

# Medical technologies evaluation programme methods guide

## 1 Introduction

The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care.

NICE selects and evaluates **medical technologies** to determine whether evidence supports the **case for adoption** in the health and social care system. For the purposes of the medical technologies evaluation programme (MTEP), a medical technology is defined as outlined in table 1.

**Table 1 Definitions of medical technologies for the programme**

Term	Definition	Source
Medical device	<p>‘Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:</p> <ul style="list-style-type: none"> <li>• diagnosis, prevention, monitoring, treatment or alleviation of disease</li> <li>• diagnosis, monitoring, treatment, alleviation of or compensation for an injury or [disability]</li> <li>• investigation, replacement or modification of the anatomy or of a physiological process</li> <li>• control of conception</li> </ul> <p>and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.’</p>	European Parliament and the Council of the European Union (2007) Council Directive 2007/47/EC of 5 September 2007 amending Council Directive 93/42/EEC concerning medical devices
Active medical device	‘Any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.’	Council of the European Communities (1990) Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)
Active implantable medical device	‘Any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.’	Council of the European Communities (1990) Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)

Term	Definition	Source
In vitro diagnostic medical device	<p>‘Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:</p> <ul style="list-style-type: none"> <li>• concerning a physiological or pathological state, or</li> <li>• concerning a congenital abnormality, or</li> <li>• to determine the safety and compatibility with potential recipients,</li> <li>• or</li> <li>• to monitor therapeutic measures.’</li> </ul>	European Parliament and the Council of the European Union (1998) Council Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices

A diagnostic technology is any medical technology with a diagnostic purpose.

Diagnostic technologies are a subset of medical technologies.

MTEP covers genetic tests only if they are used for a medical purpose and fall within the scope of Directive 98/79/EC (in vitro diagnostic medical devices).

MTEP identifies medical technologies that have the potential to offer substantial benefit to patients and/or to the health and social care system, and that are likely to be adopted more consistently and more rapidly if NICE were to develop guidance or advice related to them.

This methods guide describes how NICE selects medical technologies for development of NICE guidance. It also describes how the medical technologies advisory committee develops guidance on selected technologies routed to it. The methods are designed to ensure that the most appropriate medical technologies are selected for evaluation, and that any guidance produced is robust, developed in an open, transparent and timely way, takes into account valid and relevant evidence, and allows appropriate input from consultees and other stakeholders. This methods guide should be read in conjunction with the [MTEP process guide](#).

Nothing in this document will restrict any disclosure of information by NICE that is required by law (including, in particular but without limitation, the Freedom of Information Act 2000).

## **2 The medical technologies evaluation programme**

### **2.1 Aims**

MTEP aims to:

- promote faster uptake of new medical technologies in the health and social care system
- encourage collaborative research (that is, both industry and the health and social care system) to generate evidence on the clinical utility or system benefits of selected technologies.

### **2.2 Main activities**

MTEP's main activities and responsibilities are:

- identifying and selecting appropriate medical technologies that would benefit from national evaluation
- routing these medical technologies to a NICE programme for evaluation
- evaluating medical technologies routed to the committee, including:
  - developing and publishing guidance, including recommendations for further research
  - developing and publishing implementation tools
  - reviewing and updating guidance as needed.

### **2.3 Characteristics of medical technologies**

Medical technologies differ from other medical interventions in several ways:

- Technologies may be modified over time in ways that change their effectiveness.
- The clinical outcomes resulting from the use of technologies often depend on the training, competence and experience of the user.

- Clinical evidence on technologies, particularly new technologies, is often limited, especially comparative evidence with appropriate alternative treatments or methods of diagnosis.
- Benefits to the health and social care system of adopting medical technologies often depend on organisational factors, such as the setting in which the technology is used or the staff who use it, in addition to the benefits directly related to the technology.
- For diagnostic tests, improved clinical outcomes depend on the subsequent delivery of appropriate healthcare interventions. Evidence for their efficacy is difficult to assess, because improved diagnostic accuracy may not be reflected in improved clinical or quality-of-life outcomes.
- Some technologies are used to manage or investigate a number of different medical conditions and may be used by different healthcare professionals and in a variety of healthcare settings.
- Costs of medical technologies often comprise both procurement costs (including associated infrastructure) and running costs (including maintenance and consumables).
- A new technology may influence costs by its effect on various aspects of the care pathway, in addition to costs directly related to its use.
- In general, medical technology pricing is more dynamic than that of other medical interventions.

