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1 Introduction

1.1 Background

The National Institute for Health and Clinical Excellence (NICE) is part of the NHS. It is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health. Further details about NICE and its work programmes are available in ‘NICE: our guidance sets the standard for good healthcare’ (available from www.nice.org.uk/aboutnice).

NICE selects and evaluates medical technologies to determine whether they should be used in the NHS. A medical technology in this context is any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its application, intended to:

- diagnose, prevent, monitor, treat or alleviate disease
- diagnose, monitor, treat, alleviate or compensate for an injury or handicap
- investigate, replace or modify the anatomy or a physiological process
- control conception.

The principal intended action of the technology should not be by pharmacological, immunological or metabolic means, but these means may be used to help with its function.¹

Genetic tests fall within the scope of the evaluation pathway provided they have a medical purpose.

¹ These include medical devices and diagnostic technologies as defined in EU directives 93/42/EEC (concerning medical devices), 98/79/EC (concerning in-vitro diagnostic medical devices) and 90/385/EEC as amended (concerning active implantable medical devices). These directives include medical devices that are used for the purpose of diagnosis.
2 What is the evaluation pathway?

2.1 Aims

The evaluation pathway was created to identify medical technologies that would benefit from national evaluation, and to provide additional appropriate forms of evaluation for such products.

The evaluation pathway aims to simplify the route by which new medical technologies pass from development into NHS use. The pathway evaluates new medical technologies that could benefit patients and improve services and encourages collaborative research, in both industry and the NHS, to generate evidence on the clinical utility of selected technologies.

2.2 Key activities

The key activities of the evaluation pathway are:

- identifying and selecting appropriate medical technologies and routing them to a NICE guidance programme for evaluation
- developing and publishing guidance on selected medical technologies to the NHS in England and its social care partners
- developing and publishing implementation tools
- reviewing and updating guidance when required
- raising awareness of the evaluation pathway in the NHS in England and in other parts of the UK if appropriate.

This document describes the principles and methods supporting the activities of the programme. The methods are designed to ensure that the most appropriate medical technologies are selected for evaluation, and that robust guidance for the NHS is developed in an open, transparent and timely way, taking into account valid and relevant evidence, and allowing appropriate input from consultees and other stakeholders. This methods guide is intended to be complementary to the process guide for the Evaluation Pathway Programme for Medical Technologies, and should be read in conjunction with it (available from www.nice.org.uk/XXX).
2.3 **Characteristics of medical technologies**

Medical technologies have certain features which differentiate them from other medical interventions. These include:

- Technologies may be modified over time in ways that alter their effectiveness.
- The clinical outcomes resulting from the use of technologies are often contingent upon the degree of training, competence and experience of the healthcare professionals that use them (this is sometimes referred to as the ‘learning curve’).
- The clinical evidence about technologies is often limited, particularly in terms of comparative studies involving comparator treatments.
- The healthcare system benefits of adopting medical technologies are often contingent upon organisational factors, for example the setting in which the technology is used or the staff who use it, rather than simple use of the technology itself.
- The ability of diagnostic tests to improve clinical outcomes is contingent upon the subsequent delivery of appropriate healthcare interventions.
- Evidence of the effect of diagnostic tests on clinical outcomes may not be available, because improved diagnostic accuracy may or may not be reflected in improved clinical or quality-of-life outcomes.
- Some technologies are indicated in the management or investigation of many different medical conditions and may be used by different healthcare professionals and in a variety of healthcare settings.
- Costs of medical technologies are often composed of both procurement costs (including associated infrastructure) and running costs (including maintenance).

In general, medical technology pricing is less stable than that of other types of medical interventions.
3 Selecting and routing medical technologies in the evaluation pathway

The Medical Technologies Advisory Committee (MTAC or ‘the Committee’) makes decisions on selecting and routing medical technologies as a deliberative process that involves discussion of the information included in the briefing note, and applying the selection and routing criteria to specific technologies. The weight and significance that the Committee applies to each of these criteria will vary between technologies, depending on the purpose and context of use of the technology, and the medical condition to which it relates.

3.1 Selecting medical technologies for national evaluation

Briefing notes on eligible topics are prepared by the evaluation pathway team and presented to the Committee to help them to make a decision about whether a technology meets the published selection criteria for national evaluation (see appendix B). The evidence and information presented in the briefing notes inform selection and appropriate routing of a technology by the Committee. The briefing notes include information about the nature of the technology and its comparators, the benefits to patients and healthcare systems claimed for the technology, the populations of patients in whom the technology is used, and a summary of the available evidence. If possible, briefing notes incorporate input from expert and patient advisers and the manufacturer of the technology, and general illustrations of potential cost considerations resulting from use of the technology.

