

NICE HealthTech programme

1 August 2025

1 Processes for developing guidance in the HealthTech programme

The processes for developing HealthTech guidance are described in the existing [NICE HealthTech programme manual](#) (section 1) and are not presented here because they are not part of this consultation.

2 Methods for guidance produced in the NICE HealthTech programme

After consultation and making any resulting changes, this chapter will be added to the existing [NICE HealthTech programme manual](#) (section 2).

Methods for guidance

Interventional procedures guidance

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

HealthTech guidance

Methods for developing HealthTech guidance are set out in the following sections. [Section 3](#) sets out specific detail for early use HealthTech guidance assessments (early value assessment [EVA]). [Section 4](#) sets out specific detail for existing use HealthTech assessments (late-stage assessment [LSA]).

2.1 Scoping

General

2.1.1 The scoping process aims to define what questions the evaluation will answer and what will be included. The scope provides the framework for the evaluation and describes a decision problem. It defines the issues for consideration and sets the boundaries for the work to be done.

2.1.2 Key overarching points to define in scoping are:

- what use or uses of the technology will be assessed (use cases; see section 2.1.3)
- what potential impacts using the technology for this use case, or use cases, may have (value proposition; see section 2.1.4).

It is important to understand how using the technology for the specified use cases is expected to achieve the proposed benefits, or value proposition. This can help to identify how the technology is expected to be used and any changes to care, practice or infrastructure that are needed for the technology to achieve its proposed impact (see sections 2.1.8 and 2.1.9).

2.1.3 The priorities of the health and care system are a key consideration in deciding aspects of the scope. These are identified and considered during topic prioritisation (see the [chapter on identifying priorities for the health and care system in NICE-wide topic prioritisation: the manual](#)). Health technologies can often be used in multiple different ways or for various purposes (use cases). For example, in different populations or at different points in a care pathway. The scope will define what uses of the technology to include in the assessment, using input from healthcare professionals, patients and other stakeholders. Considerations include what uses of the technology are most likely to maximise benefit to the NHS, the population of England and areas of unmet need.

- 2.1.4 Scoping will establish the potential impacts of a technology, compared with current practice (its value proposition). This can involve direct impacts on people's health and aiding earlier diagnosis. It can also involve improving access to services and changing how care is delivered. For example, improving efficiency of service delivery, particularly if this will address current system infrastructure or workforce capacity constraints or burden.

Components of the scope

Interventions

- 2.1.5 HealthTech guidance can include multiple health technologies or defined groups or classes of health technology (see section 2.1.7). This is if there is likely benefit to the NHS of evaluating multiple technologies for the use cases being assessed, and they are alternative options for 1 or more of the use cases being assessed. These are specified in the scope.
- 2.1.6 The scope can set out the criteria that technologies need to meet to be included in the assessment. These will typically be based on advice from healthcare professionals and patients. Criteria will include features or functions that are considered essential for the technology to be used in the way being assessed (use case) or to have the proposed impact (value proposition).
- 2.1.7 In some instances, interventions may be defined as a group or class of technologies that have shared features or functions. For example, laboratory tests for a particular genetic marker or analyte. This may be considered when:
- the features of technologies, what they do or how they function are very similar or the same
 - assessing technologies in this way is likely to be of most benefit to the NHS, for example, when decisions about which

technologies to use within the group or class are likely to be strongly influenced by local factors and considerations.

2.1.8 The scope can specify further detail on a technology if needed to understand its proposed use, particularly if this is integral to its value proposition. For example:

- who would use the technology and the setting for use
- how it should be used, including in relation to other technologies (for example, in a sequence of tests)
- components or features of the technology
- for technologies producing information, such as for diagnosis or prognosis or for monitoring and response assessment, how this information is intended to be used and any specific test thresholds.

In some instances, assessments may evaluate different ways technologies could be used (for example, tests used in different sequences), which can be defined in the scope.

2.1.9 The scope should describe any changes to infrastructure, care pathways, staffing or care delivery that are expected to be needed for the technology to be used in practice and achieve its proposed impact. For example, any additional equipment, resource, staff training or changes to service arrangements.

2.1.10 NICE will not develop HealthTech guidance on a technology outside of its indication or intended purpose or use, as defined by any regulatory approval for use in the UK.

2.1.11 Technologies not yet available in England or without appropriate regulatory approval may be included within a scope. The appropriate regulatory approval is usually a UK Conformity Assessed (UKCA) or CE mark (as a medical device). The Medicines and Healthcare products Regulatory Agency (MHRA)

may apply different regulation procedures to certain products, such as in-house tests.

- 2.1.12 For technologies assessed as a group or class (see section 2.1.7), at least 1 available technology must have appropriate regulatory approval.

The population

- 2.1.13 The scope defines the population for whom the technology is being evaluated as precisely as possible. It may highlight potential subgroups for which the technology's clinical effectiveness or value for money might differ from the overall population, or groups that need special consideration.
- 2.1.14 Identifying groups for whom the clinical or cost effectiveness may differ from the overall population is particularly important if differences relate to a potential equality issue that will need to be considered in guidance (see section 2.1.29).

Comparators

- 2.1.15 The scope identifies relevant comparators that are established practice in the NHS or are recommended in existing guidance from NICE or other bodies. This can include 'no activity' if nothing is done in current practice. Comparators may include technologies that do not have regulatory approval for the population defined in the scope if they are considered established clinical practice in the NHS. The comparator will typically not include use of the intervention being assessed, even if it is currently in use in practice to some degree. Exceptions include when the assessment is focused on assessing different ways that current care can be delivered (for example, using a different threshold for established tests or using an established technology in a different setting).

- 2.1.16 The comparator should be defined as precisely as possible. It is important this accurately represents current care. It is also important that any challenges with current care which may form part of the value proposition for the intervention are accurately represented (for example, access to care, or delays to having treatment or appointments).