### **3        Selecting and routing technologies**

NICE's topic oversight group selects and routes medical technologies by discussing the case for adoption and applying the selection and routing criteria. Although the selection criteria are of equal weight, the significance that is applied to each of these criteria varies among technologies, depending on the context of use of the technology and the medical condition(s) to which it relates.

#### **3.1        *Selecting medical technologies for evaluation***

Notifications of medical technologies are received primarily from companies or sponsors (referred to as sponsors in this document). MTEP prepares topic briefings on eligible topics and presents them to the topic oversight group to inform their

decision about whether a technology meets the selection criteria (see appendix C and the [MTEP process guide](#)). The topic briefing is based on the sponsor's case for adoption and includes information about the technology and its comparators, the claimed benefits to patients and the health and social care system compared with current management, patients in whom the technology is used and a summary of the available evidence. Topic briefings incorporate input from [expert advisers](#), patient and carer organisations if possible, and the sponsor of the technology. They include the potential costs of using the technology.

### **3.2      *Routing selected medical technologies for evaluation***

Once the topic oversight group has selected technologies for evaluation, it routes them to an appropriate evaluation programme using the topic briefing and the published routing considerations (see appendix D) as a guide. Selected technologies may be routed to 1 of the NICE guidance programmes:

- medical technologies
- diagnostics
- interventional procedures
- technology appraisals
- guidelines.

The topic oversight group may also route the technology to other NICE programmes, or other national programmes outside of NICE.

More information about the considerations for routing to these programmes is given in appendix D.

#### **3.2.1      *Diagnostic technologies***

After the topic oversight group has selected a diagnostic technology for evaluation, it may decide to develop medical technologies guidance or it may route the technology to the diagnostics assessment programme (DAP). Diagnostic technologies that, compared with those in current use, have similar benefits but cost less or more benefits at the same cost are more likely to be evaluated according to the methods described in this guide (that is, by MTEP). Diagnostic technologies that have more benefits but cost more than those in current use are more likely to be routed to DAP.

NICE does not select or develop guidance on diagnostic tests that are mainly used for population screening. Generally, such tests are likely to be routed to an appropriate evaluation body such as the UK National Screening Committee.

## **4 Principles for developing medical technologies guidance**

In developing medical technologies guidance, NICE aims to:

- evaluate a single medical technology based on its own claimed patient and healthcare system benefits, not compared with similar technologies in a broader class
- evaluate the case for adoption, with particular emphasis on technologies that when compared with current management may provide more benefits at the same or lower cost, or provide the same benefits at a lower cost
- take a comparative effectiveness approach, with current practice or management usually being used as a comparator
- evaluate the impact of the technology on the health and social care system, alongside its clinical benefits for patients
- use appropriate health economic approaches to support the committee's decision-making
- prioritise questions for future research to help reduce any uncertainty in the evidence as quickly and efficiently as possible.

The single technology approach is fundamental to achieving MTEP's aims of promoting faster uptake of innovative technologies. It enables the specific claimed benefits of innovative products to be rapidly evaluated and relevant guidance published.

If the topic oversight group considers that a technology selected for evaluation is in an area where there are a number of equivalent new medical technologies in development, and that these may merit consideration of their own potential benefits, then it may route the technologies to a NICE programme which uses multiple technology evaluation methods (for example, technology appraisals or diagnostics).

The characteristics of medical technologies (section 2.3) mean that the evidence presented to the committee about their claimed benefits may be associated with a large degree of uncertainty. Because of this, MTEP may encourage targeted research or data collection on certain technologies.

## **5 Scope**

The scope is the first document to be produced after the topic oversight group has selected a technology for consideration. It provides the framework for assessing the technology, taking into account how it works, its comparator(s), the relevant patient population(s), and its effect on clinical and system outcomes. The scope is based on the sponsor's case for adoption. It defines issues relevant to the evaluation, addresses the clinical and resource impact questions that need to be answered, and sets the boundaries for assessing the evidence and the committee's decision-making. The scope includes:

- a description of the technology and its claimed benefits
- information about the disease, condition or clinical problem relevant to the technology
- the regulatory status of the technology
- the topic oversight group's rationale for selection, which can include any relevant equality considerations
- the [decision problem](#) to be addressed by the evaluation of the technology
- a list of the professional and patient organisations who will be providing comments on the technology
- a list of the societies and organisations that will be invited to comment on the scope.

The scope may also include technical questions raised by the committee or the programme team at selection stage, which may relate to the technology's ease of use or likelihood to provide its claimed patient or healthcare system benefits. The technical questions do not extend to a full technical evaluation of the device.



