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1 Introduction

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.

The evaluation pathway identifies medical technologies that have the potential to offer substantial benefit to patients and/or the NHS and are likely to be adopted more consistently and more rapidly if NICE develops guidance on them. The selection and evaluation of technologies is carried out within NICE’s Evaluation Pathway Programme, which comprises the Medical Technologies Advisory Committee (MTAC or ‘the Committee’) and an

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.
Evaluation Pathway Programme team which is responsible for technical tasks and project management. The Evaluation Pathway Programme team is employed by NICE. All members of the Committee are independent of NICE.

This process guide describes how NICE selects medical technologies for national evaluation and how it develops its guidance. The procedure is designed to ensure that robust guidance is developed for the NHS in an open, transparent and timely way, allowing appropriate input from and other stakeholders. This process guide is complementary to the ‘Evaluation Pathway for Medical Technologies methods guide’ (available from www.nice.org.uk/XXXXXXX).

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).

Terms in this document, indicated in bold text at their first mention, are listed in the glossary (appendix A).
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 between 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 Programme 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.

2.3 Key audiences

The evaluation pathway has several audiences that are expected to take note of NICE’s medical technologies guidance:

- NHS commissioners – for example, when specifying services incorporating use of medical technologies.
- Practitioners, including clinicians, using medical technologies in clinical or research settings.
• Provider management in primary and secondary care, particularly when planning services or facilities in which medical technologies are used.
• Purchasing and procurement organisations, when planning procurement of these products.

Patients and carers of people who may be affected by the technology are also a key audience for the guidance.
2.4 **Timelines**

2.4.1 **Selecting and routing medical technologies**

NICE has to collect sufficient information on specific technologies to select and route them correctly. The amount of time needed to collect this information can vary depending on the technology, and table 1 is therefore a guide only.

**Table 1 Approximate timings for selection and routing**

<table>
<thead>
<tr>
<th>Weeks (average) from notification</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>The manufacturer or sponsor notifies the medical technology to NICE</td>
</tr>
</tbody>
</table>
| 2                                 | The evaluation pathway team considers the technology against the eligibility criteria (see appendix B)  
NICE initiates preparation of a briefing note  
NICE carries out a literature search  
NICE requests advice from expert advisers and patient advisers |
| 6                                 | NICE completes the briefing note |
| 10                                | MTAC selects the technology for evaluation and routes it to the appropriate NICE programme for evaluation or MTAC does not select the technology for evaluation |

2.4.2 **Evaluating medical technologies**

The timings in table 2 apply when a medical technology is routed to the Evaluation Pathway Programme. These are approximate timings and may vary in response to individual requirements.
<table>
<thead>
<tr>
<th>Weeks (average) from selection</th>
<th>Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>MTAC meets and selects a medical technology for evaluation</td>
</tr>
</tbody>
</table>
| 2                             | NICE finalises the scope of the technology  
NICE requests the manufacturer’s or sponsor’s submission  
NICE invites contributions from expert advisers and patient advisers |
| 4                             | NICE receives the manufacturer’s or sponsor’s evidence submission  
NICE asks the external assessment centre to prepare an assessment report |
| 8                             | NICE receives the manufacturer’s or sponsor’s cost model submission  
The external assessment centre clarifies evidence and model submissions with the manufacturer or sponsor |
| 13                            | NICE receives the assessment report from the external assessment centre |
| 14                            | NICE sends the assessment report to the manufacturer or sponsor for fact checking |
| 15                            | NICE compiles the assessment report summary |
| 16                            | NICE distributes the assessment report and the summary to MTAC members |
| 18                            | MTAC meets and develops draft recommendations |
| 19                            | MTAC prepares and agrees the medical technology draft guidance document |
| 20                            | NICE edits the medical technology consultation document |
| 21                            | Consultation starts |
| 25                            | Consultation ends |
| 26                            | NICE collates consultation comments |
| 27                            | MTAC considers the consultation comments and develops final recommendations |
| 30                            | **NICE Guidance Executive** approves guidance for publication  
Resolution period starts |
| 33                            | Resolution period ends |
| 38                            | NICE publishes medical technologies guidance |
3 Who is involved in the Evaluation Pathway Programme?