Outcomes and costs

- 2.1.17 Relevant outcomes and costs are those resulting directly or indirectly from the technologies being evaluated. The perspective taken in NICE's reference case (see [section 4.2 of NICE health technology evaluations: the manual](#)) should be considered when deciding relevant outcomes and costs to include in the scope.
- 2.1.18 Consideration of potentially relevant outcomes and costs should reflect the value proposition for the technology (see section 2.1.4) and any potential negative impacts that using the technology, compared with the comparators, could have for patients and the healthcare system.
- 2.1.19 If available, a high-quality 'core outcome set', developed with people with the condition, may help with outcome selection. One source is the Core Outcome Measures in Effectiveness Trials (COMET) database. The Core Outcome Set Standards for Development (core outcome sets-STAD) and Core Outcome Set Standards for Reporting (core outcome sets-STAR) should be used to assess the suitability of identified core outcome sets.
- 2.1.20 Included outcomes should reflect what is important to address for the decision problem set out in the scope, rather than outcomes for which evidence is known to exist.
- 2.1.21 In addition to clinical outcomes, the scope can specify any outcomes related to the NHS and personal social services (PSS)

that may be impacted by use of the technology. These can include outcomes related to resource use and system efficiency.

- 2.1.22 Further outcomes can be considered when relevant, including those related to technology functions, for example, measures of ability to perform a specific task or function, and those related to people's behaviour or activity. The extent to which such outcomes can be used in estimates of cost effectiveness is likely to depend on the extent to which they are predictive of impact on clinical or resource-use outcomes.
- 2.1.23 Quantitative outcomes are needed to evaluate the cost effectiveness of a technology. Consideration should be given to how potential impacts could be captured quantitatively when identifying relevant outcomes. For example, for technologies that are proposed to be easier to use, relevant outcomes may be related to procedure times, incidences of successful procedures or need to repeat procedures.
- 2.1.24 Outcomes related to the needs and preferences of patients and healthcare professionals for different technologies (quantitative or qualitative; see section 2.1.25), or particular functions or features of technologies, may be useful for decision making and can be specified in the scope. This may particularly be the case when there are multiple technologies defined as interventions in the scope, and evidence that compares clinical and system outcomes between these technologies is likely to be absent or weak.
- 2.1.25 To supplement quantitative outcome measures, or when these are not possible or unlikely to be collected, qualitative outcomes can be specified in the scope. This can include informational outcomes of value to the patient for the relief, or infliction, of anxiety or for personal planning. Qualitative research can explore areas such as values, preferences, acceptability, feasibility and equity implications.

Prioritisation of outcomes

- 2.1.26 When the number of potentially relevant outcomes is large, the scope may prioritise or only include key outcomes that are most relevant to addressing the decision problem. Input should be sought from stakeholders and experts during the scoping process. The views of people with the condition and users of the technology will be particularly important considerations here. This will ensure that specified outcomes reflect the preferences of patients, and when relevant their carers, and healthcare professionals or other staff who would use the technology.

Assessment and guidance details

- 2.1.27 The scope will include, when relevant, details of the type of evaluation that will be done during the assessment phase. This will be informed by considerations of which type of evaluation is most appropriate for the technology and value proposition being considered. For example, a cost-comparison approach to economic evaluation may be specified for technologies considered likely to provide similar health benefits at similar or lower cost than comparators. This can be the case for technologies likely to have only a healthcare system benefit.
- 2.1.28 The scope will also specify what guidance will be developed in terms of the lifecycle approach to be used (for early, routine or existing use guidance). General principles for this decision are described in table 2. Note that an initial decision about whether guidance is developed for a technology or topic, and that this should be done by the HealthTech programme, are taken according to [NICE-wide topic prioritisation: the manual](#).

Table 2 General principles used to determine what lifecycle approach to take for producing guidance

Lifecycle approach	General principles for selecting which lifecycle approach to take
Early use	<ul style="list-style-type: none"> • Limited or no current use in NHS • Limited evidence available for all technologies • Technologies have the potential to address a high unmet need in the NHS • Usually recent, ongoing or upcoming appropriate regulatory approval for use in the UK
Routine use	<ul style="list-style-type: none"> • Greater level of evidence available that means some technologies may be suitable for routine widespread use in the NHS • Any technologies that have been previously assessed in early use guidance and have gone through the evidence generation period
Existing use	<ul style="list-style-type: none"> • In widespread or established use in NHS

Equality considerations

2.1.29 The scope will include, when relevant, details of:

- issues relating to advancing equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics and society as a whole
- potential issues relating to health inequalities, including whether the technology could address inequality or unfairness in the distribution of health across society.

Existing NICE guidance

2.1.30 Identifying related NICE guidance (both published and in development) is a key element of scoping. This helps to see where and how the potential recommendations are likely to relate to existing recommendations in other guidance. The scope can include, when relevant, details of related NICE guidance, such as other evaluations and clinical guidelines, and related policy developments.

2.2 Evidence

- 2.2.1 Evidence is identified during the assessment phase and presented in the assessment report. This is based on the scope for the assessment and the decision problem described therein.
- 2.2.2 [Sections 3.1 and 3.2 in NICE health technology evaluations: the manual](#) describe approaches to assessing the evidence and guiding principles for evidence.

Types of evidence

- 2.2.3 All types of evidence can be considered for evaluations (although not all types will be included in the assessment report; see section 2.2.11). This includes evidence from published and unpublished data, data from non-UK sources and economic evaluations of technologies. The assessment report will comment on the quality of evidence sources and the type and quality of evidence will be considered by the committee in its decision making (see section 2.4.6).
- 2.2.4 The [NICE real-world evidence framework](#) describes best practices for planning, doing and reporting real-world evidence studies (this includes the [conduct of qualitative research studies, described in appendix 4](#)). [NICE's evidence standards framework for digital health technologies](#) outlines critical considerations for evidence generation for digital health interventions.
- 2.2.5 Evidence exploring the views and experiences of people with the condition and healthcare professionals who will use the technology may be presented to committee. This evidence may come from published sources or from evaluations done specifically for the assessment.

