NICE National Institute for Health and Care Excellence

Medical technologies evaluation programme process guide

Process and methods

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Contents

This corporate should be read in conjunction with PMG33.

1 Introduction

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

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

Table 1 Definitions of medical technologies for the programme

Term	Definition	Source

Medical device	'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.
Active medical device	'Any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.'	Council of the European Communities (1990) Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC).

Active implantable medical device	'Any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.'	Council of the European Communities (1990) Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC).
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 subset of medical technologies.

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

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

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

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

2 The medical technologies evaluation programme

2.1 Aims

MTEP aims to:

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

2.2 Main activities

MTEP's main activities and responsibilities are:

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

2.3 Key audiences

Medical technologies guidance is designed for several main audiences:

- Practitioners, including clinicians, who use medical technologies in clinical or research settings.
- NHS and social care commissioners (such as when specifying services incorporating use of medical technologies).
- Healthcare operational and planning managers in primary and secondary care provider organisations, 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 who may be affected by the technology.

3 Who is involved in the medical technologies evaluation programme

3.1 The MTEP team

MTEP is part of NICE's Centre for Health Technology Evaluation. The programme team consists of the associate director and technical, project management and administrative staff who support the committee in developing medical technologies guidance. The main tasks of the team are:

- assess notified technologies against the eligibility criteria
- prepare topic briefings used by the topic oversight group during selection and routing
- produce medtech innovation briefings (MIBs).

For all technologies that are routed to the committee for evaluation, the team will:

- prepare scopes
- commission external assessment centres to assess evidence
- prepare overviews of the assessment reports, and additional analyses and evidence if needed
- arrange public consultation on the committee's draft recommendations
- draft the final guidance
- ensure that agreed timelines and quality assurance processes are followed.

3.2 Editors

NICE editors review the draft and final guidance, making changes for consistency, accuracy and plain English. The editors also provide a lay explanation of the recommendations and the rationale behind them ('information for the public') and prepare the final guidance for publication.

3.3 Adoption support

NICE provides advice and tools to support the local implementation of its guidance. In general, the adoption support team:

- ensures intelligent dissemination to the appropriate target audiences

- actively engages with the health and social care system, local government and the wider community
- works nationally to encourage a supportive environment
- provides tools to support putting NICE guidance into practice
- demonstrates significant costs or savings at local and national levels
- evaluates uptake of NICE guidance
- shares learning
- develops educational material to raise awareness of NICE guidance and encourages people to contribute to its development.

NICE may develop adoption support tools depending on the needs identified for the individual technology. These tools are developed with advice from expert advisers, patient and carer organisations, the sponsor and committee members, as appropriate.

3.4 Guidance information services

The guidance information services team searches for information and evidence from conventional sources and 'grey' literature. This MTEP team then uses this information to inform topic briefings for the topic oversight group.

3.5 Public involvement programme

The public involvement programme recruits and supports lay members of the committee, identifies patient and carer organisations (see section 3.9), encourages members of the public and patient organisations to contribute during consultation, and establishes links with patient organisations with an interest in medical technologies guidance. NICE uses the terms 'patient organisation' and 'patient group' when referring to patients, carers, and community and other lay organisations and charities, including those representing people from groups protected by equalities legislation.

3.6 Topic oversight group

The topic oversight group comprises representatives from the related NICE guidance programmes, NICE advisory committees, external stakeholders and other programme team members.

The group has 2 functions:

- to assess notified medical technologies and determine if the team should produce a topic briefing on the technology and/or a medtech innovation briefing
- to review topic briefings, determine if the technologies are suitable for evaluation, and route them to the appropriate NICE programme.

3.7 Medical technologies advisory committee

The committee is an independent standing committee with a range of expertise. It comprises clinicians who develop and use medical technologies, scientists, people who can provide a lay perspective on the issues affecting patients and the health and social care system, experts in regulation and the evaluation of healthcare, and people with experience of the medical technologies industry.

The committee normally meets monthly in public. Agendas and minutes of committee meetings are published on the NICE website. The minutes record only what was discussed by whom and in what order; they do not record the committee's draft recommendations. Committee members must declare any conflicts of interest in line with the NICE policy on conflicts of interest.

3.7.1 The role of the committee

The committee is responsible for making recommendations for the use of medical technologies including, if appropriate, recommendations for further research.

3.7.2 How committee members are appointed

Committee members are recruited in accordance with the NICE recruitment and selection to advisory bodies policy and procedure.

3.8 Expert advisers

Expert advisers are usually healthcare professionals or technical specialists who use the medical technology in a clinical or research setting or have experience of the condition and the related clinical pathway.