3.1 The evaluation pathway team

The Evaluation Pathway Programme is part of NICE's Centre for Health Technology Evaluation. The evaluation pathway team consists of the associate director, technical, project management and administrative staff who support the Committee in developing medical technologies guidance. Members of the evaluation pathway team:

- assess notified technologies against the eligibility criteria
- prepare briefing notes used by the Committee during selection and routing
- prepare clinical evidence and commentary considered by the Committee, and commission external assessment centres to assess evidence
- arrange public consultation on the Committee's draft recommendations
- prepare guidance for publication
- ensure agreed timelines and quality standards are followed.

3.2 Editors

The editors review the documents that are produced during the development of the guidance, including evidence overviews and draft and final guidance. If the technology being assessed is of particular relevance to patients and carers, NICE editors will provide further support, for example, by providing a lay explanation of the recommendations.

3.3 Implementation

The implementation team produces implementation support tools (such as costing tools and audit tools) to help the NHS implement NICE's guidance. These tools are developed with advice from expert advisers, patient advisers and Committee members, as appropriate.
3.4 **Information services**

The information services team searches for information and evidence relevant to the technologies under evaluation. This information is used by the evaluation pathway team to prepare information for the Committee, including the briefing notes for selection and routing.

3.5 **The Patient and Public Involvement Programme**

The Patient and Public Involvement Programme (PPIP) is the team at NICE that recruits and supports lay members of the Committee, identifies patient advisers (see section 3.8), encourages members of the public and patient organisations to respond to consultation, and establishes links with patient organisations with an interest in medical technologies guidance. NICE uses the terms 'patient organisation' and 'patient group' to include patients, carers, and community and other lay organisations, including those representing people from groups protected by equalities legislation.

3.6 **The Medical Technologies Advisory Committee**

The Medical Technologies Advisory Committee is an independent standing committee consisting of about 25 members with a range of expertise. It includes clinicians who develop and use medical technologies, people who can provide a lay perspective on the issues affecting patients and the NHS, experts in regulation and the evaluation of healthcare, and representatives from the medical technologies industry.

The Committee normally meets monthly (excluding August) in public. Agendas and minutes of Committee meetings are published on the NICE website (www.nice.org.uk/XXXX). The minutes record only what was discussed by whom and in what order. They do not record the Committee's draft recommendations. Committee members are required to submit a declaration of interests every year, and to declare any conflicts of interest at each Committee meeting, in line with NICE’s code of practice for declaring and dealing with conflicts of interest (www.nice.org.uk/aboutnice/Codeofpractice).
3.6.1 The roles of the Committee

- To identify medical technologies suitable for evaluation and route them to the appropriate NICE programme for evaluation.
- If technologies are routed to the Evaluation Pathway Programme, the Committee develops NICE medical technologies guidance including, if appropriate, recommendations that further research is needed.

The ‘Evaluation Pathway Programme for Medical Technologies methods guide’ has more information about how the Committee makes its decisions, and the types of recommendation it makes.

3.6.2 How Committee members are appointed

Committee members are recruited through an open advertisement (normally posted on the NICE website) and are appointed for a period of up to 3 years by a panel consisting of an executive or centre director, a non-executive director and the chair of the Committee. The time period may be extended by mutual agreement, up to a maximum of 10 years. A list of current members is published on the NICE website (www.nice.org.uk/xxxxxx).

NICE is committed to the values of equality and diversity and welcomes applications for membership of the Committee from all sectors of the community.

3.7 Expert advisers

Expert advisers are normally clinicians who use the medical technology being evaluated or developers of medical technologies in a clinical or research setting. Details of how expert advisers' opinions are presented to the Committee are given in section 5.5.
3.7.1 The role of expert advisers

Expert advisers provide advice about medical technologies that complements findings from research. Expert advisers may be asked to give advice on:

- the validity of the notification and whether the technology is relevant to the NHS
- preparing the scope
- preparing the assessment report
- developing implementation support tools, such as costing tools or audit tools (see section 7)
- developing information for patients and carers.

They may be asked to give evidence at Committee meetings if necessary.

3.7.2 The identification of expert advisers

NICE identifies expert advisers as follows:

- NICE asks professional bodies (including Royal Colleges, specialist societies and other professional associations) to nominate expert advisers.
- NICE selects expert advisers on a topic basis from a pool of expert advisers.
- Current expert advisers may recommend others with relevant knowledge; expert advisers identified in this way are ratified by their professional body.
- The manufacturer suggests clinicians with experience of using the technology, or technology developers with relevant knowledge; expert advisers identified in this way are ratified by their professional body.
- The chair, vice chair or Committee members recommend people with relevant knowledge; expert advisers identified in this way are ratified by their professional body.