Synthesis of evidence

Evidence review

- 2.2.6 [Section 3.4 of NICE health technology evaluations: the manual](#) details approaches for assessing evidence for an evaluation. Literature searches are done as an integral part of evidence identification during the assessment phase.
- 2.2.7 In addition to literature searches, evidence provided or identified by companies or other stakeholders is considered, if provided at appropriate points in response to a request from NICE (see [section 1.3.4](#)). Any unpublished evidence provided should be accompanied by sufficient details to enable a judgement as to whether it meets the same standards as published evidence and to determine potential sources of bias. Ideally it should be structured and presented in the form of a research publication. Methodological detail should be provided in line with relevant reporting guidelines (for example, those endorsed by the [EQUATOR network](#)) to allow critical appraisal of unpublished evidence.
- 2.2.8 Evidence on predecessor versions of a technology may be considered if there is limited evidence on the currently available model or version. But the extent to which it is appropriate to use such evidence should be considered and commented on in the assessment report, for the committee to consider in its decision making.
- 2.2.9 Existing systematic reviews and meta-analyses may be used or updated, if possible and in line with the decision problem outlined in the scope. As part of the assessment a judgement will be made on which elements of the previous systematic review can be reused, and which need to be redone or updated.

- 2.2.10 The evidence review should flag when no appropriate data for outcomes specified in the scope has been identified. When possible, the assessment report should describe any identified ongoing studies or real-world data sources that may be able to address these evidence gaps.

Study selection

- 2.2.11 There can be many available studies, or study types, that report on a particular outcome. This may require decisions to be made about which studies are prioritised in an assessment report for consideration by committees. The [NICE Decision Support Unit technical support document 27](#) provides guidance on potential approaches.

Critical appraisal

- 2.2.12 The quality of a study's overall design, its execution, and the validity of its results determine its relevance to the decision problem. Studies should be appraised using a checklist appropriate for the study design. An assessment of the generalisability of data from studies to the decision problem is also an important consideration, particularly for non-UK studies. When there are large numbers of studies, critical appraisal may be prioritised for studies considered to be key for decision making, particularly those providing data used for economic models.
- 2.2.13 Whenever possible, checklists for assessing published studies should be used to assess the validity of unpublished studies.

Further considerations and evidence synthesis challenges

- 2.2.14 [Section 3.4 of NICE health technology evaluations: the manual](#) includes detail related to evidence synthesis, including factors that can affect effectiveness estimates and the use of pairwise meta-analysis, indirect comparisons and network meta-analyses.

- 2.2.15 Meta-analysis of test accuracy data can be complicated because of the correlation between sensitivity and specificity. In addition, there are likely to be many sources of heterogeneity across test results, arising from differences in setting, patient population, reference standard, equipment, procedures and skill levels of test operators. The cut-off point at which test accuracy data is reported may also differ between studies. Several methods for meta-analysis of test accuracy data exist. They vary in complexity and in the assumptions that need to be made. The appropriate choice of method depends on the data available and should be justified. [NICE's Decision Support Unit technical support document 25](#) provides guidance on methods for meta-analysis of test accuracy data.

2.3 Economic evaluation

- 2.3.1 [Chapter 4 of NICE health technology evaluations: the manual](#) provides detail of the methods that should be used to assemble and synthesise evidence on a technology in an economic evaluation. This is needed to estimate the technology's relative clinical effectiveness and value for money compared with current practice in the NHS. It includes a [reference case](#), which specifies the methods NICE considers to be the most appropriate for analysis when developing guidance. This does not prevent additional analyses being done in which 1 or more aspects of the methods differ from the reference case. However, these must be justified and clearly distinguished from the reference case.

Economic evaluation

- 2.3.2 The methods NICE considers to be most appropriate for estimating value for money are cost-utility analysis and cost-comparison analysis.

2.3.3 These analyses show the impacts of using a technology, relative to a comparator or other health technologies specified as interventions, in terms of changes in costs, or changes in both costs and quality-adjusted life years ([QALYs](#)). These changes can be based on both the short- and long-term impacts, potentially occurring across a patient's lifetime. [Sections 4.2.22 to 4.2.25 of NICE health technology evaluations: the manual](#) explain the time horizon used in economic evaluations.

2.3.4 [Sections 4.3 and 4.4 of NICE health technology evaluations: the manual](#) provide detail on measuring and valuing health effects in cost-utility analyses and the use of evidence on resource use and costs.

2.3.5 Distributional cost-effectiveness analysis (DCEA) will not be done in economic evaluations produced for HealthTech guidance. DCEA evidence can be provided by companies as part of the information requested on the evidence base and their technology. For more information on these analyses, see [section 4.12 of NICE health technology evaluations: the manual](#).

2.3.6 When any impacts of a technology are not captured, or not fully captured, in terms of incremental costs or QALY outputs from modelling and therefore cost-effectiveness estimates:

- The economic evaluation should clearly highlight that such impacts are not captured in the cost-effectiveness estimates.
- The assessment report should present, when possible, any incremental differences in non-cost or QALY outcomes generated from the model, or available from identified studies, that help quantify the impact of the technology that has not been captured in cost-effectiveness results (see section 2.3.26).
- If linking effects to a QALY gain is not possible for all health-related impacts of a technology, links to a clinically relevant or

a related outcome should be considered to help illustrate and quantify the impact of a health technology, compared with current practice (see above bullet point).

