National Institute for Health and Clinical Excellence

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Medical Technologies Evaluation Programme

Methods guide

National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London WC1V 6NA

www.nice.org.uk

Contents

NHS Evidence has accredited the process used by the Medical Technologies Evaluation Programme to produce guidelines. Accreditation is valid for five years from November 2011 and is applicable to guidance produced using the processes described in the Medical Technologies Evaluation Programme Process and Methods guides. More information on accreditation can be viewed at www.evidence.nhs.uk.

List of abbreviations

MTAC	Medical Technologies Advisory Committee
NICE	National Institute for Health and Clinical Excellence
PPIP	Patient and Public Involvement Programme

1 Introduction

The National Institute for Health and Clinical Excellence (NICE) provides guidance, sets quality standards and manages a national database to improve people's health and prevent and treat 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/whatwedo).

Technical terms in this document are given in **bold text** on their first mention and are defined in the glossary (appendix A).

NICE selects and evaluates **medical technologies** to determine whether the **case for adoption** in the NHS is supported by the evidence. For the purposes of the Medical Technologies Evaluation Programme a medical technology is defined as outlined in table 1.

Table 1 Definitions of medical technologies for the Programme

Term	Definition	Source
A medical device	'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: – diagnosis, prevention, monitoring, treatment or alleviation of disease, – diagnosis, monitoring, treatment, alleviation of or compensation for an injury or [disability], – investigation, replacement or modification of the anatomy or of a physiological process, – control of conception, 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'	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
An 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)
An 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
An in vitro diagnostic medical device	'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: – concerning a physiological or pathological state, or – concerning a congenital abnormality, or – to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures.	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 sub-set of medical technologies.

Genetic tests are covered by the Programme provided they are used for a medical purpose and fall within the scope of Council Directive 98/79/EC.

The Medical Technologies Evaluation Programme identifies medical technologies that have the potential to offer substantial benefit to patients and/or to the NHS and that are likely to be adopted more consistently and more rapidly if NICE develops guidance on them.

This methods guide describes how NICE selects medical technologies for national evaluation. It also describes how the Medical Technologies Advisory Committee (MTAC, 'the Committee') develops guidance on selected technologies routed to it for evaluation. The methods are designed to ensure that the most appropriate medical technologies are selected for evaluation, and, when the Committee produces guidance, that it 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 'Medical Technologies Evaluation Programme process guide', available on NICE's website (www.nice.org.uk/mt).

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 What is the Medical Technologies Evaluation Programme?

2.1 Aims

The aims of the Programme are:

- to promote faster uptake of new medical technologies in the NHS
- to encourage collaborative research, in both industry and the NHS, to generate evidence on the **clinical utility** and/or healthcare system benefits of selected technologies.

2.2 Key activities

The key activities of the Programme are:

- Identifying and selecting appropriate medical technologies that would benefit from national evaluation.
- **Routing** these medical technologies to a NICE guidance programme for evaluation.
- Evaluating medical technologies routed to the Committee, which involves:
  - developing and publishing guidance for use by the NHS in England and its social care partners, including recommendations for further research
  - developing and publishing implementation tools
  - reviewing and updating guidance when required.

2.3 Characteristics of medical technologies

Medical technologies are different from other medical interventions because:

- 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 (sometimes referred to as the 'learning curve').

- Clinical evidence on technologies, in particular new technologies, is often limited, especially comparative studies against appropriate alternative treatments or methods of diagnosis.
- The healthcare system benefits 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.
- When the technology is a diagnostic test, improved clinical outcomes depend on 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 not be reflected in improved clinical or quality-of-life outcomes.
- Some technologies are indicated in managing or investigating 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 the use of the technology.
- In general, medical technology pricing is more dynamic than that of other types of medical interventions.

3 Selecting and routing medical technologies in the Medical Technologies Evaluation Programme

The Medical Technologies Advisory Committee makes decisions on selecting and routing medical technologies by discussing the case for adoption and applying the selection and routing criteria to specific technologies. Although the selection criteria are of equal weight, the significance that the Committee applies to each of these criteria varies among technologies, depending on the purpose and context of use of the technology, and the medical condition(s) to which it relates.