NICE encourages nominations of expert advisers from all sectors of the community.
NICE appoints expert advisers for a 3-year term and gives them the option to renew their term. Clinicians are not eligible to advise the evaluation pathway if they retire from practice.

NICE publishes a list of expert advisers on its website (www.nice.org.uk/xxxxx).

### 3.8 Patient advisers

The Committee asks **patient and carer organisations** to nominate patient advisers. Patient advisers can provide information about living with the condition to which the technology relates, and about using the technology and/or comparator technologies. Patient advisers can provide insight into outcomes, and describe ease of use, discomfort, impact on diverse activities and other aspects of quality of life.

### 3.9 External assessment centres

NICE commissions external assessment centres from a range of organisations, including the NHS and academic bodies. The external assessment centre assesses the evidence and produces an assessment report for the Committee (see section 5.4). These centres have knowledge of and expertise in medical technologies and appropriate methods of evaluation.

### 3.10 Manufacturers

Normally, manufacturers of medical technologies notify technologies to NICE for evaluation. They should provide sufficient information for the Committee to decide whether or not to select the product for evaluation. The manufacturer also provides information for the scope.

The manufacturer provides an evidence submission that includes the relevant modelling. This may be based on published or unpublished data, including confidential data prepared for regulatory purposes (see section 5.3).

The manufacturer also has the opportunity to comment on the Committee's draft recommendations during consultation (see section 5.10), and to request clarification during resolution (see section 6).
3.11 **Registering an interest**

NICE encourages interested parties (people and organisations) to register an interest in a technology via the NICE website. NICE sends electronic updates to those who register an interest throughout the evaluation. These updates are triggered by changes to the website page for the technology (for example, when consultation begins). Individuals and organisations who register an interest have the option to comment on the draft guidance, and those who make comments can also make a resolution request later in the process.

The evaluation pathway team notifies relevant professional bodies, and the PPIP notifies relevant patient and carer organisations when a technology that may be of interest to them is first mentioned on the website.

3.12 **Members of the public**

To promote public attendance at Committee meetings NICE publishes a notice and draft agenda on its website announcing each meeting at least 20 working days before the meeting. At this point, members of the public who wish to attend the meeting can register on NICE's website. Up to 20 places are available, depending on the size of the venue. In the event that attendance at any meeting is oversubscribed, NICE selects attendees according to its allocation procedure (for further information, see [www.nice.org.uk/media/FC7/9D/PublicMeetingsInformation.pdf](http://www.nice.org.uk/media/FC7/9D/PublicMeetingsInformation.pdf)). To allow wide public access, NICE reserves the right to limit attendees to one representative per organisation. The closing date for receipt of completed application forms is 10 working days before the meeting. NICE publishes the final agenda on its website 5 working days before the meeting. Once registration has closed, NICE contacts successful applicants to invite them to the meeting. Along with the invitation, applicants receive a code of conduct for public attendees and frequently asked questions. If a meeting is cancelled, NICE gives attendees as much notice as possible.

Public access to meetings is granted in accordance with NICE policies and subject to the standing orders of the Committee.
4 How are technologies identified and selected for evaluation?

4.1 How NICE becomes aware of new medical technologies

4.1.1 Notifications from manufacturers

NICE receives notifications of medical technologies for evaluation primarily from product manufacturers or sponsors. The manufacturer provides information on the technology, including its uses, costs, sources of evidence and benefits to patients and the NHS. The benefits include:

- Benefit to patients: the medical technology claims measurable benefit to patients over currently available NHS technologies in terms of its impact on quality and/or length of life.
- Benefit to NHS: the impact of the medical technology is likely to reduce the burden on NHS staff or reduce resource use, for example, staff or facilities.

The evaluation pathway team initially considers notified medical technologies using the eligibility criteria (see appendix B):

- They have a CE mark or equivalent regulatory compliance, or this is expected within 2 years.
- The topic is within the remit of a NICE evaluation programme, and is not currently being evaluated.
- The technology is new, or is a substantial modification to an existing technology, with clear benefits for patients or healthcare systems.

Medical technologies that do not conform to the eligibility criteria are not taken onto the evaluation pathway.

Manufacturers or sponsors may re-notify medical technologies even if they have previously been assessed as ineligible for the evaluation pathway. This should occur only if the technology has changed in such a way that it offers significant additional benefits to patients and/or the NHS.
4.1.2 Other sources of information on new medical technologies

Horizon scanning is a process by which technologies are identified before they come on to the market. The National Horizon Scanning Centre, based at the University of Birmingham, undertakes this process on behalf of NICE. Once the centre identifies a medical technology as being at a suitable point in development, it may suggest that the manufacturer or sponsor notify the technology to NICE.