- The assessment report should narratively discuss how the uncaptured impacts may impact on health and resource use.

2.3.7 Understanding the magnitude of any uncaptured impact, and how this could affect cost-effectiveness estimates, is important for decision making. Any analyses that could inform this consideration would be beneficial.

Existing economic evaluations

2.3.8 Existing economic evaluations can be used as an alternative or supplement to de novo modelling, if they are adequate, appropriate and relevant to the decision problem. Such evaluations include those identified in a literature review, done to support existing guidance from NICE or other bodies, and any identified in responses to requests for information (see [section 1.3.4](#)). Economic models produced for existing NICE guidance should be used whenever possible.

Modelling approach

2.3.9 [Sections 4.5 to 4.7 of NICE health technology evaluations: the manual](#) describe NICE's preferred approaches to discounting, modelling methods to generate estimates of clinical and cost effectiveness and cost comparison, and exploring uncertainty. Providing an all-encompassing definition of what constitutes a high-quality model is not possible. Economic evaluations for HealthTech guidance are made available for review (see [sections 1.4.7 and 1.4.8](#)).

2.3.10 Models produced for HealthTech assessments may require strong assumptions to be made. Provided that such assumptions are clearly highlighted, the committee can consider them in its

decision making and decide on their appropriateness (see section 2.4.6). Assumptions included in models should, when appropriate, be validated by relevant experts.

- 2.3.11 Using expert elicitation or expert opinion should be considered to provide evidence to support economic evaluation work. When the elicited data is to be quantitative, preference should be given to formal elicitation techniques (see [sections 3.3.21 to 3.3.23 of NICE health technology evaluations: the manual](#)).
- 2.3.12 Details about services that would be impacted by using the technologies and how they would be impacted (in terms of greater or reduced use) should be discussed. This should include direct impacts of using the technologies, and any impacts that are likely to occur up- or downstream of use (ideally model outputs will help to estimate the size of impact; see section 2.3.25). Details of any changes to service organisation and any other activities needed to implement the technologies should also be described.

Surrogate and intermediate outcomes

- 2.3.13 Guidance on the use of surrogate outcomes is provided in [sections 4.6.6 to 4.6.11 of NICE health technology evaluations: the manual](#). Lower levels of evidence to support validation of a surrogate end point (including biological plausibility of relationship between surrogate end point and final outcomes) are acceptable to justify use in modelling; the acceptability of this and associated uncertainty can be considered in decision making for guidance recommendations (see section 2.3.10). Stronger evidence that the relative effect of a technology on the surrogate end point is predictive of its relative effect on the final outcome will increase confidence in generated cost-effectiveness results. When possible, the uncertainty associated with the relationship between the surrogate end points and the final outcomes should be quantified and captured in the model's probabilistic analysis.

- 2.3.14 For evaluations of diagnostic technologies (including prognostic and predictive tests and models), there may be some direct benefits from the knowledge gained and some direct harm from the testing. But most of the outcomes typically come after testing because of treatment or preventive measures being started, modified or stopped. Tests can sometimes be evaluated using clinical trials, but this is unusual. If direct data on the impact of a diagnostic technology on final outcomes is not available, it may be necessary to combine evidence from different sources. A linked evidence modelling approach should be used, which links data from different studies together to estimate impact. The links used, such as between test results, decisions about care or treatment based on this result and final outcomes should be specified and justified, for example, with relevant data or justification of assumptions.
- 2.3.15 When only surrogate or intermediate outcomes (such as test accuracy) are available to support a value proposition, it is beneficial that companies provide any supporting information in responses to requests for information that support use of such outcomes. For example, evidence that the relative effect of a technology on the surrogate end point is predictive of its relative effect on the final outcome.

Impacts on system efficiencies and capacity

- 2.3.16 Value propositions for technologies can include a proposed impact on system efficiencies, which can potentially increase capacity to deliver healthcare. Relevant outcomes in such cases will be specified in the scope (see section 2.1.21).
- 2.3.17 Evidence should quantify the effect of the technology on resource use in terms of physical units (for example, days in hospital or visits to a GP). These effects should be valued in monetary terms using appropriate prices and unit costs, such as unit costs found

in the [Personal Social Services Research Unit \(PSSRU\) report on unit costs of health and social care](#).

- 2.3.18 Any health or other benefits that may arise from system efficiencies, such as ruling out need for unnecessary procedures or reducing waiting times, can be considered in estimates of cost effectiveness (for example, for reducing waiting times, through impacting progression to more advanced disease states), or noted as uncaptured benefits if this is not possible (see section 2.3.6).

Technology costs

- 2.3.19 Reference-case analyses should be based on prices that reflect as closely as possible the prices that are paid in the NHS. This could be the public list price. When there are nationally available price reductions, the reduced price can be used in the reference-case analysis to best reflect the price relevant to the NHS. Analyses based on price reductions for the NHS will be considered only when the reduced prices are transparent and consistently available across the NHS, and when the reduced price is available for a guaranteed period. In the absence of a published list price and a price agreed by a national institution, an alternative price may be considered, provided that it is nationally and publicly available. If no other information is available on costs, local costs may be used.
- 2.3.20 When a group of related technologies is being evaluated as part of a group or class (see section 2.1.7), an analysis using the individual costs for each technology should be presented in the reference case. Exceptionally, if there is a very wide range of technologies and costs to be considered, then analyses should use the weighted mean cost and the highest and lowest cost estimates.