3.1 Selecting medical technologies for national evaluation

Notifications of medical technologies are made through the NICE website (www.nice.org.uk/mt) and are received primarily from product **manufacturers** or **sponsors** (referred to as sponsors in this document). The Medical Technologies Evaluation Programme team prepares **briefing notes** on eligible topics and presents them to the Committee to inform their decision about whether a technology meets the selection criteria for national evaluation (see appendix B).[1] The briefing note is based on the sponsor's case for adoption and includes information about the technology and its **comparators**, the claimed benefits to patients and healthcare systems compared with current management, the populations of patients in whom the technology is used, and a summary of the available evidence. Briefing notes incorporate input from **expert advisers**, **patient and carer organisations** if possible, and the sponsor of the technology. They include an indication of potential costs of using the technology.

3.2 Routing selected medical technologies for evaluation

Once the Committee has selected technologies for evaluation it routes them to an appropriate evaluation programme using the briefing note and the published routing considerations (see appendix C) as a guide. Selected technologies may be routed to:

- NICE Medical Technologies Evaluation 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.

More information about these programmes is given in appendix C and on the NICE website (www.nice.org.uk).

[1] See the 'Medical Technologies Evaluation Programme process guide' for a description of the notification process and the eligibility criteria.

3.2.1 Diagnostic technologies

After the Committee 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. Diagnostic technologies that have similar benefits at less cost or more benefits at the same cost compared with those in current use, are more likely to be evaluated according to the methods described in this guide. Diagnostic technologies that potentially have more benefit but at greater cost compared with those in current use are more likely to be routed to the Diagnostics Assessment Programme.

The Medical Technologies Evaluation Programme does not develop guidance on diagnostic tests that are primarily used for population screening. Generally, such tests are likely to be routed for consideration to an appropriate evaluation body such as the UK National Screening Committee or another body with a similar remit.

The rest of this guide describes the methods for developing guidance on medical technologies that are routed to the Medical Technologies Advisory Committee. A technology routed to any other NICE guidance programme is evaluated according to the processes, methods and timelines of that programme – see NICE's website for more details (www.nice.org.uk).

4 Principles for developing medical technologies guidance

The principles for developing medical technologies guidance are:

- to evaluate a single medical technology based on the claimed patient and healthcare system benefits and not comparing it with similar technologies in a broader class
- to evaluate the case for adoption in the NHS, with particular emphasis on technologies that have the potential either to provide additional benefit to patients at the same or lower cost to the NHS, or to provide equivalent benefit to patients at lower cost to the NHS

- to take a comparative effectiveness approach, with current practice or management in the NHS usually being used as comparator(s)
- to evaluate the impact of the technology on the healthcare system, alongside its clinical benefits for individual patients
- to use appropriate health economic approaches to support decision-making
- to 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 the Programme's aims of promoting faster uptake of innovative technologies in the NHS. It enables the specific claimed benefits of innovative products to be rapidly evaluated and guidance published to the NHS. If the Committee 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 potential incremental benefits, then it has the option to route the technologies to a NICE programme with multiple technology evaluation methods.

The characteristics of medical technologies outlined in section 2.3 mean that the evidence presented to the Committee about the claimed benefits of medical technologies, may have high uncertainty. The Medical Technologies Evaluation Programme may encourage targeted research or data collection on the clinical utility of medical technologies that are considered to have potential advantages for patients compared with current treatment, and/or to use significantly fewer resources.

5 The scope

The scope provides the framework for assessing the technology, taking into account how it works, its comparator(s), the relevant populations of patients, and its impact on clinical and **system outcomes**. The scope is based on the sponsor's case for adoption. It defines issues relevant to the evaluation, it addresses the clinical and resource impact questions that need to be answered, and it 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 Committee's rationale for developing medical technologies guidance, 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 involved in providing comments on the technology
- a list of the societies or organisations to 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 ability to generate the 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 following:

- the submission from the sponsor: a clinical and economic evidence submission, based on the scope, which includes relevant cost modelling; the sponsor is responsible for ensuring that the submission contains all relevant data required to evaluate whether the case for adoption is supported
- evidence presented by the External Assessment Centre (which is independent of NICE): 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 two aims:

- to ensure that a comprehensive evidence base is available to the Committee
- 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 (such as evidence synthesis or modelling studies).