3.2 Routing of selected medical technologies for evaluation

Technologies selected for national evaluation by the Committee are then routed to an appropriate programme for evaluation. On the basis of the briefing notes as a guide to its decision-making, the Committee uses its judgement to route technologies for evaluation, using the published routing criteria (see appendix C).

Programmes that could evaluate selected medical technologies include:

- NICE Evaluation Pathway Programme
- NICE Interventional Procedures Programme
- NICE Diagnostics Assessment Programme
• NICE Technology Appraisal Programme
• other NICE programmes such as Clinical Guidelines
• other national programmes outside of NICE.

Following selection of diagnostic technologies for evaluation by NICE, MTAC may route them to the Diagnostics Assessment Programme, or may decide to develop medical technologies guidance. Diagnostics that are considered by the Committee at the routing stage to be likely to confer similar benefit at less cost, or more benefit for the same cost, compared with diagnostics in current use, are more likely to be suitable for medical technologies guidance. As with other technologies for which NICE develops medical technologies guidance, a cost consequences approach will be used for their evaluation.

Methodological considerations that apply to medical technologies described in this methods guide also apply to diagnostic technologies. NICE is developing its methods for application in the Diagnostics Assessment Programme, and considerations about specific features of evaluation of diagnostic tests contained in those methods will also inform the development of medical technologies guidance on diagnostic tests.

MTAC does not routinely develop medical technologies guidance on diagnostic tests whose primary purpose is the identification of asymptomatic disease among healthy individuals. Generally, such tests are likely to be more appropriately evaluated by the UK National Screening Committee or other bodies with a similar remit.

The rest of this guide refers to the methods for developing medical technologies guidance. A technology routed to another programme at NICE is evaluated according to the processes, methods and timelines of that programme – see NICE’s website for more details.
4 Developing medical technologies guidance

The principles for medical technologies guidance development are:

- A focus on single medical technologies, as opposed to similar technologies within a broader class.
- A focus on quality and productivity, with particular emphasis on technologies that have the potential to reduce overall resource use.
- A comparative effectiveness approach, with the current practice or management usually being used as comparators.
- Evaluating the impact of the technology on the healthcare system, alongside its clinical benefits for individual patients.
- Appropriate health economic approaches to support decision-making.
- Prioritising questions for future research to help to reduce any uncertainty in the evidence as quickly and efficiently as possible.

Additionally, the characteristics of medical technologies outlined in section 2.3, mean that the Committee’s decision-making process about the usefulness of medical technologies may involve some uncertainty. Therefore, the evaluation pathway encourages targeted research or data collection on the clinical utility of medical technologies that have the promise to offer advantages to patients compared with standard treatment, and/or to release significant resources.
5 Developing the scope of the evaluation

The scope provides the framework for assessing the technology, taking into account how it works, its comparators, the relevant populations of patients, and its impact on clinical and system outcomes. The scope clearly defines issues relevant to the evaluation and sets the boundaries for the assessment of the evidence and the Committee’s decision-making. This is done by defining the clinical and resource impact questions that the evaluation of the technology needs to answer. The scope includes the following:

- description of the technology
- the Committee’s rationale for developing medical technologies guidance
- information about the disease, condition or clinical problem relevant to the technology
- the comparator
- current healthcare pathways and management options upon which the technology will impact
- the selection of appropriate clinical and system benefit outcomes
- relevant equality impact considerations
- description of the approach to evidence synthesis, cost measurement and cost-impact analysis
- list of the professional and patient organisations involved in providing commentary on the technology.
6 Evidence, advice and commentary supporting the evaluation

6.1 Key components of the evaluation
The Committee makes recommendations on the basis of a submission to NICE from the manufacturer or sponsor. The submission consists of relevant clinical evidence and a cost model, as defined by the scope. An external assessment centre prepares a critique of the submission in the form of an assessment report, which is presented to the Committee with relevant advice and commentary from expert and patient advisers.

6.2 Types of evidence and commentary presented to the Committee
In developing its recommendations, the Committee considers the following types of evidence, commentary and information:

- evidence in the public domain (including peer-reviewed publications)
- evidence from other sources, including the submission from the manufacturer or sponsor of the technology
- expert advice
- patient’s experience of technology use
- information about the conduct of future research.

