

Proposed changes to existing programme manuals and interim documents on publication of the update to the NICE HealthTech programme manual

1 August 2025

Interim documents for archiving from NICE website

- [LSA interim process and methods statement](#).
- [Interim addendum on access proposals](#) (PDF only).

Minor amendments to existing programme manuals

Table 1 Minor amendments to existing [NICE health technology evaluations: the manual](#)

Existing wording	Section	Proposed change
DCEAs will not be done in economic evaluations produced by EAGs on behalf of NICE for HealthTech guidance and multiple technology appraisals. For these types of evaluations, DCEA evidence can be provided by companies as part of the information requested on the evidence base and their technology.	4.12.4	Delete words in bold. DCEAs will not be done in economic evaluations produced by EAGs on behalf of NICE for multiple technology appraisals. For these types of evaluations, DCEA evidence can be provided by companies as part of the information requested on the evidence base and their technology.
Patient access schemes, commercial access agreements, managed access proposals and any related process and documents apply to technology appraisals and highly specialised technologies only, unless specifically stated otherwise. For diagnostics guidance please refer to the interim addendum on access proposals.	6.1.14	Delete sentence in bold. Patient access schemes, commercial access agreements, managed access proposals and any related process and documents apply to technology appraisals and highly specialised technologies only, unless specifically stated otherwise.
For medical technologies evaluated through the medical technologies evaluation programme, the concept of a quantitative QALY weight is not	6.2.19	Delete

applicable. The severity of the condition should be considered deliberately within decision making.		
Recommendation with evidence generation (diagnostics guidance and medical technologies guidance only) Title and whole of sections 6.4.12, 6.4.13, 6.4.14, 6.4.15	6.4.12 6.4.13 6.4.14 6.4.15	Delete all 4 sections and title.
Whole row of table: Case is currently not fully supported but the technology has potential to provide significant patient or healthcare system benefits if the uncertainties in the evidence are addressed. Recommended with data collection [Technology] can be used as an option in the NHS during the evidence generation period 6.4.12 to 6.4.15	Table 6.3	Delete whole row of table

Table 2 Minor amendments to existing [NICE HealthTech programme manual](#)

Existing wording	Section	Proposed change
To avoid duplication, this guide refers to the existing evaluation manual (NICE health technology evaluations: the manual) for methods and processes that remain the same. This guide sets out the new approaches in the HealthTech programme including further detail for clarity. Section 1 covers process (except for guidance that focuses on HealthTech products in existing use, which is currently set out in the late-stage assessment (LSA) interim methods and process statement) . Section 2 covers methods (except for guidance that focuses on HealthTech products in existing use, which is currently set out in the LSA interim methods and process statement, and interventional procedures guidance which can currently be found in NICE's interventional procedures programme manual).	Introduction	Delete text in bold. To avoid duplication, this guide refers to the existing evaluation manual (NICE health technology evaluations: the manual) for methods and processes that remain the same. This guide sets out the new approaches in the HealthTech programme including further detail for clarity. Section 1 covers process. Section 2 covers methods (except for interventional procedures guidance which can currently be found in NICE's interventional procedures programme manual).