- 2.3.21 For technologies that have multiple uses in the NHS beyond the uses under evaluation, for example, diagnostic tests that could identify multiple markers or technologies that can be used across multiple populations, the average cost should initially be identified. This should be based on the expected use or throughput of the device for only the uses being evaluated. In some cases, an analysis using marginal costs may be provided in addition to the analysis based on average costs. This is if a technology is already recommended for another purpose and enough spare capacity exists to allow the use for the condition in the current evaluation.
- 2.3.22 Analyses using adjusted or apportioned technology costs can also be provided as non-reference-case analyses, for example, if the technology has multiple uses beyond the indication under evaluation and introducing the new technology will lead to identifiable benefits that are not captured in health technology evaluations (see [section 4.4.15 of NICE health technology evaluations: the manual](#) for further detail).
- 2.3.23 When the cost of introducing the technology is likely to be high, for example, disruptive technologies requiring new ways of working or changes to care pathways, sensitivity or threshold analyses investigating the impact of higher upfront costs associated with adopting the new technology may be beneficial to assess robustness of cost-effectiveness estimates.

Subgroups

- 2.3.24 For many technologies, the level of benefit will differ for patients with differing characteristics. This can be explored by providing clinical and cost-effectiveness estimates separately for each relevant subgroup. [Section 4.9 of NICE health technology evaluations: the manual](#) provides further guidance and considerations. When possible, potentially relevant subgroups will be identified at the scoping stage (see section 2.1.14). However,

this does not prevent the identification of subgroups later in the process, for example, during the assessment period or during the committee discussions.

Outputs

- 2.3.25 Guidance for presenting model results is described in [section 4.10 of NICE health technology evaluations: the manual](#). In addition to costs and QALYs, outputs from the model should be provided that are useful to help understand the estimated impact of the technologies and what has been captured in cost-effectiveness estimates. For example, values that would be meaningful for healthcare professionals and those that show the impact of technology use on services, such as staff time and resource use.
- 2.3.26 Any outputs from models should be presented that help quantify impacts that are not captured or not fully captured in incremental cost and QALY outputs (see section 2.3.6), or composite measures of these (for example, net health benefit).
- 2.3.27 For technologies that are likely to have rapid iteration and multiple new versions after guidance is published, threshold analyses can be beneficial for parameters related to technology performance or impact that drive cost-effectiveness results, to identify a parameter 'switching value'. A switching value is the value of an input variable that would change a decision on whether the technology represents a good use of NHS resources for a given threshold (for example, £20,000 and £30,000 per QALY gained).

Priorities for further research

- 2.3.28 Key drivers of decision uncertainty should be identified in the economic evaluation to inform any recommendations for further research (see sections 2.4.20 and 2.4.21). Because the extent of further research activities that are feasible may be limited,

uncertainties should be highlighted that are essential to resolve for future guidance development.

Impact on the NHS

2.3.29 Resource impact assessment for HealthTech guidance can be done by NICE alongside, or after, guidance production (see the [webpage on assessing the resource impact of NICE guidance](#)).

The assessment can:

- support decisions about uses of the technologies under evaluation
- complement any other economic evaluation done
- help assess the expected changes in expenditure and capacity requirements as a result of implementing the guidance.

2.3.30 The committee may consider resource impact assessments when considering the level of uncertainty about the value for money associated with a technology (see section 2.4.9).

2.4 Committee recommendations

Decision making

2.4.1 The committee bases its recommendations on the evidence presented, including:

- information provided by non-company stakeholders or other organisations, (see [section 1.3.9](#))
- the assessment report
- comments received on the assessment report or economic model (see [sections 1.4.7 and 1.4.8](#))
- views expressed by experts, including clinical experts, particularly their experience of the condition, current care and technology use in clinical practice, and the experience of people with lived experience of the condition.

- 2.4.2 The committee uses estimates of cost effectiveness based on cost-utility or cost-comparison analyses as the primary consideration when making decisions about the acceptability of technologies as a cost-effective use of NHS resources. Analyses will typically contain an estimate from a base-case analysis, generated using the external assessment group's (EAG's) preferred model assumptions and input parameters. Analyses will also include scenario and [sensitivity analyses](#) which can show uncertainty in, and explore the impact of alternative parameter values and model assumptions on, generated cost-effectiveness estimates. The committee considers all analyses in its decision making and can decide whether the EAG's base case is its preferred analysis, or how much weight to apply to this in decision making.
- 2.4.3 The committee should also consider the extent that any impacts of a technology are not captured, or not fully captured, in cost-effectiveness estimates, the potential magnitude of this, and how it would affect cost-effectiveness estimates (see sections 2.3.6 and 2.3.7).
- 2.4.4 Interventions with an incremental cost-effectiveness ratio (ICER) below £20,000 per QALY gained are generally considered to be cost effective. Above this, decisions about the acceptability of the technology as an effective use of NHS resources will specifically consider the following factors:
- the degree of certainty about cost-effectiveness estimates
 - aspects that relate to uncaptured benefits and non-health factors. Specifically, the committee will consider:
 - if its decisions have a bearing on broader social considerations and the extent that these are covered by principles on social value judgements in [our principles on the NICE website](#)

- if there are strong reasons to suggest that the health benefits of the technology have been inadequately captured, or otherwise considered and may therefore misrepresent the health utility gained
- aspects that relate to health inequalities.

As the ICER for a technology increases between £20,000 and £30,000 per QALY gained, and particularly over £30,000 per QALY gained, the committee will need to identify an increasingly stronger case for supporting the technology as an effective use of NHS resources, considering the factors listed in the bullets above.

2.4.5 A severity decision modifier will not be applied for HealthTech guidance.

2.4.6 Decisions about the acceptability of a technology as an effective use of NHS resources will specifically take into account the degree of certainty around the value for money. Considerations include uncertainty expressed in cost-effectiveness estimates, and factors that may not be captured, or fully captured, in these analyses, including:

- the assumptions necessary in the economic modelling
- the source of parameters used to estimate cost effectiveness, typically model parameters that differ between intervention and comparator (or between different interventions). The committee should consider the reliability and generalisability of the evidence presented when considering cost-effectiveness estimates. This includes study type and assessment of study quality.