6.3 Evidence in the public domain (including peer-reviewed publications)
Valid, publicly available evidence that is relevant to the scope is identified with two aims:

- To support a narrative critique of the evidence for presentation to the Committee in the assessment report.
- To inform evidence synthesis (meta-analysis) and modelling studies (see section 7) when these are needed.
Evidence may relate to primary clinical research or secondary research (for instance, in the form of research synthesis or any type of modelling studies).

6.3.1 Search for evidence in the public domain

The literature search for evidence in the public domain is informed by the scope, and is carried out by the external assessment centre. The purpose of this search is to identify any relevant evidence not included in the manufacturer’s submission, to ensure that a comprehensive evidence base is available to the Committee.

The search typically encompasses relevant efficacy, effectiveness and safety outcomes (including intermediate clinical outcomes) and available clinical or modelling studies of any type (including any type of health economics studies). To minimise the risk of any relevant evidence source being missed, a range of medical literature databases are 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. Given the novel nature of technologies normally considered by the Committee, and its focus on single technologies, it is frequently the case that the search strategy only identifies a limited number of relevant evidence sources.

Appropriate standardised evidence appraisal and bias assessment instruments and checklists may be used, if appropriate, in relation to assessing the relevance of the evidence identified.

6.4 Unpublished evidence

6.4.1 Purpose and rationale

To ensure that all available evidence is taken into account, the Committee considers research that is not in the public domain, if it is valid and within the scope of the evaluation. As is the case for evidence in the public domain, unpublished evidence may relate to primary clinical or secondary research. Unpublished evidence is submitted to NICE by the manufacturer 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.
6.4.2 Unpublished evidence sources

There are two main sources of unpublished evidence:

- As part of their submission, technology manufacturers or sponsors are invited to provide unpublished evidence within the scope of the evaluation, including directly observed clinical outcomes, evidence synthesis, outcomes modelling and any type of health economic studies relating to the technology. NICE expects the manufacturer or sponsor to provide all relevant unpublished evidence in its possession as part of its submission, including studies not submitted for publication or rejected following submission.

- In addition, the external assessment centre identifies other sources of unpublished evidence, such as ad-hoc analysis of data from observational research sources, including professional or manufacturer-sponsored registers, if they have not been identified in the manufacturer’s submission.

6.4.3 Unpublished evidence submitted in confidence

Normally, unpublished evidence is not considered confidential and may, therefore, be disclosed in guidance documents placed in the public domain. 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 closed session of the meeting. If the owner of any unpublished data submitted believes it should be marked as either ‘commercial-in-confidence’ or ‘academic-in-confidence’, the rationale for marking evidence as ‘in confidence’ should be clearly stated and should be consistent with the following principles:

- Information and data that have been put into the public domain anywhere in the world are not considered confidential.

- When it has been decided that release of trial results will occur through journal publication at a date later than the first release by NICE of documentation quoting data from such trials, a structured abstract relating to future relevant publication should be made available for disclosure, as a minimum.
NICE will ask 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.

6.5 \textit{Expert advice}

\textbf{Expert advisers} make an important contribution to the evaluation of new technologies by providing knowledge and opinion to help the Committee interpret the evidence. They have the knowledge and experience to supplement the published evidence with information on anecdotal or theoretical outcomes, and other information relevant to the evaluation of the technology and its comparators, and the conditions for which it will be used. Such information can relate to the technical specification of the technology if this might affect its capability in delivering the claimed benefit; the training and experience required to use it; and organisational factors that might influence its technical performance or use in clinical practice.

Expert advice can also be used as part of \textit{elicitation} processes for adjustment of bias in the evidence base, as part of evidence synthesis or modelling studies.

Expert advice is sought using a standardised structured questionnaire that allows free text responses, covering key evaluative aspects of the technology.

6.6 \textit{Patients’ experience of the technology}

NICE recognises that the experience of patients who have been treated or diagnosed using a medical technology, and that of their carers, can provide unique insights that may be of value to the Committee when formulating its recommendations. Patients and carers can provide information about living with the condition to which the technology relates, and about the use of the technology and/or comparator technologies. Patient advisers can provide insight into outcomes not fully described in the scientific literature, such as ease of use, discomfort, and impact on diverse activities and other aspects of quality of life. The programme therefore uses advice from patients and carers, if this is available, to inform the assessment of medical technologies. This advice is normally obtained through contact with patient organisations.
NICE will periodically evaluate its experience of obtaining patients’ advice on medical technologies with the aim of refining its approach.

7 Evidence synthesis and modelling studies

If the cost modelling that forms part of the manufacturer’s submission is not sufficient to support the Committee’s decision-making, the external assessment centre may carry out evidence synthesis or modelling studies, as requested by NICE.