<p>Interventional procedures guidance</p> <p>Interventional procedures involve making an incision, a puncture or entry into a body cavity, or using ionising, electromagnetic or acoustic energy.</p> <p>Recommendations are made based on assessment of the efficacy and safety of new, significantly modified or established procedures. Although some interventional procedures can involve implanting or using a health technology, the guidance and recommendations are about the procedure.</p>	<p>Introduction</p>	<p>Some text from the Introduction (section 1) and Remit of the programme (section 3) sections of the Interventional procedures programme manual (PMG28) to be moved the introduction section for clarity.</p>
<p>This section covers the process for developing guidance in the HealthTech programme. Links are made to sections in NICE health technology evaluations: the manual as appropriate. This guide supersedes other sections in the manual, including interim statements, for guidance produced in the HealthTech programme (excluding the late-stage assessment (LSA) interim methods and process statement).</p>	<p>1</p>	<p>Delete text in bold.</p> <p>This section covers the process for developing guidance in the HealthTech programme. Links are made to sections in NICE health technology evaluations: the manual as appropriate. This guide supersedes other sections in the manual, including interim statements, for guidance produced in the HealthTech programme.</p>
<p>NICE will share a copy of the external assessment report with companies that have a named technology in the assessment (that is, the technology name is specified in the assessment scope as an intervention or comparator) for comment in advance of committee meetings. Comments should be submitted on issues of factual accuracy in the assessment report, and model if produced. Factual accuracy would include issues such as inaccuracies in reports or models.</p>	<p>1.4.7</p>	<p>NICE will share a copy of the external assessment report with companies that have a named technology in the assessment (that is, the technology name is specified in the assessment scope as an intervention or comparator) for comment in advance of committee meetings. Comments should be submitted on issues of factual accuracy in the assessment report, and model if produced. Factual accuracy would include issues such as inaccuracies in reports or models. When produced the results from a user preference assessment will also be sent to companies with a named technology in the assessment at this time.</p>
<p>2 Methods for guidance produced in the NICE HealthTech programme</p>	<p>2</p>	<p>This section introduction will be removed and replaced with the '2 Methods for guidance produced in the NICE HealthTech programme'</p>

<p>Methods to develop health technology evaluation guidance are as described in NICE health technology evaluations: the manual (including scoping, evidence, economic evaluation and committee recommendations). For early-use HealthTech guidance assessments, some further detail and considerations are set out in section 2.1.</p> <p>Technologies considered in HealthTech early- and routine-use guidance can be assessed using cost-utility or cost-comparison analysis (see sections 4.2.11 to 4.2.13 in NICE health technology evaluations: the manual). Methods for health technology evaluation guidance for technologies in existing use are currently described in NICE's late-stage assessment (LSA) interim methods and process statement.</p> <p>Detail on methods for interventional procedures guidance (based on an assessment of efficacy and safety) can currently be found in NICE's interventional procedures programme manual.</p> <p>An overview of the types of recommendations used in guidance produced in the HealthTech programme, and what they mean in practice, is shown in table 2. Different recommendations can be made for technologies included in the same guidance.</p> <p>Table 2 Overview of recommendations used in HealthTech programme guidance [table 2]</p>		<p>being consulted on in this consultation exercise.</p>
<p>The standard approach to assessing the evidence for a NICE evaluation is outlined in section 3 of NICE health technology evaluations: the manual. Early-use assessments happen earlier in the lifecycle of a technology and so the evidence assessment has been adapted to reflect this. Pragmatic or rapid review methodology and</p>	<p>2.1.4</p>	<p>Amend initial text in bold and delete second section of text in bold:</p> <p>The approach to assessing the evidence for an evaluation is outlined in section 2.2 [note this refers to content being consulted on in this consultation exercise] Early-use assessments happen earlier in</p>

principles can be used. For example, the Cochrane Rapid Reviews Methods Group provides guidance on doing rapid reviews of the effectiveness of health interventions.		the lifecycle of a technology and so the evidence assessment has been adapted to reflect this.
Evidence reviews can be done using pragmatic or rapid review approaches.	2.1.9	Replace with: Pragmatic or rapid review methodology and principles can be used in the literature review, with specific components of the systematic review process either being restricted or omitted. For example, the Cochrane Rapid Reviews Methods Group provides guidance on doing rapid reviews of the effectiveness of health interventions. Justification and rationale for this should be described in the assessment protocol, along with clear explanation of the components of the review process that have been restricted or omitted.
The economic evaluation should highlight uncertainties that are essential to resolve for future guidance development, focusing on those that are most important to address.	2.1.4	Delete
The economic evaluation should give details about services that would be impacted by using the technologies and how they would be impacted (in terms of greater or reduced use). This should include direct impacts of using the technologies, and any impacts that are likely to occur up- or downstream of use (ideally model outputs will help to estimate size of impact; see section 2.1.20). Details of any changes to service organisation and any other activities needed to implement the technologies, for example, training, should also be described.	2.1.15	Delete
Guidance for presenting model results is described in section 4.10 of NICE health technology evaluations: the manual. In addition to any final model outputs, such as total costs and quality-adjusted life	2.1.20	Delete

years, outputs from the model that are useful to help understand the estimated impact of the technologies should also be provided. For example, values that would be meaningful for healthcare professionals and those that show the impact of technology use on services.		
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Table 3 Minor amendments to existing [Interventional procedures programme manual](#)