## **6 Evidence and expert advice**

### **6.1 *Types of evidence and advice presented to the committee***

In developing its draft recommendations, the committee considers:

- the sponsor's submission, comprising clinical and cost evidence (based on the scope) and relevant cost modelling; the sponsor is responsible for ensuring that the submission contains all necessary data to properly evaluate the case for adoption
- evidence presented by the external assessment centre (which is independent of NICE), comprising a detailed analysis and critical appraisal of the submission in the form of an assessment report
- evidence from the programme team or other relevant organisations or working groups
- contributions from expert advisers
- contributions from patient and carer organisations
- information about ongoing or future research.

### **6.2 *Published evidence***

Valid publicly available evidence that is relevant to the scope is identified with 2 aims:

- to ensure that a comprehensive evidence base is available to the committee
- to inform evidence synthesis (meta-analysis) and modelling studies (section 7) when these are needed.

Evidence may relate to primary clinical research or secondary research (such as evidence synthesis or modelling studies).

#### **6.2.1 Search for published evidence**

The scope informs the literature search for evidence. The sponsor carries out a literature search as part of its submission, and the external assessment centre validates this search to support its critical appraisal of the evidence in the assessment report.

The search typically covers relevant efficacy, effectiveness, usability and safety outcomes (including intermediate clinical outcomes) and available clinical and health economics studies of any type, including non-UK studies. A range of medical literature databases is systematically searched, including: primary research databases; registers or databases of systematic reviews; meta-analyses and technology assessment evaluations; registers or databases of ongoing clinical trials (including experimental or observational studies); and conference proceedings. The external assessment centre reproduces the sponsor's search to validate that all relevant evidence has been identified.

## **6.3      *Unpublished evidence***

### **6.3.1      Purpose and rationale**

To ensure that all available relevant evidence is taken into account, the committee considers unpublished research if it is within the scope of the evaluation. As with publicly available evidence, such as that in peer-reviewed journals, unpublished evidence may relate to primary clinical or secondary research. Unpublished evidence may be included in the sponsor's submission or identified by the external assessment centre. Unpublished data may be used to support a narrative review of the evidence, as well as to inform the design and conduct of new secondary research studies (section 7).

### **6.3.2      Unpublished evidence sources**

There are 2 main sources of unpublished evidence:

- As part of their submission, sponsors are invited to provide unpublished evidence within the scope of the evaluation, including directly observed clinical outcomes, non-clinical studies such as in vitro research, evidence synthesis, outcomes modelling and health economics studies relating to the technology. It is the sponsor's responsibility to identify all relevant unpublished evidence as part of its submission, including studies not submitted for publication or rejected after submission.
- In its critical appraisal of the sponsor's submission, the external assessment centre may identify other unpublished evidence, such as analysis of data from

observational research sources, including professional or company-sponsored registers.

### **6.3.3 Unpublished evidence submitted in confidence**

Unpublished evidence is not normally considered confidential and may therefore be disclosed in publicly available guidance documents. However, it may occasionally be necessary for the committee to review data provided to the programme in confidence. The committee considers such evidence in a private part of the meeting.

Unpublished evidence is accepted under agreement of confidentiality and is not made available to the public. Such evidence includes commercial-in-confidence information (confidential' because its public disclosure may affect the commercial interests of a particular company) and academic-in-confidence data (confidential because the full data are yet to be published).

If the owner of any unpublished data included in the submission believes that the data should be treated as commercial- or academic-in-confidence, they should clearly state the rationale, taking into account the following principles:

- Information and data that have been made publicly available anywhere are not considered confidential.
- When trial results are to be published in a journal at a date later than the first public release by NICE of documentation quoting data from these trials, a structured abstract relating to the future journal publication should, as a minimum, be made available for disclosure.

NICE asks data owners to reconsider restrictions on release of data either when the reason for the restrictions is not clearly explained, or when such restrictions would make it difficult or impossible for NICE to show the evidential basis for its guidance.

## **6.4 Contributions from expert advisers**

Expert advisers contribute to the evaluation of technologies by providing additional knowledge, opinion and experience to the committee. They provide opinions on the published evidence and supplement it with information on anecdotal or theoretical outcomes, and other information relevant to the evaluation of the technology, its

comparators and the conditions for which it is used. Such information can relate to: the technical specification of the technology if this might affect its capability in delivering the claimed benefits; to the training and experience needed to use the technology; and to organisational factors that might influence the technology's technical performance or use in clinical practice.

Expert advice can also be used as part of evidence synthesis or modelling studies.

Experts advisers also contribute to the scope, give clinical advice when needed to the external assessment centre, and are involved in presenting the evidence to the committee. See the MTEP process guide for more information about how expert advisers are chosen.

