includes several touchpoints:

- Six months after guidance publication, NICE will contact companies to confirm they are engaging with NICE processes and have begun evidence generation.
- Twelve months after guidance publication NICE can ask for a summary of overall progress with evidence generation and the status of data collection. Ideally, companies will share their study protocol and, when relevant, evidence of engagement with implementation partners.
- Annually from 12 months, companies will be expected to report on their data collection. At this point they can also be asked if they consider that the evidence generated is sufficient to address the essential uncertainties.

1.7.13 In addition to routine monitoring, companies should inform NICE as soon as possible of anything that may significantly affect ongoing evidence generation, including:

- any substantial risk that the evidence will not be collected as planned
- any safety concerns
- the technology significantly changing in a way that affects the evidence generation process.

1.7.14 If data collection is expected to end later than planned, the company should contact NICE.

1.8 Re-evaluation of technologies recommended for use while further evidence is generated

1.8.1 Technologies recommended for use while further evidence is generated that complete the evidence generation process will be re-evaluated by NICE. This is to decide whether the technology can be recommended for routine use, considering the further evidence generated. Details on the process of scoping in this scenario are described in section 1.3.24.

1.8.2 As part of monitoring done during the evidence generation process, companies can submit evidence at the touchpoints if they consider the evidence generated is sufficient to address the essential uncertainties identified in the guidance and evidence generation plan (see section 1.7.12). NICE may consider evidence provided before the end of the evidence generation period. This will follow the surveillance review process set out in sections 8.3 and 8.4 of NICE health technology evaluations: the manual. It will consider if re-evaluation of some or all of the technologies in the guidance should start before the end of the evidence generation period. When doing the surveillance review, NICE will consider the status of evidence generation for other technologies recommended for

use with evidence generation in the same guidance and how close the end of the evidence generation period is. This may lead to the surveillance review being deferred to a later date to consider evidence generated by other companies, or not being done if it is likely completion would be close to or after the end of the evidence generation period. It is expected that most re-evaluations will take place after the full evidence generation period.

2 Methods for guidance produced in the NICE HealthTech programme

Methods to develop health technology evaluation guidance are as described in NICE health technology evaluations: the manual (including scoping, evidence, economic evaluation and committee recommendations). For early use HealthTech guidance assessments, some further detail and considerations are set out in section 2.1.

Technologies considered in HealthTech guidance can be assessed using cost utility or cost comparison analysis (see sections 4.2.11 to 4.2.13 in NICE health technology evaluations: the manual).

Detail on methods for guidance that focuses on interventional procedures (based on an assessment of efficacy and safety) can be found in NICE's interventional procedures programme manual.

Methods for health technology evaluation guidance for technologies in existing use are currently described in NICE's late stage assessment interim methods and process statement.

An overview of the types of recommendations used in guidance produced in the HealthTech programme, and what they mean in practice, is shown in table 2.

Table 2 Overview of recommendations used in HealthTech programme guidance

Recommendation type	What this means in practice
Can be used	**HealthTech guidance** There is enough evidence that the technology provides benefits and value for money, so it should be routinely available across the NHS. **Interventional procedures guidance (previously 'standard arrangements')** There is enough evidence on the safety and efficacy of this procedure for clinicians to consider it as an option. Clinicians do not have to offer this procedure and should always discuss the available options before making a decision.
Can be used during the evidence generation period	**HealthTech guidance** The technology can be used if needed in the NHS during the evidence generation period and paid for using core NHS funding, as long as any clinical, economic or system risks posed are managed. During this time, more evidence will be collected to address uncertainties. After this, NICE will review this guidance, and the recommendations may change. The technology can only be used if evidence is being generated, in line with NICE's evidence generation plan. **Interventional procedures guidance (previously 'special arrangements')** There are uncertainties around the safety or efficacy of this procedure. It can be used if needed while more evidence is generated to check if it is safe or clinically effective, and any risks are appropriately managed. This guidance will be reviewed and the recommendations may change.
More research is needed	**HealthTech guidance** There is not enough evidence to support funding the technology in the NHS. Access to technology should be through company, research or non-core NHS funding, and clinical and financial risks should be appropriately managed. **Interventional procedures guidance** There is not enough evidence to know if this procedure is effective/safe. It should only be done as part of formal research.

Recommendation type	What this means in practice
Should not be used	**HealthTech guidance** The technology does not offer benefit or value for money and should not be used in the NHS. **Interventional procedures guidance** The evidence suggests that the procedure does not work well enough or there are unacceptable safety risks. So, it should not be used in the NHS.