7.1 Evidence synthesis

Depending on the size and quality of the evidence base, evidence synthesis or meta-analysis studies may be needed as a means of elucidating the degree of uncertainty and undertaking sensitivity analysis. Appropriate quantitative evidence synthesis or meta-analysis approaches and techniques, including evidence adjustment and indirect and mixed treatment comparisons (‘network meta-analysis’), may be used if appropriate to provide evidential inputs to models.

7.2 Modelling of indirect and intermediate clinical and system outcomes

In some circumstances, the available evidence may not provide information on all necessary clinical or system outcomes, particularly those that occur at some point in the future, or that are not directly linked to immediate use of the technology. If this is the case, appropriate modelling studies may be commissioned by NICE from the external assessment centre, to help to provide the Committee with estimates.

7.3 Modelling of cost consequences

7.3.1 Rationale and context for cost-consequence analysis

Some technologies may require new modelling studies to be conducted to quantify required resources and expected outcomes associated with the technology under consideration against current comparator management options and healthcare pathways. Such studies may not be needed if evidence containing relevant good quality modelling studies is already available. The approach to modelling studies is informed by the scope. Given the remit of the Committee, the approach expected to be appropriate for most technologies is that of cost-consequence analysis.
Cost-consequence analysis covers a spectrum of approaches that incorporate the consideration of costs and resource consequences resulting from, or associated with, the use of comparative technologies, as well as the consideration of relevant clinical benefits (for example, effectiveness outcomes) alongside the cost analysis.

The range of costs and resource consequences to be included in cost-consequence analysis will vary depending on the clinical characteristics of individual medical technologies and their comparators. Generally, the following will apply:

- Cost-consequence analysis may be particularly applicable when the technology under evaluation can be assumed to be therapeutically near-equivalent to comparator technologies.
- More typically, cost-consequence analysis frameworks could encompass the calculation and presentation of estimates of resource use and of clinical benefits as separate domains of the evaluation.
- Estimates of resource use could either solely encompass comparative costs of technology (and infrastructure) acquisition, use and maintenance; or could also encompass the comparative monetary value of healthcare service use outcomes or events (such as length of hospital stay, or number of hospitalisations or outpatient or primary care consultations) associated with the use of the technology or its comparators.

All the approaches do not necessitate the valuation of patient health status or treatment preferences.

### 7.3.2 General principles of cost-consequence modelling studies

The construct and assumptions of models must be informed by the purpose of the evaluation and the key questions of relevance to decision-making, which are defined in the scope.

Modelling studies should capture and quantify the key aspects of the impact of introducing a new technology to current healthcare pathways and routine NHS use.

Discounting principles are consistent with those used by NICE’s other cost-effectiveness analysis programmes. Currently, a discount rate of 3.5% is used to reflect the time value of costs and benefits, as recommended by HM Treasury.
The time horizon for accrual of benefits and costs should be determined in the context of the medical technology under evaluation, and as determined by the scope, and should reflect the time horizon over which these costs and benefits are realised.

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

Methodologies that capture the full lifetime costs of the investment should be used when costing investments of infrastructure associated with the use of new technologies.

In certain circumstances, acquisition and infrastructure costs relating to a specific medical technology may impact the treatment of more than one disease area or patient group. If it is likely that the indication for the technology may extend beyond the purpose for which it was notified, this is identified during scoping to inform costing considerations with appropriate apportioning of costs between different indications and uses of the technology.

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

It is acknowledged that some technologies may be associated with outcomes that are entirely non-clinical (that is, they have only a system impact). Examples include different types of imaging technologies with nearly equivalent diagnostic performance, and different types of laboratory equipment with nearly equivalent diagnostic analytical and clinical validity. In such circumstances the evaluation may focus solely on these system outcomes if evidence is presented of equivalence with existing approaches.
8 Evaluation of the evidence and decision-making by the Committee

8.1 Key considerations in decision-making

There are two key domains of relevance to the Committee’s decision making:

- Benefit to patients: Whether the medical technology has measurable net benefits for patients that are equivalent to or greater than those delivered by currently available management options in terms of its influence on relevant patient outcome indicators.
- System impact: whether the net impact of the medical technology is likely to reduce resource utilisation (pay and non-pay, capital and other relevant costs).

The Committee makes its recommendations based on the evidence and informed by commentary from expert and patient advisers. The Committee needs to be confident that the evidence is sufficient in quality, quantity and consistency to form the basis of a robust recommendation.