## **6.5      *Contributions from patient and carer organisations***

NICE recognises that the experience of patients and carers can provide unique insights that may be of value to the committee when developing its recommendations. The public involvement programme always approaches patient and carer organisations to obtain their views on the technology (see the MTEP process guide). Patients and carers can provide information about living with the condition to which the technology relates, about any subgroups of patients who may need special consideration in relation to the technology, and about using the technology and/or comparator technologies. Patient and carer organisations can provide insight into outcomes and describe ease of use, discomfort, how the technology affects daily activities, and other aspects of quality of life.

NICE periodically reviews its experience of obtaining information on medical technologies from patient and carer organisations with the aim of refining its approach.

## **7            Evidence synthesis and cost-consequence analysis**

This section describes the methods used in preparing the sponsor's submission and in guidance development. In addition, sponsors may wish to ask the programme team for guidance and/or seek specialist advice.

The sponsor, as part of the submission, is responsible for evidence synthesis and developing economic models. After receiving the sponsor's submission, NICE may request further data collection and analysis from the sponsor, the external assessment centre or another organisation commissioned by NICE.

## **7.1      *Evidence synthesis***

Depending on the size and quality of the evidence base, evidence synthesis or meta-analysis may be used both to summarise evidence from different studies and to measure uncertainty and undertake sensitivity analyses. Quantitative evidence synthesis or meta-analysis approaches and techniques, including indirect and mixed treatment comparisons (network meta-analysis), may be used if appropriate to provide evidential inputs to models.

## **7.2      *Analysis of indirect and intermediate outcomes***

The available evidence may not always provide information on all clinical and system outcomes, particularly those in the future or that are not linked to immediate use of the technology. If this is the case, the sponsor's submission should include appropriate modelling of outcomes and these should be reflected in the cost analysis.

## **7.3      *Analysis of costs and consequences***

### **7.3.1      *Rationale and context for cost-consequence analysis***

As part of the sponsor's submission, analysis may be needed to quantify the resources and expected outcomes associated with the technology under consideration compared with current comparators and healthcare pathways defined in the scope. Such analysis may not be needed if relevant high-quality economic evaluations are already available. Given the remit of the programme, the approach expected to be appropriate for most technologies is cost-consequence analysis.

Cost-consequence analysis considers the costs and resource consequences resulting from, or associated with, the use of the technology under evaluation and comparator technologies, as well as considering relevant clinical benefits (for example, effectiveness outcomes) alongside the cost analysis.

The range of costs and resource consequences to be included in the analysis depends on the clinical characteristics of individual medical technologies and their comparators. Generally, the following apply:

- Typically, cost-consequence analyses include calculating and presenting estimates of resource use and of clinical benefits as separate domains of the evaluation.
- Estimates of resource use should include comparative costs of technology (and infrastructure) acquisition, use and maintenance. Focusing on these costs may be particularly applicable when the clinical effects of the technology can be assumed to be almost the same as those of comparator technologies.
- Estimates of resource use may also include the comparative value of healthcare service use outcomes (such as length of hospital stay, or number of hospitalisations, outpatient or primary care consultations) associated with the use of the technology or its comparators.

### **7.3.2 General principles of cost-consequence models**

The decision problem, as defined in the scope, determines the construction and assumption of any models. Models should quantify the effect of introducing a new technology into current healthcare pathways and routine health and social care system use.

Discounting principles are consistent with those used in cost-effectiveness analysis in other NICE guidance programmes. A discount rate of 3.5%, as recommended by the Treasury, is used to reflect the time value of costs and benefits.

The time horizon for accrual of benefits and costs should be determined for the medical technology under evaluation, and may be specified in the scope.

Costs resulting from or associated with the use of the technology should be estimated using prices relevant to the health and social care system and personal social services, and should include acquisition (including infrastructure) and maintenance costs.

Methods that capture the lifetime costs should be used when estimating investments in infrastructure associated with the use of the technology.

If a technology notified to the programme for a particular indication is found to affect more than 1 disease area or patient group, the sponsor should clearly present the assumptions and calculations used to calculate acquisition and infrastructure costs for different indications and uses of the technology in its submission.

Uncertainty analysis techniques (relating to chance, evidential and model uncertainty) should be done. The level of complexity should be appropriate for the specific technology and its comparator healthcare pathway. Various analyses of different complexity may be used, such as scenario-based deterministic sensitivity analyses, threshold analyses or probabilistic sensitivity analyses.