People and organisations other than manufacturers can make notifications. For products to progress along the evaluation pathway, the manufacturer must give information about their product to NICE, and may need to make a formal submission. Therefore, people considering making a notification are encouraged to discuss their intention with the manufacturer of the product before doing so.

4.2 Information about technologies notified to the programme

Details of all products for which medical technologies guidance will be developed are available on the NICE website. The website provides information about each technology evaluated by the evaluation pathway, including a description of the technology and its uses, and links to important documents developed by NICE.

The status of the topic is also included. There are two main categories:

- Guidance issued – guidance has been published and is available on the NICE website.
- In progress – the technology is being evaluated.
4.3 Selection and routing

Selection is the process used to identify and decide which medical technologies should be evaluated. Because the number of technologies that can be evaluated is limited, the Committee selects technologies that are most likely to benefit patients and the NHS.

The evaluation pathway team prepares briefing notes for the Committee on eligible technologies. Briefing notes include input from the relevant patient and carer organisations whose views on the technology, and its potential benefits, are sought by the PPIP team. These views are sought in all cases, and presented to the Committee where they are received. Briefing notes also include relevant information relating to equality and diversity considerations.

The Committee selects from the eligible technologies those suitable for evaluation, and routes them to the most appropriate NICE programme. The Committee normally makes selection decisions at each of its monthly meetings, during a session that is not open to members of the public or press (see the 'Guide to methods of the Evaluation Pathway Programme for medical technologies' for more information about how the Committee reaches its decisions).

The rest of this guide refers to the process of developing guidance on medical technologies that are routed to the Evaluation Pathway Programme for evaluation. A technology routed to a programme at NICE other than the Evaluation Pathway Programme is evaluated according to the processes, methods and timelines of that programme – see the NICE website for more details.
5 How is medical technologies guidance developed?

For further details of how the evaluation pathway develops medical technologies guidance, see the ‘Evaluation Pathway Programme for Medical Technologies methods guide’ (available from www.nice.org.uk/xxxxxx).

5.1 Equality and diversity considerations

The evaluation pathway was developed in accordance with the NICE equality scheme (available from www.nice.org.uk/aboutnice/equalitiescheme). Equality and diversity considerations are taken into account at each stage of the development of medical technologies guidance, including topic selection, scoping, and when the Committee produces draft and final recommendations. The equality and diversity issues raised at each development stage for a topic are recorded in the equality and diversity impact assessment (in accordance with the documented impact assessment procedure. The impact assessment is approved by the programme or centre director and published with the final guidance. Any equality and diversity issues that relate directly to the guidance topic are included in the final guidance itself.

5.2 The scope

After the Committee has selected and routed a medical technology to the evaluation pathway for evaluation, the evaluation pathway team prepares a draft scope. The scope provides the framework for assessing the product, 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 questions about clinical and resource impacts that the evaluation of the technology needs to answer. The scope includes:

- the clinical problem, the populations and any relevant subgroups in which treatment with or use of the technology is being considered
- the clinical setting or situation in which the technology will be used
• the principal health outcome measures appropriate for analysis
• the comparator
• the measures of costs to be assessed
• appropriate approaches to health economics and modelling – normally cost impact modelling of healthcare system resource use and healthcare events avoided
• the length of time over which the benefits and costs are considered
• special considerations and issues that are likely to affect the Committee’s consideration, including equality and diversity issues.

The draft scope is subject to discussion with stakeholders including the manufacturer, and relevant expert and patient advisers. Once the Committee chair and the programme director have agreed the final scope, the medical technology formally becomes part of the Committee’s work programme. At this point, NICE posts on its website that development of medical technologies guidance for a particular technology is in progress.

5.3 The manufacturer's submission

The manufacturer makes a submission to NICE using NICE's submission template. The contents of the submission are based on the scope, which guides the selection of relevant evidence and modelling.

The submission is made in two parts:

• Clinical evidence submission: 2 weeks after the scope is agreed the manufacturer submits all relevant clinical evidence to NICE.
• Cost model submission: 6 weeks after the scope is agreed the manufacturer submits its model of relevant costs.

NICE provides guidance notes for completion of the submission template.