6.2.1 Search for published evidence

The literature search for evidence is informed by the scope. The sponsor carries out a literature search as part of the evidence submission, and the External Assessment Centre validates this search to support their 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 (see section 7).

6.3.2 Unpublished evidence sources

There are two main sources of unpublished evidence:

- As part of their submission, technology 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 their 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 manufacturer-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. If the owner of any unpublished data included in the submission believes the data should be treated as 'commercial-in-confidence' 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 in the world 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 required 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 required to the External Assessment Centre, and are involved in presenting the evidence to the Committee. Please see the 'Medical Technologies Evaluation Programme 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 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 developing its recommendations. The Patient and Public Involvement Programme (PPIP) always approaches patient and carer organisations to obtain their views on the technology (see the 'Medical Technologies Evaluation Programme process guide' for more details). 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, impact on diverse activities and other aspects of quality of life.

NICE periodically 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 analysis. 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 clinical and system outcomes

The available evidence may not always provide information on all clinical and 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, 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 analysis frameworks 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 construction and assumptions of models are determined by the decision problem as defined in the scope.

Models should capture and quantify the impact of introducing a new technology into current healthcare pathways and routine NHS 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 HM 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 NHS 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 one disease area or patient group, the assumptions and calculations used to calculate acquisition and infrastructure costs for different indications and uses of the technology should be clearly presented in the sponsor's submission.

Uncertainty analysis techniques (relating to chance, evidential and model uncertainty) should be undertaken. 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 analysis, threshold analysis or probabilistic sensitivity analysis.

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 healthcare 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 NHS technologies, measured by relevant outcome indicators.
- Benefit to the NHS: whether the impact of the medical technology is likely to reduce the burden on NHS 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 their uncertainties in the 'Committee considerations' section of the guidance.

The Committee considers how medical technologies guidance may potentially impact 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 Medical Technologies Evaluation Programme 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' (see www.nice.org.uk/aboutnice/howwework/socialvaluejudgements/socialvaluejudgements.jsp).

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 healthcare system benefits.

Case for adoption and potential benefits	**Type of recommendation(s) which are normally made**	**For details see section**
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
Case for adoption is partially supported **and** technology has potential to provide significant patient or healthcare system benefits	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** 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** technology does not have potential to provide significant patient or healthcare system benefits	Recommendation highlighting this	8.2.4

The guidance document includes the Committee's recommendations and its considerations. These considerations summarise the key evidence taken into account by the Committee, its view of this evidence, and the areas of contention and uncertainty that arose during the discussions, including the contributions from expert advisers and patient and carer organisations. The considerations section aims to

describe the degree of uncertainty on which the Committee's recommendations are based, 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 produces at least equivalent clinical and/or healthcare system benefits compared with current management options and with a net reduction in resources required **or**
- there is sufficient certainty that the technology produces significantly greater clinical and/or healthcare system benefits compared with current management options for similar investment of resources.

The Committee may make recommendations for use of the technology in specific circumstances only, such as for patients with a particular condition, 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 clinical and healthcare system 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 NHS
- 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 NHS 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, the Committee produces guidance highlighting this. 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, available on the NICE website (www.nice.org.uk).

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 carrying out research. This is 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 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 during consultation are considered by the Committee and if necessary appropriate changes are made to the final medical technology guidance issued by NICE.

9 Reviews

Medical technologies guidance is not published with a fixed review date. Guidance is considered for review by the NICE **Guidance Executive** if significant new evidence becomes available.

The process of reviewing guidance and submitting review proposals to the Guidance Executive forms part of the normal workload of the Programme. NICE includes guidance updated as a result of the review process in the Programme's annual target for guidance development.