3.8.1 The role of expert advisers

NICE seeks advice from expert advisers on each technology. Expert advisers provide advice about technologies which complements clinical evidence and findings from research. New 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 may not be familiar with the technology, in which case they provide advice and opinion based on their clinical or technical experience, and insights into the potential usefulness of the technology in the relevant care pathway.

Expert advisers may be asked to give advice on:

- the validity of the notification and whether the technology is relevant to the health and social care system
- the topic briefing
- the scope
- the assessment report
- adoption support tools, such as costing tools and audit tools (see section 7)
- any potential equality issues in relation to the technology.

Expert advisers are asked to declare conflicts of interest in line with the NICE policy on conflicts of interest. These are presented to the topic oversight group and the committee when topics are considered.

Experts who meet one or more of the criteria below are not eligible to advise the programme:

- a doctor who is under investigation by the General Medical Council, and who has had interim restrictions placed on their practice, or who has been removed from the Medical Register
- other professionals who are under investigation for professional misconduct, or who have been found to be in breach of appropriate professional standards by the relevant professional body
- anyone who has received a prison sentence or a suspended sentence of 3 months or more in the last 5 years
- anyone who has retired from clinical practice.

During topic selection, expert advisers complete a questionnaire about the topic and/or comment on the topic briefing. On request, NICE sends copies of the completed questionnaires to the professional body that nominated or ratified each expert adviser. Completed questionnaires are

also available from NICE on written request, in accordance with the provisions of the Freedom of Information Act 2000.

During the evaluation itself, the MTEP team decides if the expert advisers identified at the topic selection stage still to have relevant experience and expertise. Any who do are invited to comment on the scope and to provide written comments to the committee during the evaluation. If additional expert advisers are needed to ensure an appropriate balance between knowledge of the technology and knowledge of the care pathway, they are selected in the same way during topic selection.

3.8.2 Identifying expert advisers

During topic selection, expert advisers are identified in several ways:

- NICE asks professional bodies (including Royal Colleges, specialist societies and other professional associations) to nominate them.
- NICE identifies them on a topic basis from NICE's existing pool of expert advisers, all of whom have been ratified by their professional body.
- Current expert advisers may recommend others with relevant knowledge; expert advisers identified in this way are ratified by their professional body.
- The sponsor 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 welcomes expert advisers from all sectors of the community.

3.9 Patients and carers

NICE asks patient and carer organisations to provide information about living with the condition to which the technology relates, about any patients who may need special consideration, and about using the technology and/or comparator technologies. Patient and carer organisations can provide insight into outcomes and describe ease of use, discomfort, effect on diverse activities and other aspects of quality of life. This information is included in the topic briefing considered by the topic oversight group.

3.10 External assessment centres

NICE commissions external assessment centres from a range of organisations, including the health and social care system and academic bodies. These centres are chosen by public tender and must meet quality control requirements. The centres provide independent assessments of the evidence and produce assessment reports for the committee (section 5.5). The centres have knowledge of and expertise in appropriate methods of evaluation.

3.11 Sponsors

Normally, sponsors of medical technologies notify technologies to NICE for evaluation. They should provide sufficient information for the topic oversight group to decide whether or not to select the product for evaluation.

If the technology is selected for guidance development, the sponsor provides a clinical and economic evidence submission, based on the scope, which includes relevant cost modelling (section 5.4). This may be based on published or unpublished data, including confidential data prepared for regulatory purposes.

The sponsor has the opportunity to comment on the draft scope, comment on the committee's draft recommendations during consultation, and to request clarification during resolution (section 6).

3.12 Stakeholders

NICE encourages interested parties (people and organisations) to register as a stakeholder in a technology through the NICE website. Registered stakeholders can register at any time during the course of an evaluation. NICE sends electronic updates to registered stakeholders throughout the evaluation. These updates are triggered by changes to the website page for the technology (for example, when consultation begins).

The programme team notifies relevant professional bodies and relevant patient and carer organisations when a technology that may be of interest to them is first mentioned on the website. Registered stakeholders are invited to comment on the draft scope.

3.13 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. If attendance at any meeting is oversubscribed, NICE selects attendees according to its allocation procedure. To allow wide public access, NICE reserves the right to limit attendees to 1 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 Identifying, selecting and routing technologies for evaluation

4.1 How NICE becomes aware of new medical technologies

4.1.1 Notifications from sponsors

Sponsors notify technologies to the programme team at medtech@nice.org.uk.

The programme team first considers notified medical technologies using the following eligibility criteria (see appendix B for details):

- They have a CE mark or equivalent regulatory approval, or this is expected within 1 year.
- The topic is within the remit of a NICE evaluation programme, and is not currently being evaluated.
- The technology is either new or an innovative modification of an existing technology, with claimed benefits for patients or healthcare systems.

NICE asks sponsors of medical technologies that meet the eligibility criteria to provide additional information to be used in the topic briefing.