2.4.7 The committee will normally be more cautious about recommending a technology if it is less certain about its cost effectiveness. But it should be proportionate and take into account

factors related to the technology and condition, and how feasible or realistic it is to generate further evidence to reduce uncertainty about cost effectiveness.

- 2.4.8 When the degree of certainty about a technology's value for money cannot be expressed quantitatively, it may be expressed qualitatively using terms expressing broad ranges of probability. To ensure that language is used consistently, terms set out in an available [common probability yardstick \(available on GOV.UK's webpage on communicating probability\)](#) may be used.
- 2.4.9 The degree of certainty of the cost effectiveness or cost savings of a technology should be proportionate to the impact of technology adoption on NHS resources and the risk to patients. The committee may need more robust evidence to support estimates of cost effectiveness or cost savings of technologies that are expected to have a large impact on NHS resources.

Technologies that provide less health benefit at a lower cost

- 2.4.10 Technologies that provide less health benefit at a lower cost relative to the relevant comparators (that is, that fall in the south-west quadrant of a cost-effectiveness plane) should be considered using the usual cost-effectiveness range of £20,000 to £30,000 per QALY. Any relevant additional factors should also be taken into account, as described above.

Subgroups

- 2.4.11 The committee can make specific recommendations for subgroups of the overall population. [Section 6.2.29 of NICE health technology evaluations: the manual](#) contains further details and consideration for this.

Economic evaluations based on cost-comparison analyses

2.4.12 When a cost-comparison analysis is done, key considerations include whether:

- there is enough certainty that the technology has at least equivalent clinical benefits to the comparator
- the technology is likely to reduce costs or resource use (for example, staff or facilities) compared with the comparator.

2.4.13 Interventions that are cost neutral or cost saving are generally considered to be cost effective. For technologies that are cost incurring, decisions about the acceptability of the technology as an effective use of NHS resources will specifically consider the following factors:

- the degree of certainty about the cost impact estimates
- aspects that relate to uncaptured benefits and non-health factors. Specifically, the committee will consider:
 - if its decisions have a bearing on broader social considerations and the extent that these are covered by principles on social value judgements in [our principles on the NICE website](#)
 - if there are strong reasons to suggest that the health benefits of the technology have been inadequately captured, or otherwise considered
- aspects that relate to health inequalities.

As the incremental cost increases, the committee will need to identify an increasingly stronger case for supporting the technology as an effective use of NHS resources, considering the factors listed in the bullets above.

Recommendations

- 2.4.14 Recommendations are only made for use of technologies in the terms of the assessed use case or use cases as set out in the scope.
- 2.4.15 When interventions in a scope are defined as a group or class of health technologies (see section 2.1.7), recommendations will typically be issued for the whole group or class. But when there is strong evidence comparing a specific technology to others within the group, it may be specified in recommendations or otherwise specified in guidance.

Types of recommendation

- 2.4.16 The committee produces recommendations based on the extent to which the potential patient and system benefits are supported by evidence. The rationale for recommendations made is described in the guidance document.

Table 3 Overview of recommendations used in HealthTech programme guidance

Recommendation type	What this means in practice
Can be used	There is enough evidence that the technology provides benefits and value for money, so it should be routinely available across the NHS, and paid for using core NHS funding.
Can be used during the evidence generation period	<p>The technology can be used as an option in the NHS during the evidence generation period and paid for using core NHS funding. During this time, more evidence will be collected to address uncertainties. Companies are responsible for organising funding for evidence generation activities.</p> <p>After this, NICE will review this guidance, and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.</p>
More research is needed	There is not enough evidence to support funding the technology in the NHS. Access to technology should be through company, research or non-core

Recommendation type	What this means in practice
	NHS funding, and clinical or financial risks should be managed appropriately.
Should not be used	The technology does not offer benefit or value for money and should not be used in the NHS.

Recommending a technology (can be used)

2.4.17 The committee will recommend that a technology can be used (as an option) when it considers that there is enough evidence that it provides appropriate benefits and value for money and so should be made available in the NHS.

2.4.18 The committee may recommend that the technology can be used only under specific circumstances. For example, the recommendation can be optimised or restricted to people who meet specific clinical eligibility criteria, to a specific subgroup of people (see section 2.4.11), or to provision by staff with certain training or in a particular care setting. Recommendations for using a diagnostic test may also be limited to specific circumstances such as:

- the patient's characteristics
- the condition's aetiology
- the training and skills of those providing the test
- availability of equipment
- availability of other portions of the care pathway.

Recommendation for use during the evidence generation period

2.4.19 In exceptional circumstances, when no technologies are recommended for use, 1 or more of the technologies may be recommended for use with evidence generation, following the approach used for early use guidance (see section 3). Considerations and rationale for decision making should follow

the approach set out in the decision making' section in the early use guidance section of this manual.

Recommendation for more research

- 2.4.20 When the evidence of clinical or cost effectiveness or impact of a technology on other health outcomes is either absent, weak or too uncertain, the committee may recommend that more research is needed.
- 2.4.21 This type of recommendation needs to be accompanied by defined uncertainties that the committee considers it worthwhile and feasible to collect further evidence to address (see section 2.4.28).

Not recommended (should not be used)

- 2.4.22 If the benefits and value for money of a technology are not supported by the evidence and are not likely to be realised in practice, even if further evidence was generated, the technology is not recommended.

Multiple intervention considerations

- 2.4.23 Evidence generated using a technology should typically not be used to show performance of others in the assessment. This is unless the committee can provide strong reasoning why it considers this appropriate, or the technology is being assessed as part of a group or class of technologies (see section 2.1.7).
- 2.4.24 Different recommendations can be made for different technologies included in the guidance.
- 2.4.25 Health technologies specified as interventions (see section 2.1.5) will be compared with each other, when possible, as well as with the comparator. If there is strong evidence that an intervention [dominates](#) the alternatives, it should normally be recommended. However, if 1 intervention is more effective but

also more costly than another, then the comparative cost-effectiveness estimate should be considered. When multiple technologies are being compared, cost-effectiveness rankings may be used to present the results of probabilistic model analyses (see [section 6.3.3 of NICE health technology evaluations: the manual](#) for further detail).