NICE requires manufacturers and sponsors of medical technologies to sign a statement declaring that all material and knowledge relevant to the evaluation of their product has been disclosed to NICE. This includes unpublished data such as register data compiled for regulators or post-marketing surveillance.
To ensure that the process is as transparent as possible, NICE considers it essential that evidence on which the Committee's decisions are based is publicly available. Under exceptional circumstances, unpublished evidence is accepted under agreement of confidentiality and is not made available to the public. Such evidence includes 'commercial-in-confidence' information (for example, the findings of a research project defined as 'confidential' because its public disclosure could have an impact on the commercial interests of a particular company) and certain data that are awaiting publication ('academic-in-confidence').

If a manufacturer considers that unpublished data should be marked as either 'commercial-in-confidence' or 'academic-in-confidence', the rationale for doing so should be clearly stated and should be consistent with the following principles:

- Information and data that are in the public domain anywhere in the world cannot be marked as 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 the trial, a structured abstract should be made available for disclosure, as a minimum.

NICE will ask manufacturers to reconsider restrictions on release of data either if there appears to be no obvious reason for the restrictions, or if such restrictions would make it difficult or impossible for NICE to show the evidential basis for its guidance.

5.4 **Assessment report**

The external assessment centre reviews the manufacturer's submission and prepares an assessment report to the technical standard required by NICE.

The assessment report reviews and critically evaluates both the clinical evidence and cost model elements of the manufacturer's submission. Exceptionally, if the external assessment centre considers that the manufacturer's submission does not adequately address the issues in the
scope, the centre may suggest to NICE that additional analysis should be undertaken. In these circumstances the additional analysis is carried out by the external assessment centre and forms part of the assessment report. If changes are made to the submitted cost model, the external assessment centre includes technical details of these amendments, and their impact, in the assessment report.

The external assessment centre approaches NICE's expert advisers for the technology under consideration if they need advice when preparing the assessment report.

External assessment centres are asked to declare conflicts of interest in line with NICE's code of practice on declaring and dealing with conflicts of interest (available from www.nice.org.uk/aboutnice/codeofpractice).

5.5 Contributions from expert advisers

NICE seeks advice from expert advisers (see section 3.7) on each technology before the Committee considers it. New medical technologies often have potential benefits and risks that are not yet fully described in the scientific literature. Expert advisers provide insight into these issues, supported by accounts of their clinical or technical experience, which complement the published evidence, particularly when this is limited.

Expert advisers complete a standard questionnaire. NICE sends copies of the completed questionnaires to the professional body that nominated or ratified each expert adviser. Completed questionnaires are also available on written request, in accordance with the provisions of the Freedom of Information Act 2000 from NICE.

The Committee chair and the evaluation pathway team review the completed questionnaires and may select suitable expert advisers to advise the Committee, in person, when the Committee meets to develop its draft recommendations.

Expert advisers are asked to declare conflicts of interest in line with NICE's code of practice on declaring and dealing with conflicts of interest (available from www.nice.org.uk/aboutnice/codeofpractice).
from www.nice.org.uk/aboutnice/codeofpractice). These are presented to the chair and the Committee when the questionnaires are considered, and when expert advisers attend meetings to advise the Committee.

5.6 Contributions from patient advisers

When the Committee first considers a technology to determine its selection and routing it decides if further detailed information is required from patient organisations, for example an insight into living with the condition to which the technology relates or the use of the technology and/or comparator technologies. The PPIP approaches patient organisations and requests this information. If the Committee does not identify any specific questions or issues, a standard list of questions is used. All the information the PPIP receives from patient organisations is presented to the Committee when it meets to develop its draft recommendations on a technology.

5.7 Meeting to develop draft guidance

The Committee meets to develop draft recommendations on the technology under evaluation. It considers:

- the assessment report and the manufacturer's submission
- a brief assessment report summary, prepared by the technical analyst, highlighting significant findings of the assessment report. This may include key features of the evidence base and the cost model, any remaining uncertainties and the need for further research, if appropriate
- the opinions of the expert advisers (see section 5.5)
- important outcomes reported by patient advisers, not identified in the literature or by the expert advisers (see section 5.6).

These meetings are open to members of the public and press. This supports NICE's commitment to openness and transparency. It allows stakeholders and the public to understand how evidence is assessed and interpreted and how consultation comments are taken into account.

The Committee considers the evidence and commentary on the technology during the public session, but does not discuss confidential information in this
section of the meeting. Expert advisers, the external assessment centre and manufacturer’s representatives respond to questions from the Committee and provide clarification.