NICE informs sponsors if medical technologies do not meet the eligibility criteria or if they are not suitable for consideration for guidance. Sponsors may re-notify NICE about medical technologies even if they have previously been assessed as ineligible. However, sponsors are encouraged to discuss this with NICE in advance because technologies need to have changed in such a way that they meet the eligibility criteria.

4.1.2 Other sources of information on new medical technologies

NICE uses a variety of sources to identify topics including NHS England, horizon scanning organisations, and health and care organisations involved in promoting innovation. The programme contacts sponsors to request further information on technologies of interest.

4.2 Selecting topics

Selection is the process by which NICE identifies and decides which medical technologies should be evaluated. Because the number of technologies that can be evaluated at 1 time is limited, the topic oversight group selects technologies that are likely to have the most benefit to patients and the health and social care system.

Sponsors of eligible technologies are asked to provide information on the technology, including its uses, costs, sources of evidence and benefits. The benefits should include either or both:

- benefit to patients (measurable benefit to patients compared with currently available technologies)
- benefit to the health and social care system (adopting the medical technology is likely to reduce the burden on health and social care system staff or reduce resource use).

4.2.1 Topic briefings

The programme team prepares topic briefings for the topic oversight group. These are composed of:

- information provided by the sponsor (in particular the claimed benefits)
- input from the expert advisers
- input from the relevant patient and carer organisations information relating to potential equality considerations (section 5.1)

The sponsor checks the draft topic briefing for accuracy.

4.3 Routing topics

Having reviewed the topic briefing and selected the technology for evaluation, the topic oversight group routes the topic to the most appropriate NICE programme (or other national evaluation programme) using the criteria in appendix D. These criteria are based on the published remits for the programmes.

4.3.1 Routing to the medical technologies evaluation programme

In summary, the criteria for routing a technology to MTEP are:

- it is likely to be cost saving or cost neutral
- it can be evaluated as a single technology
- it can be evaluated on a short timescale.

4.3.2 Routing to the diagnostics assessment programme

In summary, the criteria for routing a technology to the diagnostics assessment programme are:

- it is likely to result in an overall increase in resource costs to the health and social care system
- it can be evaluated as 1 of a class of similar technologies or as a single technology
- it can only be evaluated using clinical and cost utility.

4.3.3 Routing to any other NICE programme

A technology routed to any other NICE programme is considered for evaluation and evaluated according to the processes, methods and timelines of that programme.

4.4 Information published about eligible and selected technologies

The following information is published on the NICE website:

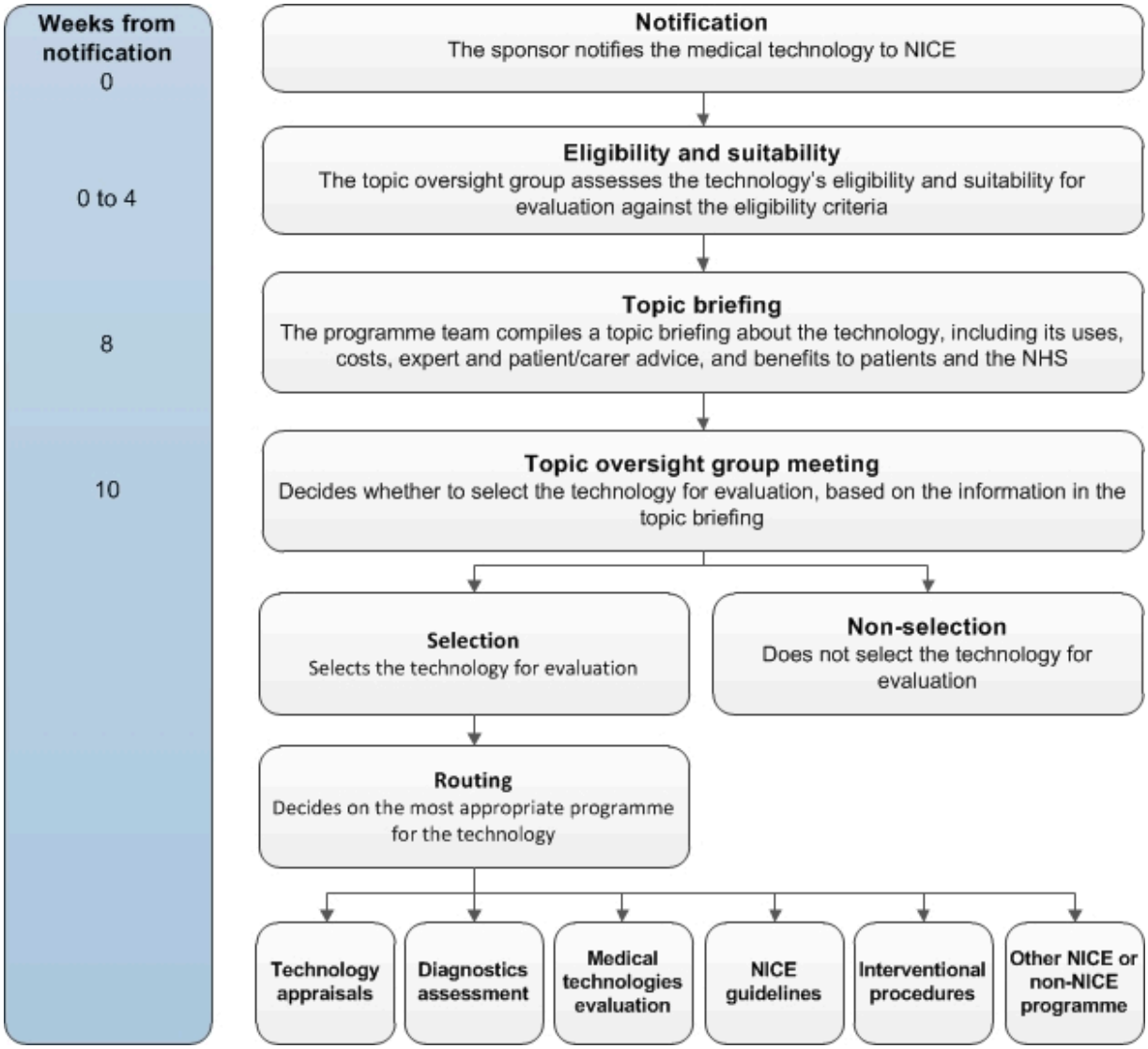
- Topics selected for evaluation by MTEP, including information about each technology and links to the evaluation documents.
- Topics selected for evaluation by another NICE guidance programme, including information about their guidance development.
- Eligible topics that are not selected for evaluation.