2.4.26 The extent of evidence comparing an intervention with alternative interventions should be considered when deciding if, when multiple interventions are considered cost effective compared with the comparator, 1 or a subset of them should be recommended in preference to others.

2.4.27 When recommending technologies that are 1 of several similar options, which cannot be distinguished from each other based on cost effectiveness (see sections 2.4.25 and 2.4.26), committees may specify what should be considered when choosing between them, if it considers this appropriate. Considerations can be related to:

- price, including a recommendation to use the least expensive option
- sustainability
- factors related to technologies that are important for patients or healthcare professionals
- health inequalities
- accommodating people with specific clinical presentations.

Areas for more research

2.4.28 For technologies with a recommendation for more research (see section 2.4.20) or for use with evidence generation (see section 2.4.19) the uncertainties that the committee needs more data on to support future decision making should be listed. While the guidance can describe broader evidence that would be

beneficial, the recommendations should focus on uncertainties that are essential to future decision making and are considered feasible to address.

Additional considerations

Phased roll out

- 2.4.29 If technologies are recommended for use in a large population, or if there are any other reasons why guidance may take longer to be implemented, the guidance may identify subgroups of the population to whom the technology could be offered initially as part of a phased roll out. This can be based on subgroups of the population for which the technology is recommended for use, for whom the clinical effectiveness or value for money of the technology is higher than the overall population. When considering subgroups, the committee pays particular attention to its legal obligations with respect to legislation on human rights, discrimination and equality.

Rationale for recommendation for use

- 2.4.30 When 1 or more technologies are recommended for use, the guidance will set out the rationale for this, such as a description of the evidence and demonstrated performance that underpins the positive recommendation.

Updated versions of technologies

- 2.4.31 For technologies that are recommended for use that may undergo rapid iteration and multiple new versions after guidance is issued, guidance may indicate ranges or values for performance of technologies or impact on outcomes that need to be maintained for it to remain cost effective (see section 2.3.27).

3 Early use HealthTech guidance assessments

Methods for developing Early use HealthTech guidance are described in the [NICE HealthTech programme manual](#) (in section 2.1) and are not presented here because they are not part of this consultation.

4 Existing use HealthTech guidance assessments

Detail set out in this section supersedes [NICE's late-stage assessment interim statement](#) and covers existing use HealthTech guidance.

4.1 Background

- 4.1.1 Existing use assessments are designed to support procurement and commissioning decisions, promote effective use of NHS resources, and improve care, through assessing technologies already in existing or established use in the NHS.
- 4.1.2 If there is price variation between alternative technologies that are options for a use case, there may be uncertainty about whether this is justified, for example, if some technologies have had continuous improvement or incremental innovation. Existing use assessments aim to determine whether differences between alternative technologies justify the price variation or otherwise identify factors that can inform decisions about which technology to purchase. This will help procurement services and commissioners make well-informed decisions. This will also ensure that effective technologies that are value for money are available for use while maintaining an appropriate level of choice in the system. This is in line with the 3 main objectives of the [Department of Health and Social Care's medical technology strategy](#) for the NHS to have the right product, at the right price, in the right place.

4.2 Scoping

- 4.2.1 The scope for existing use assessments will follow the methods described in section 2.1, except that:
- Value propositions should focus on how the interventions differ from each other and the potential impacts of these differences.
 - Specific characteristics of the technologies being assessed can be identified, including any additional functions or features that may not be essential for use but are proposed to be beneficial. These can relate to clinical or system impacts and outcomes, but also potential impacts on the usability of a technology and patient experience.
 - Technologies included in the scope of an assessment may be grouped according to shared features, functions or other characteristics. This may particularly be the case when a feature, function or characteristic is proposed to drive beneficial impact (see previous bullet point and section 2.1.7).
 - The scope may not define a comparator.
 - The scope may include relevant information on how technologies are currently provided to the NHS, for example, procurement frameworks.
- 4.2.2 Scoping will identify the relevant user groups for user preference assessment and may outline potential methods (see section 4.4.6).
- 4.2.3 Technologies in existing use are more likely to be present in registries or post-marketing surveillance datasets than newly available technologies. Scoping may identify real-world data sources that could support the evaluation.

4.3 Evidence

- 4.3.1 Section 2.2 describes the approaches for using evidence for HealthTech guidance assessments.

Evidence identification

- 4.3.2 The aim of the evidence review is to identify the most relevant evidence relating to the decision problem defined in the scope. 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 problem, a broader evidence base may be considered. For example, evidence from the technology's use in a different population or setting.
- 4.3.3 Post-market surveillance data and non-clinical technical assessments may be used, if appropriate, when topics have little or no evidence, or to complement published clinical evidence.

Evidence reviews

- 4.3.4 The evidence review will be done as described in sections 2.2.6 to 2.2.15.
- 4.3.5 Pragmatic or rapid review methodology and principles can be used in the literature review, with specific components of the systematic review process either being restricted or omitted. For example, the Cochrane Rapid Reviews Methods Group provides guidance on doing rapid reviews of the effectiveness of health interventions. Justification and rationale for this should be described in the assessment protocol, along with clear explanation of the components of the review process that have been restricted or omitted.
- 4.3.6 Technologies assessed in existing use guidance may have larger volumes of evidence than technologies at an earlier stage of their lifecycle. Decisions about what studies to include, or prioritise, in the assessment report will need to be made. The protocol for the assessment should describe the approach taken. [NICE's Decision](#)

[Support Unit technical support document 27](#) provides guidance on potential approaches.