2.1 Early use HealthTech guidance assessments

Detail set out in this section supersedes NICE's early value assessment interim statement and covers early use HealthTech guidance (methods for guidance that focuses on interventional procedures can currently be found in NICE's interventional procedures programme manual).

Background

2.1.1 Early use assessments are an evidence-based approach designed to improve the care of people and effective use of NHS resources through quicker access to promising health technologies that address high unmet need for patients or the NHS. It champions stronger partnership working between regulatory, healthcare and research organisations to benefit people and better support innovators while ensuring value for money for the NHS.

2.1.2 There are 4 key aims of the early use assessment approach:

- To focus on promising innovations that meet the needs and priorities of people, and the health and social care system.
- To enable earlier access to useful innovations through faster assessments and timely guidance production.
- To better support use of technologies and evidence generation by embedding early use assessments in cross-partnership working.

- To realise the benefits of promising innovations and ensure value for money for the health and social care systems.

2.1.3 The aims will be achieved for selected technologies by:

- identifying available evidence
- exploring if the technologies have the potential to address the identified unmet need and offer value for money
- helping direct further evidence generation for future evaluations
- determining if any clinical, economic and system risk posed by early use can be managed and, consequently, if the technologies should be used while further evidence is generated.

Evidence

2.1.4 The standard approach to assessing the evidence for a NICE evaluation is outlined in section 3 of NICE health technology evaluations: the manual. Early use assessments happen earlier in the life cycle of a technology and so the evidence assessment has been adapted to reflect this. Rapid review methodology and principles can be used. For example, the Cochrane Rapid Reviews Methods Group provides guidance on doing rapid reviews of the effectiveness of health interventions.

Evidence identification

2.1.5 It is expected that the available evidence will vary significantly between topics and technologies. If no evidence is identified that is directly relevant to the decision question, a broader evidence base should be considered. For example, evidence from the technology's use in a different population or setting.

2.1.6 Data on final outcomes may be limited so surrogate and intermediate outcomes should be considered. Supplemental searching and grey literature searching may also be helpful for technologies with limited published evidence. Companies and other

stakeholders will be given the opportunity to provide evidence to NICE in response to a request for information (see section 1.3.4). Published and unpublished studies provided by companies and other stakeholders should be considered.

2.1.7 Searches should also identify existing economic evaluations and resource and cost-impact analysis that addresses similar or related decision problems that may provide relevant information for the economic evaluation.

2.1.8 Searches for ongoing studies should also be done.

Evidence reviews

2.1.9 The evidence reviews should usually be done using pragmatic rapid review approaches. For example, single screening and data extraction with 20% of studies checked by a second reviewer.

2.1.10 A full critical appraisal of all studies and outcomes is not expected. But discuss the potential biases in key studies, how the risk of bias could affect key outcomes, and the generalisability of the results to clinical practice in the NHS. Work in this area, for example development of topic specific signalling questions for quality assesment tools, is likely to be useful to inform planning of further studies.

2.1.11 The review should describe evidence gaps and suggest outcomes to focus on in future evidence generation, including those relating to patient safety. The report should describe any identified ongoing studies or data collections or real-world data sources that may address the evidence gaps.

Economic evaluation

2.1.12 The economic evaluation that will be most beneficial for committee decision making is likely to vary by topic, needing flexibility from assessment groups. Discuss planned work with NICE from an early stage of the assessment.

2.1.13 The key objectives of the economic evaluation are to:

- assess how well the technologies are likely to resolve the specified unmet need
- assess how likely the technologies are to offer value for money (such as being cost effective or providing similar or greater health benefits at similar or lower cost than the relevant comparator)
- identify uncertainties that are likely to be key drivers of decision-uncertainty.

2.1.14 Highlight uncertainties that are essential to resolve for future guidance development, focusing on those that are most important to address.

2.1.15 Give details about services that would be impacted by using the technologies and how they would be impacted (in terms of greater or reduced use). This should include direct impacts of using the technologies, and any impacts that are likely to occur downstream of use (ideally model outputs will help to estimate size of impact; see section 2.1.20).

2.1.16 The economic evaluation should ideally generate estimates of clinical and cost effectiveness, or cost comparison, following as closely as possible the modelling methods and exploration of uncertainty as described in sections 4.6 and 4.7 in NICE health technology evaluations: the manual. Advice on approaches to follow can be found in the NICE Decision Support Unit's report on economic evaluation in NICE early value assessments. For example, making greater use of existing models or model outputs, or if these are not available then producing simplified models or reporting intermediate outcomes with threshold analyses.