No information is published about topics notified to MTEP that are not considered for selection.

4.5 Timeline

NICE needs to collect sufficient information on individual technologies to select and route them correctly. Figure 1 indicates the timelines for selection and routing.

Figure 1 The selection and routing process



5 How medical technologies guidance is developed

For information on the technical assessment of medical technologies, please refer to the MTEP methods guide.

5.1 Agreement of evaluation schedule

Once a topic is selected for evaluation, NICE schedules the evaluation. If the sponsor does not consider the timing to be appropriate, NICE is not able to guarantee when the evaluation will start.

5.2 Scope

The scope is the first document to be produced after the topic oversight group has selected a technology for consideration. It provides the framework for assessing the technology, taking into account how it works, its comparator(s), the relevant patient population(s), and its effect on clinical and system outcomes. The scope is based on the sponsor's case for adoption. For further information, see the MTEP methods guide.

Once the start date for the evaluation has been agreed, the programme team prepares a draft scope. The scope is intended to define the most important questions about clinical and resource impacts. It sets the boundaries for assessing the evidence and for 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 TOG'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 TOG 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.

MTEP then makes the draft scope available for comment, and invites contributions from within 5 working days from the sponsor, the expert adviser(s), relevant patient and carer organisations, professional societies and other registered stakeholders. An interest can be registered at any time after the selection decision is published (section 4.4). The committee chair reviews the comments and agrees changes to the scope as appropriate. The chair and the programme director then agree the final scope before it is published on the NICE website. Once the scope if published, the medical technology formally becomes part of the committee's work programme and the website records that guidance development for this technology is in progress.

5.3 Equality considerations

MTEP was developed in accordance with the NICE equality scheme. At specific stages of guidance development the committee considers how medical technologies guidance may affect equality, including scoping and during its draft and final recommendations. Any potential equality issues raised and considered for a topic are recorded in an equality impact assessment. The programme or centre director approves the equality impact assessment and it is 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.

5.4 Sponsor's submission

The sponsor makes a submission to NICE using the template and guidance notes. The contents are based on the scope, which guides the selection of relevant clinical and economic evidence and analysis.

The submission is made in 2 parts:

- Clinical evidence submission. This is submitted within 2 weeks of the scope being published, and includes all relevant clinical evidence and the decision problem.
- Economic evidence submission with cost model. This is submitted within 6 weeks of the scope being published, and includes all relevant economic evidence with a model of relevant costs.

If the sponsor has developed an economic model, it must submit a fully executable electronic copy of the model to NICE with full access to the programming code. The submitted versions of the model and the written content of the evidence submission must match. NICE accepts executable

economic models using standard software, specifically Excel, TreeAge Pro, R or WinBUGs. If the sponsor plans to submit a model in a non-standard package, it must inform NICE in advance. NICE and the external assessment centre will investigate whether the requested software is acceptable, and establish if either NICE or the external assessment centre need temporary licences for the non-standard software for the length of the assessment. NICE reserves the right to reject economic models in non-standard software.