Equality and diversity considerations are taken into account at each stage of the development of medical technologies guidance. The equality and diversity issues raised at each development stage for a topic will be recorded in the equality and diversity impact assessment (in accordance with the documented impact assessment procedure. In developing its recommendations, the Committee considers relevant legislation on human rights, discrimination and equality. It also takes into account advice from NICE on the appropriate approach to making scientific and social value judgements. Advice on social value judgements is informed by the work of the Citizens Council. Guidelines that describe the social value judgements that should, generally, be considered by the Committee are provided in the Institute’s document, ‘Social value judgements: principles for the development of NICE guidance’.
8.2 **Types of recommendation**

The Committee produces two types of recommendations on technologies that, on the basis of the evidence and commentary they consider, appear either to confer the benefits claimed by the product manufacturer or sponsor, when compared with current alternatives, or to show plausible promise of doing so:

- Recommendation for use of a technology (see section 8.2.1)
- Recommendation for use in a research context (see section 8.2.2).

Where a technology does not, in the Committee’s view, confer the claimed benefits compared with current alternatives, it develops guidance that states this (see section 8.2.3).

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 evidence that the technology produces at least equivalent clinical and/or system benefits in relation to currently used comparator management options and
- There is sufficient evidence and certainty that use of the technology will not increase the net use of resources or that it will release resources, and reduce the overall cost burden beyond those released by the comparator or current management options. Technologies with equivalent cost impact may be recommended if they are demonstrated to provide more clinical or system benefit than comparator management options.

The Committee’s considerations form part of the guidance document, and this section of the guidance represents an important component of the Committee’s work. The section identifies the key evidence taken into account by the Committee and its view of this evidence. It describes the Committee’s thoughts on each aspect of the guidance. It highlights the areas of contention and uncertainty that have arisen during the Committee’s discussions of the evidence, and presents a general description of the Committee’s views of the advice that has informed their decision. In general, where the Committee makes a recommendation to use a technology, it is
likely that the degree of uncertainty over the benefits of the technology, or the impact of any uncertainty, is low. The Committee aims to qualify the degree of uncertainty upon which its recommendations are based, and the potential impact of such uncertainties.

In its recommendations for use of a technology the Committee may also include suggestions for observational data collection. The primary aim of this is to generate further evidence to reduce uncertainty on specific issues, for example, whether benefits suggested in the evidence presented to the Committee are capable of being realised in practice in normal clinical settings. Observational data collection may also support quality assurance and monitoring of implementation. In medical technologies guidance with this type of recommendation, the Committee may also make suggestions for further research on the technology, but in these circumstances its use is not dependent on that research being carried out.

8.2.2 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 plausible promise of providing substantial benefits to patients as claimed by the manufacturer or sponsor, and of having a sufficiently significant beneficial impact on the NHS in terms of release of resources, but that there is insufficient evidence, and therefore substantial uncertainty, about whether these clinical and system benefits are realisable.

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

- Describe the most important evidence gaps relating to use of the technology in the NHS.
- State the nature of clinical utility or other studies that could help address these evidential gaps efficiently and credibly.
- When the Committee makes a recommendation for use in a research context, it clearly states the research questions that future studies need to address (see section 8.3).
8.2.3 Technologies that do not confer the claimed benefit

Where a technology does not, in the Committee's judgement on the evidence and commentary, confer the benefit claimed by the manufacturer or sponsor, the Committee develops medical technologies guidance that states that the technology does not appear to confer the claimed additional benefit when compared with current alternative treatment or management (as defined in the scope).

8.3 Development of further evidence

In some cases, the evaluation pathway considers technologies that are not supported by adequate evidence of clinical utility to support a definitive evaluation, or to support the production of definitive recommendations. Enabling timely research on medical technologies that the Committee considers to have plausible promise of benefit is therefore an essential component of medical technologies guidance.

The Committee may recommend that a technology can be used in a research context (or with arrangements for data collection to produce further evidence to inform a future review of the guidance) in the following circumstances:

- There is good reason to believe that the technology achieves at least equivalence with current practice in terms of its impact on the quality or length of patients' lives and reduces NHS costs over and above the comparator management option.
- The available evidence leaves the Committee uncertain about whether the likely benefits will be realised in practice. 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).