Some technologies may have only a healthcare system benefit. Examples include imaging technologies with nearly equivalent diagnostic performance and laboratory equipment with nearly equivalent diagnostic analytical and clinical validity. If there is evidence of equivalence with existing approaches, the evaluation may concentrate on the health and social care system outcomes.

## **8 Evaluation of the evidence and decision-making by the committee**

### **8.1 *Main considerations in decision-making***

The committee's main considerations when making its decisions are:

- Benefit to patients – whether the medical technology has measurable benefit to patients over currently available health and social care system technologies, measured by relevant outcome indicators.
- Benefit to the health and social care system – whether the medical technology is likely to reduce the burden on health and social care system staff or reduce resource use (for example staff or facilities) compared with current management.

The committee makes its recommendations based on the clinical and economic evidence, and informed by contributions from expert advisers and patient and carer organisations. The committee needs to be confident that the evidence is of sufficient quality, quantity and consistency to form the basis of robust recommendations. If

there are any uncertainties, the committee makes informed judgements and describes its uncertainties in the guidance.

The committee considers how the implications of medical technologies guidance on equality at specific stages of guidance development, including topic selection, scoping and when the committee produces draft and final recommendations. Any potential equality issues raised and considered for a topic are recorded in an equality impact assessment, which is completed in accordance with the MTEP equality impact assessment procedure. The equality impact assessment is approved by the programme or centre director and published with the scope and the final guidance. Any relevant equality issues that relate directly to the guidance topic and recommendations are also accounted for in the final guidance itself. In developing its recommendations, the committee considers relevant legislation on human rights, eliminating unlawful discrimination and promoting equality. It also takes into account advice from NICE on making scientific and social value judgements. This advice is informed by the work of the [Citizens Council](#). The committee considers the social value judgements provided in [social value judgements: principles for the development of NICE guidance](#).

## **8.2      *Types of recommendation***

The committee produces recommendations based on the extent to which the case for adoption is supported and the potential patient and health and social care system benefits.



**Table 2 Committee recommendations and the case for adoption**

<b>Case for adoption and potential benefits</b>	<b>Type of recommendation(s) which are normally made</b>	<b>For details see section</b>
Case for adoption is fully supported.	Recommendation for use	8.2.1
Case for adoption is partially supported	Recommendation for use in specific circumstances	8.2.1
	Recommendation for use in specific circumstances and recommendation for development of further evidence	8.2.1 and 8.2.2
Case for adoption is not currently supported but the technology has potential to provide significant patient or healthcare system benefits.	Recommendation for use in a research context	8.2.3
Case for adoption is not supported and the technology does not have potential to provide significant patient or healthcare system benefits.	Recommendation highlighting this	8.2.4

The guidance includes the committee's recommendations and its considerations. These considerations summarise the main evidence taken into account by the committee, its view of this evidence, and the areas of contention and uncertainty that arose during its discussions, including the contributions from expert advisers and patient and carer organisations. The considerations section of the guidance aims to describe the degree of uncertainty associated with the recommendations, and the potential impact of such uncertainties.

### **8.2.1 Recommendation for use of a technology**

The committee usually produces a recommendation for use of a technology when it considers that:

- there is sufficient certainty that the technology has at least equivalent clinical and/or health and social care system benefits compared with current management, and overall uses less resources **or**
- there is sufficient certainty that the technology has significantly greater clinical and/or health and social care system benefits compared with current management, and overall uses similar resources.

The committee may make recommendations for use of the technology in specific circumstances only, such as only for patients with a particular condition or by staff with certain training or in a particular care setting.

### **8.2.2 Recommendation for development of further evidence**

When technologies are not supported by adequate evidence of clinical utility to allow a comprehensive evaluation, or to produce recommendations covering the sponsor's entire case for adoption, the committee may recommend use in specific circumstances, and may also recommend development of further evidence.

The aim of recommending the development of further evidence is to reduce uncertainty about specific issues, such as whether particular benefits suggested in the evidence submission can be realised in normal clinical settings. When recommending the development of further evidence the committee follows the framework outlined in section 8.3.

### **8.2.3 Recommendations for use in a research context**

The committee usually produces recommendations for use in a research context when it considers that:

- the technology has the potential to provide substantial benefits to patients and/or of releasing significant resources **but**
- the case for adoption is not fully supported and there is uncertainty about whether these benefits are realisable in normal clinical settings; uncertainties may relate to whether clinical outcomes will be achieved, or to service impact (for example, the likelihood of the technology being introduced in a way that leads to the claimed benefit of released resources).