Sponsors must 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. If the company is not the data owner (for example, register data), it should provide NICE with enough information for it to identify all relevant data owners.

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

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

- Information and data that have been made publicly available anywhere 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.

5.5 Assessment report

The external assessment centre reviews the sponsor's submission and prepares an assessment report.

The assessment report reviews and critically evaluates the sponsor's clinical and economic evidence and cost model. In some rare cases, if the external assessment centre considers that the sponsor's submission does not adequately address the issues in the scope, the centre may suggest to the MTEP team that further analyses should be done; these may include a new cost model. In these circumstances the additional analysis is usually done by the external assessment centre, as directed by the programme team, 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.

If necessary, the external assessment centre will approach experts in the technology when preparing the assessment report. These experts are listed in the report. The external assessment centre may also ask the sponsor questions when preparing the assessment report. The sponsor has the opportunity to review the report for factual accuracy.

External assessment centres are asked to declare conflicts of interest in line with the NICE policy on conflicts of interest.

5.6 Contributions from expert advisers

Depending on the scope and the characteristics of the technology, 1 or more expert advisers (see section 3.7) advise the committee, in person or by telephone, when the committee meets to develop its draft and final recommendations. The MTEP team produces a summary of their advice which is published alongside the draft and final guidance.

5.7 Contributions from patient and carer organisations

The public involvement programme always approaches patient and carer organisations to obtain their views on the technology. The committee may identify a need for detailed information from patient organisations or individual patients and carers (for example, an insight into living with the condition to which the technology relates or the use of the technology and/or comparator technologies). If the committee does not identify any specific questions or issues, a standard list of questions is used. The programmes presents all the information it has from patient and carer organisations to the committee when it meets to develop its draft recommendations on a technology.

5.8 Developing draft recommendations

The committee meets to develop draft recommendations on the technology under evaluation. It

considers:

- The assessment report and the sponsor's submission.
- An overviewof the assessment report, prepared by the MTEP team. This may include the main features of the evidence base and the cost model, any additional analyses done, important uncertainties and the main issues the committee may wish to discuss (as well as the need for further research, if appropriate; see the MTEP methods guide for more details).
- The contributions of the expert advisers
- Important outcomes reported by patient and carer organisations, including outcomes not identified in the literature or by the expert advisers.

The committee meets in public, in line with NICE's commitment to openness and transparency. This allows stakeholders and the public to understand how evidence is assessed and interpreted.

In the public part of the meeting (part 1), the committee considers the evidence and commentary on the technology and invites expert advisers, the external assessment centre and the sponsor's representatives to respond to questions from the committee and provide clarification.

In the private part of the meeting (part 2), the committee considers any commercial-in-confidence or academic-in-confidence information and agrees its recommendations for use of the technology. The chair may ask the specific representatives to remain for some of part 2, specifically to respond to questions about confidential information in the submission. Otherwise part 2 of the meeting is closed to the public, including the expert advisers and the sponsor's representatives.

On occasion a meeting may be entirely public or entirely private (public if there is no confidential information and the committee is not making any decisions, and private if all the content of the meeting is confidential). This decision is made by the committee chair and the programme director and is published on the NICE website.

5.9 Draft guidance

When the committee has made draft recommendations, NICE issues a medical technology consultation document. This includes:

- the draft recommendations
- a brief description of the technology, the indications under review and its intended benefits

- a summary of the evidence considered by the committee, including a summary of the advice from expert advisers and patient and carer organisations
- 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.

5.10 Consultation

Any person or organisation may comment on the medical technology consultation document. NICE informs the following groups when consultation starts and where to find the consultation document on the website:

- national patient organisations
- the Association of British Healthcare Industries and the British In Vitro Diagnostics Association, which in turn inform their members
- relevant expert advisers
- professional bodies of the relevant expert advisers, and professional bodies whose members might use the technology
- the sponsor of the technology being evaluated.

In addition, people and organisations who have registered an interest on the website receive an automatic email alert when consultation starts.

NICE publishes the following documents on its website for the 4-week consultation period:

- the medical technology consultation document
- the scope
- the sponsor's submission (with confidential information redacted)
- the assessment report
- the overview

- the names and professional organisations of the expert advisers
- a summary of comments from expert advisers and patient and carer organisations.

NICE makes an executable version of the cost model available to those who register an interest in the topic, on request and with the following conditions:

- NICE releases the model as long as it does not contain information that was designated confidential by the model owner, or the confidential material can be redacted by the model owner without producing severe limitations on the functionality of the model.
- The recipient must sign a confidentiality agreement and is advised that the model is protected by intellectual property rights, and can be used only for the purposes of commenting on the model's reliability and informing comments on the medical technology consultation document. The recipient agrees to these terms in writing before receiving the model.