8.3.1 Types of evidence generation likely to be recommended

Recommendations on use in research may take several forms, in order to deal with these different types of uncertainty. The Committee will specify the research questions that need to be answered, and important outcome measures. The Committee may also make suggestions about study design, which could include randomised controlled trials or observational studies and registers.
The Committee may request randomised controlled trials to be carried out comparing the technology against current management. The Committee will indicate that these trials should have certain features in order to provide useful evidence on medical technologies in this context. For example, in order to enable future decision-making by the Committee such studies are likely to:

- include clinical, service organisation and economic measurements of the effect of the technology compared with current practice on related aspects of the healthcare pathway
- be conducted in a ‘real world’ setting
- aim to include patients whose condition would normally be managed using the technology, rather than specially selected groups
- encompass outcomes relevant to the claimed advantages of the technology, whether to patients or to the NHS
- include ‘clinical utility’ outcomes (that is, outcomes of benefit to patients, rather than focusing only on measurements such as diagnostic accuracy).

If a technology is recommended as suitable for more widespread introduction, there may still be uncertainties about some aspects of its effects (for example, its impact in everyday use on patients’ lives and their use of health service facilities, its influence on other parts of the care pathway, and its long-term efficacy, safety or durability). In such circumstances, observational studies may be an appropriate way of generating further evidence.

By contrast with randomised controlled trials, patients in observational studies will not be randomised, but the technology or current practice will be offered to them at health centres that are undertaking the studies. For example, the technology might be introduced into selected hospitals or healthcare settings. Defined outcomes will then be observed in those settings, and compared with the outcomes of current management in settings where the technology has not been introduced. The principles for outcomes included in observational studies in this context will be the same as those for randomised controlled trials listed above.
If use of the technology is recommended conditional upon data submission, a register may be suggested by the Committee. This may be:

- an established register specific to the technology
- an established register that covers a number of related technologies
- a new register, created as a result of the Committee’s recommendations.

Before an established register is recommended, the programme team confirms that the dataset in the register is adequate for submitting relevant details about the use of the technology and its outcomes in order to inform future review of recommendations, or that such adequacy could be easily achieved by suitable modifications. Another requirement for a register to be recommended in guidance is that all data required for future review of the recommendations will be made available to NICE in due course. Furthermore, the register should have credible clinical supervision (for example, being clinically supervised by an independent board, committee or steering group).

Other study designs may be recommended by the Committee, appropriate to specific uncertainties that arise from their consideration of the evidence.

### 8.3.2 Considerations relating to the conduct of future research

The Committee considers the following factors when deciding whether to recommend future evidence generation and data collection:

- the most important evidence gaps relating to the degree of 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
- methodological issues related to carrying out research into that technology
- ethical or practical aspects of conducting further research.

These considerations aim to help to guide decisions about investment in future research by taking into account the population health gain that could be derived by the generation of new evidence, in a way that is intended to help the prioritisation of studies that will address those research questions of greatest value to population health.
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.

All comments received at consultation are considered by the Committee, which recommends appropriate changes to be included in the final medical technologies guidance for issue by NICE.

8.5 Technologies not within the remit of the Evaluation Pathway Programme

There may be circumstances in which the evidence presented to the Committee on a particular technology indicates that, contrary to the Committee’s expectation at the routing stage, it does not fall within the remit of medical technologies guidance. For example, this could be if a technology brings about a patient benefit at an additional cost not offset by the release of system resources. In these circumstances NICE may suspend the development of medical technologies guidance, and refer the technology to another NICE programme for evaluation.

9 Reviewing and updating guidance

NICE may consider reviewing and updating guidance if there are significant developments in the evidence base likely to lead to a major change in the current guidance (for example, new safety or health economic evidence, or other substantial new evidence that casts doubt on the validity or relevance of the original recommendations).

If the guidance on a technology recommends clinical utility research, the guidance is reviewed and updated when the results of the research are available.
Appendix A: Glossary

Citizens Council The Citizens Council brings the views of the public to NICE decision-making about guidance on the promotion of good health and the prevention and treatment of ill health. A group of 30 people drawn from all walks of life, the Citizens Council tackles challenging questions about values, such as fairness and need.

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.

Consultee A person or organisation that submits a comment during consultation.

Cost–consequence analysis A comparative evaluation of the costs and resource use consequences of two or more interventions.

Cost-impact analysis A comparative evaluation of the costs resulting from the acquisition, implementation and use of two or more interventions.

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

Elicitation The process of acquisition of expert opinion about plausible assumptions and estimates (and ranges of estimates) that can be used in evidence adjustment or sensitivity analysis approaches.

Evidence adjustment A process based on experts’ elicitation, by which primary evidence values are adjusted to different estimates, to remove perceived external (generalisability) or internal (validity) biases in the primary evidence.

Evidence synthesis (meta-analysis) A statistical technique for combining 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.