When making a recommendation for use in a research context, the committee aims to:

- describe the most important clinical, economic, technical or other evidence gaps relating to use of the technology in the health and social care system
- explicitly state the research questions that future studies need to address.

For this type of recommendation the committee follows the framework outlined in section 8.3. Such a recommendation is not intended to preclude the use of the technology in the health and social care system but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.

#### **8.2.4 Case for adoption not supported**

If the sponsor's case for adoption is not supported by the evidence and the contributions from expert advisers and patient organisations, this is indicated in the committee's recommendations. The committee's rationale is described in the committee considerations section of the guidance.

### **8.3 *Framework for research recommendations***

The committee develops research recommendations in medical technologies guidance using the principles described in NICE's research recommendations manual.

The committee considers the following factors when deciding whether to recommend future evidence generation and data collection on medical technologies:

- the most important evidence gaps relating to the uncertainty about the technology, and the value of information that could be derived from generating evidence to address them
- information about ongoing or planned research on the technology
- ethical and/or practical aspects of conducting further research
- the likely costs and benefits of the research (to ensure that a research recommendation does not become a barrier to innovation).

These considerations aim to help guide decisions about investment in future research by identifying the types of studies that will address research questions and generate new evidence of greatest value to the NHS.

### **8.4 *Consultation on draft recommendations***

Once the committee has made its decision on a technology, draft guidance is produced and is made available for public consultation for 4 weeks.

The committee considers all comments received during consultation and, if necessary, appropriate changes are made to the draft guidance.

## **9           Reviews**

The review process for published guidance is detailed in the interim addendum on guidance reviews [here](#).

## **10          Updating the methods guide**

The methods guide is subject to the approval of the NICE board and will normally be reviewed 3 years after last publication. It may be necessary to make minor changes to the methods of developing medical technologies guidance before that time.

Changes to the methods guide will be made according to NICE policy. Minor changes that may be made without consultation are those that:

- do not add or remove a fundamental stage in the process
- do not add or remove a fundamental methods technique or step
- do not disadvantage stakeholders
- improve the efficiency, clarity or fairness of the process or methodology.

Changes meeting these criteria will be published on the NICE website 4 weeks before their implementation. The online version of this guide will also be updated at that time and a note to this effect placed on the overview page.

Any changes considered to be more significant than minor will only be made after a public consultation of 3 months.

## **Appendix A: Glossary**

### **Assessment report**

A report produced by 1 of NICE's independent external assessment centres that reviews the sponsor's evidence submission and may include additional analysis of the submitted evidence or new clinical and/or economic evidence.

**Case for adoption**

The clinical and cost benefits that would be realised if the technology were used in place of the best available alternative.

**Expert Adviser**

A person nominated or ratified by their professional body to advise the committee and/or topic oversight group about medical technologies about which they have specific knowledge or expertise. Expert advisers may be healthcare professionals with knowledge of using the technology in practice, or medical scientists with technical knowledge.

**Clinical utility**

The clinical usefulness of a technology. For example, the clinical utility of a diagnostic test is its capacity to rule a diagnosis in or out, and to help make a decision about adopting or rejecting a therapeutic intervention.

**Comparator**

The standard intervention against which the technology under evaluation is compared. The comparator is usually a similar or equivalent technology used as part of current management. For the purposes of modelling, the comparator can be 'no intervention'.

**Consultee**

A person or organisation that submits a comment during consultation.

**Cost analysis**

A comparative evaluation of the costs and resource use consequences of 2 or more interventions.

**Cost-consequence analysis**

A comparative evaluation of the costs and resource use consequences of 2 or more interventions considered alongside the relevant clinical benefits.

**Decision problem**

The decision problem describes the proposed approach to be taken in the sponsor's submission of evidence to answer the question in the scope. This includes the population, intervention, comparator(s), outcomes, cost analysis, subgroup analysis and any special considerations.

**Diagnostic technology**

A medical technology with a diagnostic purpose. Diagnostic technologies are a subset of medical technologies.

**Discounting**

Costs and benefits incurred today are usually valued more highly than costs and benefits occurring in the future. Discounting reflects society's preference for when costs and benefits are to be experienced.

**Efficacy**

The extent to which an intervention is active when studied under controlled research conditions.

**Equivalence**

An assumption that two or more technologies result in the same clinical (efficacy and safety) outcomes.

**Evidence synthesis (meta-analysis)**

A statistical technique for combining (pooling) the results of a number of studies that address the same question and report on the same outcomes to produce a more precise summary estimate of the effect on a particular outcome.

**Guidance executive**

A team comprising the executive directors and centre directors at NICE who are responsible for approving the final guidance before publication.