Anyone may submit comments through the website, by email, fax or post. Comments longer than 20 pages are not normally accepted, other than at NICE's discretion in exceptional circumstances.

NICE is committed to having due regard to the need to eliminate unlawful discrimination and to promote equality, and fostering good relations between people with a characteristic protected by the equalities legislation and others. NICE encourages comments from all sectors of the community and specifically asks if there are any equality-related issues that need special consideration which are not covered in the document.

The committee particularly welcomes the following:

- comments on the draft recommendations
- notification of factual inaccuracies
- additional relevant evidence, with bibliographic references if possible
- views of patients, their 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.

5.11 Final guidance

After the consultation period ends, NICE collates the comments and presents them to the committee. Comments received after the consultation period are only shown to the committee if agreed in advance by the programme director, who consults with the chair and associate director.

The committee meets to discuss whether to amend its draft recommendations in view of the consultation comments. This meeting is held in public on the same basis as the first meeting.

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 consultation document for a further public consultation. The programme director makes this decision in consultation with the committee chair.

The committee agrees the final recommendations and submits them to NICE's guidance executive for approval. After approval, the guidance proceeds to resolution as outlined in section 6.

5.11.1 Late receipt of evidence

In exceptional circumstances (for example, if relevant information is published while the final guidance is being developed or because of comments received during consultation), NICE may choose to do further analyses. The external assessment centre (or another organisation commissioned by NICE) normally carries out these analyses before NICE circulates the final guidance for comment. The centre director makes this decision after discussion with the committee chair and the MTEP team. The decision is not taken lightly and is made to ensure that NICE is able to provide robust guidance to the health and social care system.

NICE reserves the right, while the final guidance is being developed, to refuse to accept evidence presented by the sponsor that could reasonably have been included in the sponsor's original submission.

5.12 Suspending or cancelling an evaluation

Appendix E lists the criteria for suspending or cancelling an evaluation. In summary, the criteria are:

- the sponsor does not bring the product to market or withdraws it
- reports of adverse events emerge

- a technology is not appropriate for medical technologies guidance
- the sponsor does not provide data for the evaluation according to the agreed schedule.

Information that has been made public before the suspension or cancellation decision will remain publicly available on NICE's website.

6 Resolution

The resolution process takes place after the NICE guidance executive has approved the guidance for publication and before it is published. 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 either this document or the programme's methods guide.

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 guidance. Resolution does not apply to the committee's decisions about selecting technologies for evaluation. It also does not apply to the assessment report or other documents produced in the course of developing the guidance, unless the resolution request on these documents is material to the issue regarding the guidance itself.

6.1 Resolution grounds

The resolution panel only considers resolution requests that clearly meet one or both of the following grounds.

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

An example would be when a step is missed in the process.

6.1.2 Ground 2: factual errors in the guidance

A factual error is an objective error of material fact in the final guidance. Conflicting scientific or clinical interpretations or judgements are not considered to be factual errors. For example, if a consultee states that a statistic quoted in the guidance is incorrect, NICE establishes whether the final guidance misquoted the statistic, or if 1 statistic was preferred out of several because the committee considered it to be more reliable. The former is a factual error; the latter is 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 emails all consultees who

responded to the draft guidance. It is important that any organisation or person who may wish to make a resolution request submits a consultation response at the appropriate time. They should bear in mind that the 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

Consultees have 15 working days after the email alert to request resolution on 1 or both of the grounds in section 6.1. NICE accepts requests by email, fax or letter addressed to the associate director of MTEP. Consultees making requests should specify the resolution they seek. NICE can then fully understand the nature of their concern and take appropriate action.

6.4 Initial scrutiny of resolution requests

All eligible resolution requests are subject to an initial scrutiny process. The associate director investigates the matters raised and reports the findings to the centre director (or their nominated deputy). The centre director decides whether the request falls within the scope of the resolution process. Initial scrutiny continues for 15 working days after the resolution request period ends. If multiple resolution requests are made, either from the same or different consultees, each request is treated as outlined below.

6.4.1 Ground 1: Breach of process

If the centre director considers that the resolution request does not meet ground 1 (breach of process; section 6.1.2), 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 director considers that ground 1 appears to have been met, the associate director convenes the resolution panel.

6.4.2 Ground 2: Factual errors

If the centre director considers that the resolution request does not meet ground 2 (factual errors; section 6.1.3), 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 director considers that the guidance contains a minor factual error or a point that requires clarification but does not affect the committee's recommendation(s), the guidance is amended and signed-off by the committee chair without being referred to the resolution panel. NICE then publishes the guidance in the usual way. If the centre director considers that there is a major factual

error that cannot be remedied by minor amendment, they instruct the associate director to convene the resolution panel.