10 Updating the methods guide

The methods guide is subject to the approval of the NICE Board and a review will normally be initiated 3 years after its 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 in accordance with NICE's 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 one or more 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 electronic version of this document will also be updated at that time and a note to this effect placed on the opening page.

Any other changes will only be made after a public consultation period of 3 months.

Appendix A: Glossary

Assessment report A report produced by one 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.

Briefing note An overview of a single technology produced by the Programme team. The Committee uses the briefing note when deciding whether to select that technology for evaluation.

Case for adoption The clinical and cost benefits that would be realised if the technology were taken up in place of the best available alternative.

Citizens Council The Citizens Council represents the views of the public when NICE is formulating guidance on the promotion of good health and the prevention and treatment of ill health. The Citizens Council consists of a group of 30 people drawn from all occupations. It 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.

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. 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 two or more interventions.

Cost-consequence analysis A comparative evaluation of the costs and resource use consequences of two 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 sub-set 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.

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 using the technology for treating or managing patients, or medical scientists with technical knowledge.

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 have an impact on 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.

Manufacturer – see ‘sponsor’

Medical technologies guidance Guidance produced by the Medical Technologies Advisory Committee on technologies that are routed to it for evaluation. Guidance on medical technologies produced by another NICE guidance programme is referred to by a different name, such as ‘diagnostics guidance’ or ‘technology appraisal guidance’.

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

Meta-analysis see ‘evidence analysis’

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

Notification The process by which a notifier (usually the manufacturer of 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 part of the technology but occurs because of it

Routing The decision taken by the Medical Technologies Advisory Committee about which NICE guidance programme or external organisation should evaluate a selected technology.

Sponsor The manufacturer, developer, distributor or agent of the technology being considered for evaluation

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

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: Selection criteria used by the Medical Technologies Advisory Committee

Selection criterion	Detail
Claimed additional benefit to patients	The extent to which a medical technology claims measurable benefit to patients over currently available NHS technologies in terms of its impact on quality of life or life expectancy.
Claimed healthcare system benefit	The extent to which the technology is likely to reduce use of staff or facility resources. For example, the extent to which a 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 • reduces length of hospital stay.
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	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. 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.
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 C: Routing considerations used by the Medical Technologies Advisory Committee

The Committee applies the selection criteria (see appendix B) 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 guidance programme. The considerations the Committee 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

The principles for developing medical technologies guidance are set out in section 4 of this guide. Following on from 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 in the NHS
- 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 NHS in a relatively short timescale

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

Considerations for routing technologies 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 new (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 guidance on safety and efficacy of the technology will benefit the NHS and patients.

Considerations for routing technologies to the Diagnostics Programme

The Diagnostics 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 NHS.

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 NHS may be more suitable for evaluation by the Medical Technologies Evaluation Programme.

Considerations for routing technologies to the Technology Appraisal Programme

The technology meets the criteria for topic selection for a 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. For more details, please refer to NICE's 'Process manual for topic selection'

(available from www.nice.org.uk/aboutnice/howwework/howguidancetopicsarechosen).

Companion diagnostic technologies with the primary purpose of enhancing the clinical or cost effectiveness of pharmaceutical products may be suitable for this Programme if an appraisal is carried out of the pharmaceutical product that they are intended to enhance. In other cases, companion diagnostic technologies may be suitable for evaluation by the Diagnostics Programme.

Considerations for routing technologies to the Clinical Guidelines Programme
Clinical guidelines are recommendations, based on the best available evidence, on the appropriate treatment and care of people with 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 Clinical Guidelines Programme are not disadvantaged compared with technologies that go through the standard topic selection process. For more details, please refer to NICE's 'Process manual for topic selection' (available from www.nice.org.uk/aboutnice/howwework/howguidancetopicsarechosen).

Considerations for routing to other national organisations for evaluation
A technology may not meet the criteria for evaluation by a NICE guidance programme but might in the view of the Committee benefit from evaluation by a national organisation. In these circumstances the Committee identifies the national programme appropriate to consider the technology for evaluation. NICE then notifies the relevant organisation, with the agreement of the sponsor of the technology.