The second part of the meeting is closed to members of the public and press. Expert advisers and manufacturer’s representatives participating in part one of the meeting also leave the proceedings at this point. During the closed session, the Committee considers any commercial- or academic-in-confidence information. It then agrees its recommendations on the technology.

There may be occasions when a meeting will be entirely open or entirely closed. This decision will be made by the Committee chair and programme director.

5.8 Technologies not within the remit of the Evaluation Pathway Programme

There may be occasions when the evidence on a particular technology, contrary to the Committee’s expectation at routing stage, does not fall within the remit of the Evaluation Pathway Programme, and is therefore not suitable for development of medical technologies guidance. This could be, for example, if the technology benefits patients but at an additional cost that is not offset by the release of NHS resources. In these circumstances NICE may suspend the development of guidance or re-route the technology to another NICE programme for evaluation.

5.9 The medical technologies draft guidance document

When the Committee has made draft recommendations, NICE issues a medical technologies draft guidance document. This includes:

- the draft recommendations
- a brief description of the technology, the indications for which it is normally used and its intended benefits
- a summary of the evidence considered by the Committee, including advice from expert and patient advisers
• the issues the Committee took into account when it developed its recommendations
• information about the implementation support tools that may be available for the guidance
• research recommendations
• related NICE guidance that has been published or is in development
• the date when the guidance will be reviewed.

5.10 Consultation

NICE informs the following groups when consultation will start and where they can find the draft guidance document on the website:

• National patient organisations
• Relevant medical device manufacturers: members of the Association of British Healthcare Industries (ABHI) and the British In Vitro Diagnostics Association (BIVDA). NICE also advertises regularly in trade publications to alert manufacturers to forthcoming consultations.
• Professional bodies: relevant expert advisers, their professional bodies and professional bodies whose members might use the technology.
• The manufacturer of the technology that is the subject of the draft guidance (or the person or organisation that notified the technology if this was not the manufacturer).

In addition, all interested parties who have registered on the website receive an automatic email alert when consultation starts (see section 3.11).

NICE publishes the medical technologies consultation document on its website, along with the assessment report, the assessment report summary and evidence from expert advisers for the 4-week consultation period. Anyone may submit comments via the website, by email, fax or post. Comments of more than 20 pages are not normally permitted; this may be waived in exceptional circumstances at NICE’s discretion. If a comment is longer than 10 pages, it should contain a summary no longer than 1 page.
NICE is committed to promoting the values of equality and diversity through its guidance, and to eliminating discrimination. NICE encourages comments from all sectors of the community, highlighting any ways in which draft guidance fails to promote equality or avoid discrimination, and how it might be improved. The Committee particularly welcomes comments on the following:

- draft recommendations
- factual inaccuracies
- additional relevant evidence, with bibliographic references if possible
- views of patients, their parents or carers and patient organisations on how well the technology works, including benefits or risks to the patient that were overlooked.

All comments are important and potentially influential in developing the guidance, including those that entirely support the draft recommendations.

Only people who comment during consultation can be involved in the resolution process (see section 6.2).

### 5.11 Final guidance

After the consultation period ends, NICE collates the comments and presents them to the Committee. NICE cannot accept comments received after the consultation period.

The Committee meets again to discuss whether to amend its draft guidance in view of the consultation comments. If the Committee’s recommendations change significantly after consultation (for example, if important new evidence emerges during the consultation period), it is normally appropriate to reissue the recommendations for a further public consultation. The programme director makes this decision in consultation with the chair.

The Committee agrees the final guidance and NICE’s Guidance Executive approves it before publication.
6 Resolution

The resolution process is a final quality-assurance step to ensure that NICE acts fairly, follows its own processes and produces clear, accurate guidance. It prevents the inadvertent publication of guidance that contains factual errors or is developed other than in accordance with this document.

The resolution process takes place after NICE's Guidance Executive has approved the guidance for publication and before it is published. If NICE receives a resolution request, it suspends publishing the guidance while it investigates the request. If NICE does not receive a request, the guidance is published as soon as possible after the resolution period ends.

The resolution process applies only to the guidance. It does not apply to the Committee's decisions about selecting technologies for evaluation.

6.1 Resolution grounds

The resolution panel (see section 6.5) only considers resolution requests that clearly meet one or both of the following grounds:

Ground 1: breach of NICE's published process for the development of medical technologies guidance.

Examples include failure to refer relevant new evidence to the Committee or a breach of published timelines.