2.1.17 There is likely to be less evidence and limited time to develop full new models for early use assessments. So, pragmatically decide how to provide analyses that inform considerations of how likely the

technologies are to offer value for money. Assessment groups can provide analyses that may be considered more exploratory or based on larger assumptions than would usually be considered to support guidance for routine use of technologies. Clearly describe the limitations of these analyses and the assumptions made for them. The committee can then decide to what extent it uses such analyses in its decision making.

2.1.18 Using expert elicitation or expert opinion should be considered to provide evidence to support economic evaluation work (see sections 3.3.21 to 3.3.23 of NICE health technology evaluations: the manual).

2.1.19 The reference case is the same as described in section 4.2 of NICE health technology evaluations: the manual. Additional analyses can be presented when 1 or more aspects of methods differ from the reference case. But these must be justified and clearly distinguished from the reference case. Discuss with NICE as early as possible if intending to provide such analyses, for example a non-reference case type of economic evaluation.

2.1.20 Guidance for presenting model results is described in section 4.10 of NICE health technology evaluations: the manual. In addition to any final model outputs, such as total costs and quality-adjusted life years, provide outputs from the model that are useful to help understand the estimated impact of the technologies. For example, values that would be meaningful for healthcare professionals and those that show the impact of technology use on services.

2.1.21 Highlight any potential impacts of technology use that are not captured in model results. This could, for example, relate to impacts on the health and social care workforce or system efficiencies.