Expert adviser A person nominated by their professional body to advise the Medical Technologies Advisory Committee about medical technologies for which they have
specific knowledge or expertise. Expert advisers may be healthcare professionals with knowledge of use of the technology for treatment or management of patients, or medical scientists with technical knowledge.

**In confidence** information (commercial-in-confidence or academic-in-confidence). Information (for example the findings of a research project) supplied to the programme that is not in the public domain. Commercial-in-confidence information is defined as confidential because its disclosure could have an impact on the commercial interests of a particular company. Academic-in-confidence information is awaiting publication, and it is confidential because its disclosure could affect the academic interests of a research or professional organisation.

**Patient adviser** Patients or carers who are asked to provide information to help inform the Committee’s evaluation of a technology.

**Uncertainty analysis** Investigation of the sensitivity of analysis results to variation in assumptions and parameters.

**Value of information** Assessment of the value associated with perfect information that can be obtained by future research, regarding different parameters in the evaluation.
Appendix B: Selection and exit or pause criteria used by the Medical Technologies Advisory Committee

1 Selection criteria

If a technology is eligible on the basis of the eligibility criteria (see process guide, available from www.nice.org.uk/XXXXX), it is assessed by MTAC using the selection criteria in table 1. MTAC forms an overall judgement of suitability of the technology using the selection criteria, assisted as necessary by a set of scores to inform their deliberations. In reaching their decision on a particular technology MTAC considers the overall value to the NHS of NICE developing guidance.

Any technology that is not selected may be reconsidered by MTAC if subsequent evidence of potential benefit emerges.
<table>
<thead>
<tr>
<th>Selection criterion</th>
<th>Detail</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claimed additional benefit to patients</td>
<td>The extent to which a medical technology claims measurable benefit to patients over currently available NHS technologies in terms of its impact on quality or quantity of life.</td>
<td>Score 1–2 = The technology is of negligible additional benefit compared with existing best available care, for example no difference in diagnostic speed, ease or accuracy; no difference in therapeutic ease, safety or efficacy. Score 3–4 = The technology is of moderate additional diagnostic or therapeutic benefit compared with existing best available care. Score 5 = The technology is of significant additional diagnostic or therapeutic benefit compared with existing best available care.</td>
</tr>
<tr>
<td>Claimed system benefit</td>
<td>The extent to which the technology is likely to reduce use of or release staff or facility resources. For example, the extent to which a new technology: • facilitates outpatient diagnosis or treatment • has the potential to replace several technologies in current use • requires fewer staff than the technologies in current use.</td>
<td>Score 1–2 = The technology has minimal or no claimed service or systems benefits. Score 3–4 = The technology has modest claimed service or systems benefit. Score 5 = The technology has significant claimed service or system benefits.</td>
</tr>
<tr>
<td>Patient population</td>
<td>The larger the population of patients on whom the technology may be used, the greater the likelihood that a national evaluation is important.</td>
<td>Score 1 = 0–1,000 people. Score 2 = 1,001–10,000 people. Score 3 = 10,001–50,000 people. Score 50,001–500,000 people. Score 5 = more than 500,000 people. Technologies for small patient populations are not automatically excluded and MTAC takes into account the disease impact, claimed benefits and relevance to sustainability agenda.</td>
</tr>
<tr>
<td><strong>Selection criterion</strong></td>
<td><strong>Detail</strong></td>
<td><strong>Score</strong></td>
</tr>
<tr>
<td>-------------------------</td>
<td>------------</td>
<td>-----------</td>
</tr>
<tr>
<td>Disease impact</td>
<td>The greater the impact of the disease or condition on quality or length of life, the greater the likelihood that a national evaluation is important. For technologies aimed at treatment, consideration should take into account likely degree of improvement in life expectancy, disease severity and quality of life, paying particular attention to these for conditions that incur social stigma.</td>
<td>Score from 1 to 5, in which: Score 1 = a low combined morbidity, mortality and/or quality of life impact. Score 5 = a high combined morbidity, mortality and/or quality of life impact.</td>
</tr>
<tr>
<td>Cost considerations</td>
<td>Consideration of the potential costs of the technology to the service, including initial acquisition costs, direct revenue costs, and influence of use of the technology on total system costs.</td>
<td>Score 1 or 3 Score 1= The cost is low or neutral. Score 3 = There are potential savings, or the cost is high.</td>
</tr>
<tr>
<td>Sustainability</td>
<td>Is the technology likely to contribute to the sustainability agenda, for example, less energy usage or less waste generation during production or clinical usage?</td>
<td>Score 1–2 = no or minimal contribution to sustainability (for example energy usage). Score 3–4 = expected contribution to the sustainability agenda. Score 5 = expected to realise sustainability benefit within the lifetime of the product.</td>
</tr>
</tbody>
</table>
2 Exit or pause criteria

Certain technologies prioritised at various points in the process may need to exit the selection process temporarily or permanently; for example, a company may decide not to progress with UK marketing. Table 2 lists exit or pause criteria for the evaluation pathway.