Ground 2: factual errors in the proposed guidance

For example, an objective error of material fact in the final guidance. It does not include disagreements about scientific or clinical interpretation or judgement, whether this refers to the appropriateness of the recommendations or to the weight given to one piece of research or evidence over another. For example, if a consultee argues that a statistic quoted in the guidance is incorrect, NICE establishes whether the final guidance misquoted the statistic or whether there was more than one piece of evidence available, with one being preferred because the Committee considered it to be more
reliable. If it is the latter, there is no factual error, but a difference of scientific or clinical judgement.

6.2 **Eligibility to make a resolution request**

After the Guidance Executive approves the guidance for publication, NICE sends an email to all consultees who responded to the draft guidance and completed a confidentiality form before the resolution process starts. NICE gives consultees access to the prepublication final guidance document and the anonymised consultation comments, with NICE’s responses. This enables consultees to identify errors or breaches of process before publication.

It is important that any organisation or person who may wish to make a resolution request submits a consultation response at the appropriate time. However, they should bear in mind that the prepublication guidance may have changed significantly from the consultation document because of comments received during consultation and considered by the Committee when formulating its final guidance.

6.3 **Resolution requests**

People and organisations have 15 working days after the email alert to request resolution on one or both of the grounds given above. NICE accepts requests by email, fax or letter addressed to the Associate Director of the Evaluation Pathway Programme. Those making requests should specify the resolution they seek. NICE can then fully understand the nature of their concern and take appropriate action if there has been a breach of process or there is a factual inaccuracy in the guidance.

Occasionally questions of factual accuracy are raised after resolution has ended or after medical technologies guidance has been published. In such circumstances the evaluation pathway team investigates these factual inaccuracies and may amend the NICE website and/or the guidance itself if necessary.
6.4 Initial scrutiny of resolution requests

All resolution requests are subject to an initial scrutiny process. The associate director investigates the matters raised and reports the findings to the centre or programme director, who decides whether the request falls within the scope of the resolution process. Initial scrutiny continues for 15 working days after resolution ends.

Ground 1: breach of process

If the centre or programme director considers that the resolution request does not meet ground 1 (breach of process), or does not have a reasonable prospect of success, the associate director informs the person or organisation who made the request and NICE publishes the guidance. If the centre or programme director considers that ground 1 appears to have been met, the associate director convenes the resolution panel (see section 6.5).

Ground 2: factual errors

If the centre or programme director considers that the resolution request does not meet ground 2 (factual errors), or does not have a reasonable prospect of success, the associate director informs the person or organisation who made the request and NICE publishes the guidance.

If the centre or programme director considers the guidance contains a minor factual error or a point that requires clarification, the guidance is amended and signed off by the Committee chair, without being referred to the resolution panel. Such an error or point of clarification would not have impacted on the Committee’s recommendations (for example, a minor amendment to describing the way in which the technology is used). NICE then publishes the guidance.

If the centre or programme director considers that there is a major factual error (for example, if a consultee challenges the contents of the guidance that cannot be remedied by minor amendment), the associate director convenes the resolution panel.
Sometimes more than one resolution request is received for a piece of guidance, but not all requests are referred to the panel. In such cases NICE informs the consultees whose requests are not referred to the panel that the panel is to convene, and NICE will tell them the outcome of their request after the panel's decision is made. This is to avoid pre-empting the outcome of resolution.

6.5 The resolution panel

The panel consists of two NICE board members (a non-executive director and an executive director not previously involved in developing guidance on the technology). The panel decides whether there has been a breach of process or factual error, and if so, what action is appropriate.

6.5.1 Meeting

The associate director organises the resolution panel meeting, which takes place within 20 working days after the initial scrutiny process has ended.

The evaluation pathway team prepares a briefing, which the panel uses when considering the resolution request. For ground 1, this means establishing what process was followed when developing the guidance and what events or omissions were alleged in the resolution request. In the case of ground 2, this involves setting out what evidence lies behind the alleged errors.

The Committee chair and the associate director attend the meeting to provide clarification if required. The Committee chair is not a member of the panel and does not contribute to the outcome of the resolution. Members of the evaluation pathway team may also need to attend to answer questions.

6.5.2 The outcome

Ground 1: breach of process

The resolution panel will either decide that there has not been a breach of process and that NICE can go ahead and publish the guidance, or that there has been a breach of process, in which case the panel must decide what action is appropriate. This is likely to mean repeating part of the assessment.
process, and if necessary, referral back to the Committee and/or another consultation.