**In confidence**

Information (for example the findings of a research project) submitted to the programme that is not in the public domain. 'Commercial-in-confidence' information

is defined as confidential because its disclosure could affect the commercial interests of a particular company. 'Academic-in-confidence' information is waiting to be published, and it is confidential because its disclosure could affect the academic interests of a research or professional organisation.

### **Medical technologies guidance**

Guidance produced by the medical technologies advisory committee on technologies that are routed to it for evaluation.

### **Medical technology**

A medical device or diagnostic technology as defined in section 1 of this guide.

### **Modelling**

Used to synthesise evidence to generate estimates of clinical and cost outcomes.

### **Notification**

The process by which a sponsor (usually the company which owns the medical technology) informs NICE about a potential technology for evaluation.

### **Patient and carer organisations**

Organisations of patients, carers, communities and other lay members, including those that represent people from groups protected by equalities legislation.

### **Register**

An organisation or system that facilitates and/or undertakes the collection and collation of patient data about specific disease and/or treatment outcomes, and supports and/or facilitates the quality assurance and analysis of these data.

### **Resource consequence**

A resource use consequence that is not directly from the technology but occurs because of it.

### **Routing**

The decision taken by the topic oversight group about which NICE programme or external organisation should evaluate a selected technology.

**Sponsor**

The company, developer, distributor or agent of the technology being considered for evaluation. The sponsor can also be a clinician, medical organisation or another NICE programme or national health body or organisation.

**System outcome**

A non-clinical outcome, typically impacting on resource capacity, resulting from a clinical (patient-level) treatment episode.

**Topic briefing**

An overview of a single technology produced by the programme team. The topic oversight group uses the topic briefing when deciding whether to select that technology for evaluation.

**Topic oversight group**

The team which selects and routes medical technologies for guidance development

**Uncertainty analysis**

Investigates the sensitivity of analysis results to variation in assumptions and parameters.

**Value of information**

Assesses the value associated with perfect information that can be obtained in future research about different parameters in the evaluation.



## Appendix B: Eligibility criteria

	Eligibility criterion	Detail
1	Within the remit of a NICE evaluation programme and not currently being evaluated	The technology is suitable for medical technologies guidance (within the definitions of a medical technology or diagnostic technology as set out in section 1 of this guide) or for another NICE guidance programme.
2	A new or innovative technology	The technology is either new or an innovative modification of an existing technology with claimed benefits to patients or the health and social care system judged against the comparator(s).
3	Appropriate timing	<p>The technology has a CE mark or equivalent regulatory approval and, if not, this is expected within 12 months.</p> <p>The technology is available to the health and social care system, or the company or sponsor has plans for the launch of the technology in the health and social care system.</p>

## Appendix C: Selection criteria used by the topic oversight group

Selection criterion	Detail
Claimed additional benefit to patients	The extent to which a medical technology claims measurable benefit to patients over currently available health and social care system technologies in terms of its impact on quality of life or life expectancy.
Claimed healthcare system benefit	<p>The extent to which the technology is likely to reduce use of staff or facility resources. For example, the extent to which a technology:</p> <ul style="list-style-type: none"> <li>• facilitates outpatient diagnosis or treatment</li> <li>• has the potential to replace several technologies in current use</li> <li>• requires fewer staff than the technologies in current use</li> <li>• reduces length of hospital stay.</li> </ul>
Patient population	The larger the number of patients on whom the technology may be used, the greater the likelihood that a national evaluation is important.
Disease impact	<p>The greater the impact of the disease or condition on quality of life or life expectancy, the greater the likelihood that a national evaluation is important.</p> <p>For technologies aimed at treatment, consideration should take into account the likely degree of improvement in life expectancy, disease severity and quality of life, paying particular attention to conditions associated with social stigma.</p>
Cost considerations	Consideration of the costs of the technology, including initial acquisition costs (including associated infrastructure) and running costs (including maintenance and consumables).
Sustainability	Is the technology likely to contribute to the sustainability agenda, for example, less energy usage or less waste generation during production or clinical usage?

## **Appendix D: Routing considerations used by the topic oversight group**

The topic oversight group applies the selection criteria (appendix C) to technologies under consideration. For selected technologies, it then decides to which evaluation programme technologies should be routed; this is usually but not always a NICE programme. The considerations the topic oversight group applies in making these routing decisions are based on the remits of the individual programmes and the characteristics of the technologies being routed.