For multiple resolution requests, not all requests may qualify for referral to the panel. In order to avoid pre-empting the outcome of resolution, NICE informs all consultees that the panel is to be convened, and that NICE will tell them the outcome of their request after the panel's decision is made.

6.5 Resolution panel

The resolution panel comprises 2 NICE board members, 1 non-executive director and 1 executive director not previously involved in developing guidance on the technology. The aim of the panel is to decide whether there has been a breach of process or factual error and, if so, what action is appropriate.

6.5.1 Resolution panel meeting

The associate director organises the resolution panel meeting, which takes place no more than 20 working days after the initial scrutiny process has ended.

The MTEP 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 associate director, and if needed the committee chair and the programme director, attend the meeting to provide clarification. They are not members of the panel and do not contribute to the outcome of the resolution. Members of the MTEP team may also attend the meeting to answer questions.

6.5.2 Resolution outcome

- If the resolution panel decides that there has been no breach of process (ground 1), NICE can publish the guidance. If the panel decides that there has been a breach of process, it decides what action is appropriate. This may involve repeating part of the assessment process and, if necessary, referring the technology back to the committee and/or carrying out another consultation.
- If the resolution panel decides that there are no factual errors (ground 2), NICE can publish the

- guidance. If the panel decides that there are factual errors or elements to be clarified, NICE produces an amended version of the guidance. The panel must decide whether the error can 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 considers whether to publish the amended guidance or whether there is a need for further consultation. This need normally arises if NICE makes a substantive change to the wording of the recommendations, or 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 all consultees who made resolution requests 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 its recommendations.

The resolution panel's decision is final and there are no further opportunities for redress within NICE.

7 Publishing medical technologies guidance

After the resolution process, guidance on the technology is published on the NICE website and any relevant healthcare professionals are notified. People and organisations who registered an interest in the technology are informed by email.

The following documents are available on the NICE website when medical technologies guidance is published:

- medical technology guidance
- scope
- assessment report and overview, updated to include any new evidence emerging in the interim
- sponsor's submission, with confidential information removed
- evidence from expert advisers and patient and carer organisations
- anonymised consultation comments and NICE's responses
- implementation support tools (usually at the same time as the guidance, and within 3 months of publication at the latest)
- a lay explanation of the recommendations.

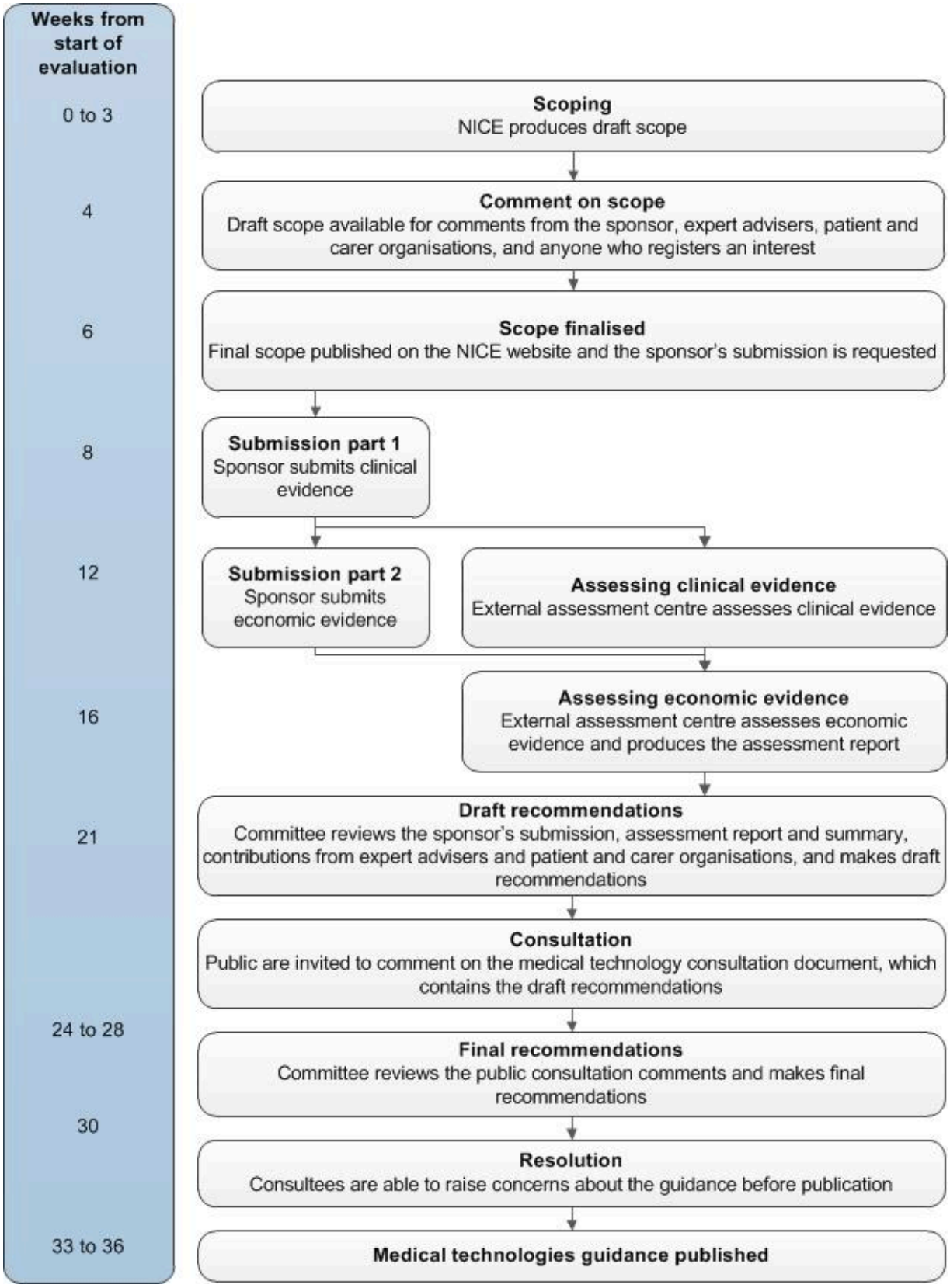
If NICE is advised of any potential errors in the guidance or the supporting documents after publication, these are dealt with according to NICE's standard procedures.