2.1.22 Present any model outputs that show how well the technologies are likely to resolve the specified unmet need.

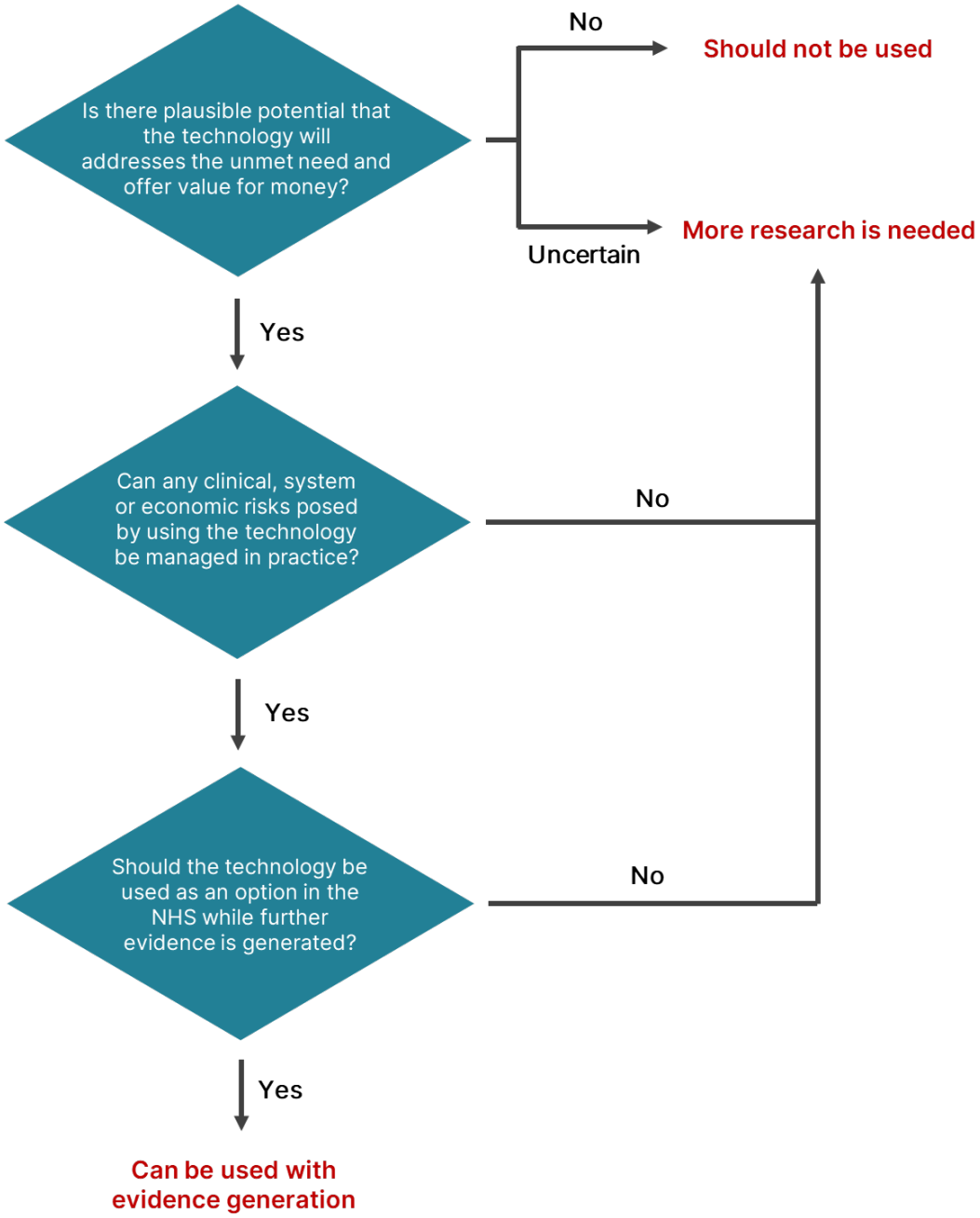
Decision making

2.1.23 Key goals for decision making in early use assessments are to decide if technologies should be used as an option in the NHS while further evidence is generated and to prioritise uncertainties that further data is needed for to support future decision making. This evidence is for future NICE guidance to decide whether to recommend a technology for routine use.

2.1.24 Recommendations will only be for the use, or uses, of the technologies as specified in the scope.

2.1.25 When making decisions the committee will consider if a technology has plausible potential to addresses the specified unmet need and offer value for money. It will also consider whether any clinical, system or economic risks of using the technology could be managed in practice (further description is provided in sections 2.1.26 to 2.1.29). The flow chart in figure 1 describes how these considerations link to available recommendations.

Figure 1 Decision making for early use



2.1.26 **Is there plausible potential that the technology will address the specified unmet need?** Considerations include the extent that this is supported by available evidence and other relevant information (including the views and experiences of people who will use the technology).

2.1.27 **Is there plausible potential that the technology offers value for money?** For example, assessing if the technology is cost effective

or provides similar or greater health benefits at similar or lower cost than the relevant comparator. Technologies considered unlikely to offer value for money typically would not meet this point. Considerations include:

- The likely size of any impacts of technology use (positive, including addressing the unmet need, and negative) on patients, and, where relevant, carers, the NHS and personal social services (including impacts on system efficiencies), and the extent that available evidence or other information supports this. This should include potential impacts on patient safety.
- Analyses done as part of the economic evaluation work to assess how likely the technology is to offer value for money.

2.1.28 **Can any clinical, system or economic risks posed by using the technology be mitigated or managed in practice?** For example, by specifying how the technology should be used or whether provision could be made for special safety monitoring measures. Or, if there could be reductions in technology cost or alternative ways in which the technology is charged for, particularly if there are large irreversible costs associated with using it.

2.1.29 **Should the technology be used in the NHS as an option while further evidence is generated?** Considering the potential of the technology to address the specified unmet need and offer value for money, and the extent that any risks of using the technology in practice can be managed.

2.1.30 When multiple technologies are considered, each should be assessed independently, unless the committee believes it is appropriate for available data that has been generated using 1 or a subset of technologies to be used for others. The committee may need to consider any difference between technologies in terms of whether they may solve the specified unmet need and any

differences in further evidence needs. Different recommendations can be made for different technologies included in the guidance.

Types of recommendations

2.1.31 **Use while further evidence is generated**

If there is plausible potential that the technology will address the unmet need and offer value for money, and that any economic, system or clinical risks posed by uncertainty in evidence can be managed then the technology can be used in the NHS if needed while further evidence is generated (the evidence generation period) and be paid for using core NHS funding. Any identified measures for mitigating risks of using the technology are presented with the recommendation.

Technologies should only be used in the NHS during the evidence generation period if the evidence outlined in the evidence generation plan is being generated (see section 1.5.20).

2.1.32 **More research is needed**

More research is needed before the technology can be used routinely or funded by the NHS. Access to the technology (for the use or uses assessed in the guidance) should only be through company, research or non-core NHS funding. This can be because it is too uncertain that the technology will address the unmet need or offer value for money.

2.1.33 **Should not be used**

If the technology will not address the unmet need or offer value for money. For example, because of how it functions, potential safety issues or based on available evidence on performance, particularly if it has a high cost.

2.1.34 For recommendations for use while further evidence is generated the uncertainties that the committee needs further data on to

support future decision making should be listed and include a focus on those that:

- are essential to future decision making, and
- can be resolved in 3 years from the point of guidance publication (4 years will be allowed in exceptional circumstances).

2.1.35 Technologies recommended for use while further evidence is generated and that complete the evidence generation process (see section 1.7) can be re-evaluated by NICE (see section 1.8).