**Ground 2: factual errors**

The resolution panel will either decide that there are no factual errors and that NICE can publish the guidance, or that there are factual errors (or elements to be clarified), in which case NICE will produce an amended version of the guidance. The panel must decide whether the error can simply be corrected and the amended guidance approved by the Guidance Executive before publication or whether the Committee should review the amended guidance wording in light of the error identified.

NICE will consider whether to publish the amended guidance or whether there is a need for further consultation. This need would normally arise if:

- NICE makes a substantive change to recommendation wording
- changes to the guidance not involving the recommendations are significant or likely to be of interest to consultees.

The associate director implements the panel's decision and informs the consultee who made the resolution request, and all other consultees who made a resolution request on that technology, of the outcome of resolution. This normally occurs 2 days before NICE publishes the guidance, although this timescale does not apply if the Committee needs to reconsider the guidance.

The resolution panel's decision is final in terms of NICE's processes.
7 Publishing the medical technologies guidance

Guidance on the technology is published on the NICE website, and relevant healthcare professionals are notified. Those who register an interest in the technology are informed electronically.

The following documents are available when medical technologies guidance is published:

- **Medical technologies guidance document.**
- Assessment report and assessment report summary, updated to include any new evidence emerging in the interim.
- Manufacturer’s submission, with confidential information removed.
- Anonymised consultation comments and NICE’s responses.
- Implementation support tools (within 3 months of publication).
- Information for patients (if appropriate).

The implementation team produces support tools that are published during the 3 months after guidance publication. These tools help the NHS to implement NICE's medical technologies guidance and may include audit support, costing tools, slide sets or bespoke products.
8 Reviews

If NICE publishes a recommendation for research for a technology, the guidance is reviewed when relevant new evidence is available.

If NICE publishes positive recommendations for a technology with no research recommendations, the guidance is reviewed only if NICE hears of a significant change in the evidence base that might affect the recommendations.

The NICE Guidance Executive receives and approves review proposals for guidance.

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.
9 Updating the process guide

NICE will review and update this document in Month 201X (3 years after its publication). It may be necessary to make minor changes to the process of developing medical technologies guidance before that time. Changes to the process 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 3 months’ public consultation.
10 More information

More information about the Evaluation Pathway Programme for Medical Technologies and the work of the Medical Technologies Advisory Committee can be found on the NICE website (www.nice.org.uk/xx). This includes:

- a link to the Evaluation Pathway Programme for Medical Technologies methods guide
- a list of expert advisers
- a list of Committee members
- minutes of Committee meetings
- frequently asked questions and answers about the evaluation pathway.
Appendix A: Glossary

**CE mark** The CE mark is a mandatory conformity mark on medical device products placed on the single market in the European Economic Area. The CE mark certifies that a product has met EU consumer safety, health or environmental requirements.

**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 an organisation that submits a comment during consultation.

**Guidance Executive** A team comprising the Executive Directors and Centre Directors at NICE who are responsible for approving the final guidance before publication.

**Medical technologies consultation document** Sets out the Committee’s draft recommendations to NICE.

**Medical technologies guidance document** Sets out the Committee’s final recommendations to NICE on the use of the technology in the NHS.

**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.
Appendix B: Eligibility criteria

Medical technologies that meet the following criteria are presented to the Committee for review and prioritisation. Information about a technology may evolve, and a rejected technology may be revisited if subsequent evidence of potential benefit emerges.

Table 3 Eligibility criteria

<table>
<thead>
<tr>
<th>Eligibility criterion</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriate timing</td>
<td>The technology has a CE mark or equivalent regulatory approval, or this is expected within the next 2 years. The technology sponsor has plans for the launch of the technology in the NHS.</td>
</tr>
<tr>
<td>Within remit of a NICE evaluation programme and not currently being evaluated</td>
<td>The technology is within the remit of the Evaluation Pathway Programme or of another NICE programme. NICE is not producing guidance for this technology within any other NICE programme. The technology is not the subject of research under a national organisation such as the National Institute for Health Research (NIHR), that might mean an evaluation by NICE is inappropriate at the time. A national organisation such as the Health Protection Agency (HPA) is not evaluating the technology.</td>
</tr>
<tr>
<td>A new technology or modification to an existing technology</td>
<td>The technology is either new or it is a modification of an existing technology with claimed benefits to patients or the NHS.</td>
</tr>
</tbody>
</table>