4.4 Economic evaluation

- 4.4.1 The economic evaluation that will be most beneficial for committee decision making is likely to vary by topic.
- 4.4.2 The key objectives of the economic evaluation are to:
- estimate the relative cost effectiveness of available technologies, or groups of technologies with certain features, functions or other characteristics
 - identify key uncertainties.
- 4.4.3 See section 2.3 for full detail on economic evaluation.
- 4.4.4 Regression analyses may be used to determine the proportion of price variation that can be attributed to different features, functions or characteristics of technologies.
- 4.4.5 Exploratory analyses may be used to investigate potential justifications for price differences. For example, threshold or sensitivity analysis to investigate how changes in the effectiveness of technologies affect whether they represent good value for money at a given threshold (for example, £20,000 per QALY gained). The committee can consider exploratory analyses in its decision making and decide on their appropriateness.

User preference assessment

- 4.4.6 Existing use assessments evaluate technologies that are in widespread or established use. People are likely to have experience of using the technologies and so can provide insights into which factors are important to them when choosing which technology to use. This experience can be useful for committee

considerations, especially when there is less evidence available to evaluate clinical and cost effectiveness.

4.4.7 Users are people whose experience with the technologies would allow them to make informed choices between different options. Ideally, they have experience of direct involvement in deciding to choose 1 technology over another. This could include people who:

- have the condition that the technology is intended for (for example, people with a stoma choosing a colostomy bag)
- prescribe the technology (for example, a nurse choosing an appropriate wound dressing)
- use the technology frequently (for example, sonographers choosing an ultrasound machine).

The most relevant user group or groups for determining user preference will be identified during scoping. Users are selected taking into account the [NICE policy on declaring and managing interests for NICE advisory committees](#) and can include experts selected to advise on other parts of the assessment.

4.4.8 Alongside the clinical and economic evaluation, additional information may be collected about factors that are important to users when selecting a technology. This information can be used to assess how well these factors are captured by the clinical and economic evaluation. A user preference assessment will involve user preference exercises and workshops. The objectives are to:

- identify users who are key decision makers when choosing a technology
- identify the key criteria that are important to users of the technology when deciding which technology to choose
- understand the importance of these criteria to users

- understand how users apply these criteria when choosing a technology
- identify how well the clinical and cost effectiveness evidence presented in the assessment report captures criteria that are important to users.

This assessment may be done by NICE or an EAG.

4.4.9 A user preference report will report the results from the user preference assessment. The user preference report is subject to factual accuracy checking (see [section 1.4.7](#)). Because the views of the users are subjective, they cannot be considered inaccurate.

4.4.10 In addition to the user preference exercises and workshops described in section 4.4.8, other activities may be done to further explore factors that influence technology choice. These may include but are not limited to:

- surveys of users or other groups of healthcare professionals or people with relevant experience
- reviews of literature which discuss relevant experience.

4.5 Decision making

4.5.1 The key goal for decision making in existing use assessments is to determine if price differences between technologies are justified. The committee will apply the same considerations as described in section 2.4.

4.5.2 The committee can consider:

- if there are differences in clinical or cost effectiveness that can justify price variations between technologies
- factors not captured in the clinical evidence or economic modelling that could affect value, such as preferences identified

through user preference assessments (see sections 4.4.6 to 4.4.10)

- if more information is needed to help choose the most appropriate technology.

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

4.5.4 Recommendations may refer to individual technologies, or groups of technologies defined by having certain features or functions, depending on the approach defined during scoping (see section 4.2.1).

Types of recommendations

Table 4 Overview of recommendations used in existing use guidance

Recommendation type	What this means in practice
Price difference is justified for a technology or technologies with certain features or functions	There is enough evidence that a technology or feature provides benefits and value for money, so it is acceptable to pay more for that technology or technologies with that feature.
Not enough evidence to justify paying extra for any of the technologies or technologies with certain features or functions	There is not enough evidence to justify paying extra for any of the technologies or technologies with certain features or functions. There may be factors that are not based in clinical or economic evidence that could be considered when choosing a technology.
Do not pay more for a technology or feature	There is evidence that a higher price is not justified for a technology or a feature of a technology, so it is not acceptable to pay more when there is a less-expensive alternative option.

4.5.5 **Price difference is justified for a technology or technologies with certain features or functions.**

If there is enough evidence that a technology, or a group of technologies with certain features or functions, provides appropriate benefits and value for money at its price relative to the prices of other options, price difference can be justified.

Recommendations may specify justifiable differences in cost for

certain technologies or technologies with certain features or functions.

4.5.6 There is not enough evidence to justify paying extra for any of the technologies or technologies with certain features or functions.

If the evidence of clinical or cost effectiveness is absent, weak or too uncertain, no technology will be recommended over others. In this circumstance, committees may specify what should be considered when choosing between the technologies, if it considers this appropriate. Considerations can be related to:

- price, including a recommendation to use the least expensive option
- sustainability
- factors related to technologies that are important for patients or healthcare professionals, including factors highlighted in the user preference report
- impact on health inequalities
- accommodating people with specific clinical presentations.

4.5.7 Do not pay more for a technology or feature.

If there is evidence that a higher price is not justified for a technology or feature of a technology because proposed benefits and value for money are not likely to be realised in practice.

4.5.8 Existing use guidance can make research recommendations when further evidence will be useful to support future decision making. See section 2.4.28.

4.5.9 Recommendations may include additional factors that the committee agrees are important considerations related to the technologies. This can include, but is not limited to:

- specifying an appropriate range of technologies that need to be available

- providing information and guidance for procurement and commissioning, people with the condition, or healthcare professionals
- guidance on the basic requirements for a technology.