Table 2 Exit or pause criteria for the evaluation pathway

<table>
<thead>
<tr>
<th>Exit or pause criterion</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altered marketing plans or withdrawal</td>
<td>The manufacturer decides to delay the introduction of the technology or choose not market the technology in the UK</td>
</tr>
<tr>
<td>Altered potential for benefit</td>
<td>The expected benefits to patient, NHS staff or healthcare services are less than initially expected such that a national evaluation would be unlikely to be of benefit</td>
</tr>
<tr>
<td>Adverse incidents</td>
<td>It is found that there are adverse incidents associated with the product that lead to the withdrawal of the product. This information may emerge at any time in the identification and evaluation of the product</td>
</tr>
</tbody>
</table>
Appendix C: Routing criteria used by the Medical Technologies Advisory Committee

The Committee applies the selection criteria of the Evaluation Pathway for Medical Technologies to the technologies that it considers. For selected technologies, it then decides which NICE evaluation programme they should be routed to. The considerations the Committee applies in making these routing decisions involve the remits of the individual Programmes at NICE and the characteristics of the technologies being routed.

Exceptionally, the Committee may decide to route a technology to another national body for evaluation. This decision is made by agreement with NICE (see section f below).

a) Considerations for routing to the Evaluation Pathway Programme for the development of medical technologies guidance

The technology is likely to conform to the principles for development of medical technologies guidance, in particular:

- it appears likely to achieve a similar clinical benefit at less cost or more benefit at the same cost
- evidence on its cost impact and benefits is capable of being assessed on the basis of a manufacturer's submission
- the technology can be evaluated as an individual product, rather than a class of products
- there are no major outstanding safety concerns about the product
- there is likely to be utility in developing guidance for the NHS within a relatively short timescale.

When identifying suitable products for evaluation through MTAC, consideration is given to fostering research, in particular whether the NHS can contribute to the generation of additional evidence by facilitating the use of the new technology on a trial basis.
b) Considerations for routing to the Interventional Procedures Programme

The technology is within the remit of the Interventional Procedures Programme and meets the programme’s selection criteria, in particular:

- it is used in an interventional procedure that involves an incision, entry into a body cavity, or use of radiation, or acoustic or electromagnetic energy
- the procedure itself is novel (that is, it is being used in the NHS 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 programme guidance on safety and efficacy of the technology will add value for the NHS and patients.

c) Considerations for routing to the Diagnostics Assessment Programme

The Diagnostics Assessment Programme undertakes evaluations of diagnostic technologies whose use holds the promise of improving health outcomes, but the introduction of the technology is likely to result in an overall increase in resource costs to the NHS.

The Diagnostics Assessment 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 new technology. This programme can evaluate classes of technologies or individual technologies.

Diagnostic technologies that are likely to confer additional benefit with the same cost impact or those that appear to confer the same benefit at a lower cost are likely to be more appropriate for the development of medical technologies guidance (see section a) above).

d) Considerations for routing to the Technology Appraisal Programme

The technology meets the criteria for topic selection for a technology appraisal.
Technologies selected for routing to the Technology Appraisals Programme progress to the pre-scoping stage of the existing technology appraisals topic selection process (decision point 3). For more details refer to the ‘NICE Topic Selection process manual’ (available from www.nice.org.uk/aboutnice/howwework/howguidancetopicsarechosen).

Companion diagnostics selected for evaluation by the Committee are likely to be suitable for evaluation by the Technology Appraisals Programme in the context of an appraisal of the pharmaceutical product whose effectiveness they are intended to enhance.

e) Considerations for routing to the Clinical Guidelines Programme

There are a number of equivalent technologies available which are all likely to deliver similar benefits, and there is an established pathway of care. The benefits of the technology are likely to be best evaluated in the context of an established care pathway.

f) Considerations for routing to other national organisations for evaluation

A technology may not meet the criteria for evaluation by a NICE programme but, nevertheless, might in the view of the Committee benefit from evaluation by another national organisation. In these circumstances MTAC identifies the national programme considered appropriate to undertake the evaluation. NICE then notifies the relevant organisation, with the agreement of the manufacturer of the technology.