7.1 Timeline

Figure 2 shows the timeline of a medical technology that is selected and routed to the committee for evaluation. Unless an alternative timetable is agreed (section 5.1), technologies are normally evaluated in the order in which they are notified. The timings are approximate and may vary in response to individual evaluation needs.

If a technology is routed to another programme it follows the timelines of the subsequent topic selection steps of that programme.

Figure 2 Summary of the evaluation process



8 Reviews

The review process for published guidance is detailed in the addendum.

9 Updating the process guide

The process guide is subject to the approval of the NICE board and will normally be reviewed 3 years after last publication. It may be necessary to make minor changes to the process of developing medical technologies guidance before that time. Changes to the process guide will be made according to NICE policy. Minor changes that may be made without consultation are those that:

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

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

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

Appendix A: Glossary

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

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

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

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

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

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

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

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

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

technologies.

Discounting

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

Efficacy

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

Equivalence

An assumption that 2 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 or ratified by their professional body to advise the committee and/or topic oversight group about medical technologies about which they have specific knowledge or expertise. Expert advisers may be healthcare professionals with knowledge of using the technology in practice, or medical scientists with technical knowledge.

Guidance executive

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

In confidence

Information (for example the findings of a research project) submitted to the programme that is not in the public domain. 'Commercial-in-confidence' information is defined as confidential because its disclosure could affect the commercial interests of a particular company. 'Academic-in-confidence' information is waiting to be published, and it is confidential because its disclosure could affect the academic interests of a research or professional organisation.

Medical technologies guidance

Guidance produced by the medical technologies advisory committee on technologies that are

routed to it for evaluation.

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

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

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

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

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

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

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

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

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

Topic briefing

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

Topic oversight group
The team which selects and routes medical technologies for guidance development.

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

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

Appendix B: Eligibility criteria

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

Appendix C: Selection criteria used by the topic oversight group

Selection criterion	Detail
Claimed additional benefit to patients	The extent to which a medical technology claims measurable benefit to patients over currently available health and social care system technologies in terms of its impact on quality of life or life expectancy.
Claimed healthcare system benefit	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 that are 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 D: Routing considerations used by the topic oversight group

The topic oversight group applies the selection criteria (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 programme. The considerations the topic oversight group applies in making these routing decisions are based on the remits of the individual programmes and the characteristics of the technologies being routed.

Considerations for routing technologies to the medical technologies evaluation programme

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

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

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

Considerations for routing technologies to the diagnostic assessment programme

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

This programme is likely to be suitable for evaluating diagnostic tests and technologies for which recommendations could only be made on the basis of clinical utility and cost-utility analysis. There

should normally be a 'gold standard' or established comparator to enable an assessment of potential benefit of the technology. This programme can evaluate classes of technologies or individual technologies.

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

Considerations for routing technologies to the interventional procedures programme

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

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

Considerations for routing technologies to the technology appraisals programme

For details of the routing considerations for technology appraisals, see the NICE guide to the processes of technology appraisal.

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

Companion diagnostic technologies with the primary purpose of enhancing the clinical or cost

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

Considerations for routing technologies to the NICE guidelines programme

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

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

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

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

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

Appendix E: Criteria for suspending or cancelling an evaluation

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

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