### ***Considerations for routing technologies to the Medical Technologies Evaluation Programme to develop medical technologies guidance***

Following on from the principles for developing medical technologies guidance, these, the specific considerations for routing a technology to the medical technologies evaluation programme are:

- the technology appears likely to achieve a similar clinical benefit at less cost or more benefit at the same cost as current practice evidence on its costs and benefits can be assessed on the basis of a sponsor's future submission
- the technology has characteristics that distinguish it from other technologies for the same indication(s) and can, therefore, be evaluated as an individual product or device
- there are no major outstanding safety concerns relating to the technology
- there is likely to be value in developing guidance for the health and social care system in a relatively short timescale.

When identifying suitable technologies for evaluation through this programme, consideration is given to promoting research, in particular whether the health and social care system can contribute to generating additional evidence by using the technology on a trial basis.

## ***Considerations for routing technologies to the Diagnostics Assessment Programme***

The diagnostics assessment programme evaluates diagnostic technologies that have the potential to improve health outcomes, but the introduction of the technology is likely to result in an overall increase in resource costs to the health and social care system.

This programme is likely to be suitable for evaluating diagnostic tests and technologies for which recommendations could only be made on the basis of clinical utility and cost-utility analysis. There should normally be a 'gold standard' or established comparator to enable an assessment of potential benefit of the technology. This programme can evaluate classes of technologies or individual technologies.

Diagnostic technologies that appear likely to achieve a similar clinical benefit at less cost or more benefit at the same cost as current practice in the health and social care system may be more suitable for evaluation by the medical technologies evaluation programme.

## ***Considerations for routing technologies to the Interventional Procedures Programme***

The specific considerations for routing a technology to the interventional procedures programme are:

- it is used in an interventional procedure that involves an incision or entry into a body cavity, use of radiation, or acoustic or electromagnetic energy
- the procedure in which the technology is used is new (that is, it is being used in the health and social care system for the first time)
- there is uncertainty about the efficacy or safety of the procedure in which the technology is used
- comparative effectiveness and health economic considerations are not relevant at this point
- interventional procedure guidance on the safety and efficacy of the technology will benefit the health and social care system and patients.

## ***Considerations for routing technologies to the Technology Appraisal Programme***

For details of the routing considerations for technology appraisals, see the [NICE guide to the processes of technology appraisal](#).

Technologies routed to the technology appraisals programme progress to the pre-scoping stage of the existing topic selection process (decision point 3). Therefore their progress through topic selection is not disadvantaged compared with technologies that go through the standard technology appraisals topic selection process.

Companion diagnostic technologies with the primary purpose of enhancing the clinical or cost effectiveness of pharmaceutical products may be suitable for this programme if the pharmaceutical product that they are intended to enhance is appraised. In other cases, companion diagnostic technologies may be more suitable for evaluation by the diagnostics assessment programme.

## ***Considerations for routing technologies to the NICE Guidelines Programme***

NICE guidelines comprise recommendations, based on the best available evidence, on the appropriate management of specific diseases and conditions. A technology is more likely to be routed for consideration to this programme if:

- there are a number of equivalent technologies available
- the equivalent technologies have been available in clinical practice for some time
- the benefits of the technology are likely to be best evaluated in the context of a care pathway in development or already developed by NICE.

Technologies selected for routing to the NICE guidelines programme are not disadvantaged compared with technologies that go through the standard topic selection process. For more details, please refer to [developing NICE guidelines: the manual](#).

### ***Considerations for routing to other NICE programmes or national organisations for evaluation***

A technology may not meet the criteria for evaluation by a NICE guidance programme but may in the view of the topic oversight group benefit from evaluation by another NICE programme or other national organisation. In these circumstances, the topic oversight group identifies the programme appropriate to consider the technology. NICE then either routes directly to a NICE programme or notifies the relevant external organisation. Any routing to an external organisation is with the agreement of the sponsor of the technology.

## Appendix E: Criteria for suspending or cancelling an evaluation

Criterion	Detail
Altered marketing plans or withdrawal	The company decides to delay the introduction of the technology or chooses not to market the technology in the UK.
Adverse events	Adverse events associated with the product may lead to the involvement of the MHRA or the withdrawal or suspension of the marketing authorisation of the product. Adverse events may emerge at any time during the identification and evaluation of the product.
Technology not appropriate for the production of medical technologies guidance	The evidence presented to the committee indicates that, contrary to expectation at the routing stage, the technology is not appropriate for medical technologies guidance. NICE may suspend the development of guidance and refer the technology to another programme for evaluation.
Data for the evaluation not provided according to the agreed schedule	When this is outside NICE's control (for example, a sponsor does not provide the submission on time) NICE will consider suspending the evaluation. This could lead to a delay in issuing the guidance.