Existing wording	Section	Proposed change
Entire	2 key activities of the programme	Delete
When NICE is notified of a procedure, it determines whether it falls within the remit of the programme. Notifications are regularly scrutinised by the interventional procedures technical team, the Chair and members of the Interventional Procedures Advisory Committee, and others as needed, to establish key facts about the procedure that were unclear in the notification. For each notified procedure, the programme team seeks advice from specialist advisers about the novelty of the procedure, its use in the UK and whether guidance from NICE would be helpful. If there are doubts about the suitability of a procedure for guidance, the final decision is made by the Centre Director in consultation with the Committee Chair. Once agreed, a scope is prepared and presented to the Committee, which considers whether the scope contains the necessary information to proceed to develop guidance.	3 Remit of the programme	Move to 'Notifications to the programme' section of the IP programme manual. Add a sub-section heading 'On receipt of notifications to the programme' Amend to: "When NICE is notified of a procedure, it determines whether it falls within the remit of the programme. Notifications are regularly scrutinised by the NICE technical team, the Chair and members of the Interventional Procedures Advisory Committee, and others as needed, to establish key facts about the procedure that were unclear in the notification. For each notified procedure, the NICE team seeks advice from experts about the novelty of the procedure, its use in the UK and whether guidance from NICE would be helpful. If there are doubts about the suitability of a procedure for guidance, the final decision is made by the Associate Director."
Notifications from the MHRA The MHRA has the statutory function of monitoring serious	4 Notifications to the programme	Replace with: Notifications from the MHRA

device-related adverse events and is responsible for overseeing the application of European medical device directives. If the MHRA gets reports of serious concerns about the safety of a procedure or device, it can notify the procedure to NICE. This will prompt NICE to consider assessing the procedure or, if interventional procedures guidance has already been published, updating this guidance.		The MHRA has the statutory function of monitoring serious device related adverse events. If the MHRA gets reports of serious concerns about the safety of a procedure or device, it can notify the procedure to NICE. This will prompt NICE to consider assessing the procedure or, if interventional procedures guidance has already been published, updating this guidance.
Sources and timing of notifications to the programme The NIHR Horizon Scanning Research & Intelligence Centre notifies NICE of procedures likely to be used for the first time in the NHS outside a formal research setting within the next year.	4 Notifications to the programme	Delete
Entire	5 Teams involved in developing interventional procedures guidance	Delete
Entire	6 Registering an interest	Delete
Producing a scope A scope is a short internal document covering key aspects of the procedure. The interventional procedures programme team prepare a scope to initiate the assessment of the procedure. Scopes are produced in line with the NICE equality scheme. A scope defines the issues of interest surrounding the procedure and, for the purposes of the assessment, sets the boundaries for the work to be done by the programme team and the Committee. This is done by defining the procedure and indications that will be used to identify relevant evidence. The programme team seeks advice from appropriate specialist Committee members and the	7 Producing a scope	Replace with: Producing a scope for interventional procedures guidance A scope defines the issues of interest surrounding the procedure and, for the purposes of the assessment, sets the boundaries for the work to be done. This is done by defining the procedure and indications that will be used to identify relevant evidence. Advice is sought from relevant Committee members and experts when preparing the scope.

<p>programme's specialist advisers when preparing the scope.</p> <p>Once the scope has been reviewed by the Committee, developing guidance on the procedure becomes part of the formal work of the programme, and NICE's website shows that guidance on the procedure is in development.</p>		
<p>Standard approach to producing a scope</p> <p>The standard scope sets out the following information relevant to the procedure (depending on the contents of the notification and the procedure, some sections may not be relevant):</p> <ul style="list-style-type: none"> • notified procedure title, and proposed procedure title (if a different title is thought necessary) • proposed lay description • proposed procedure description, using a generic (non-proprietary) description • notified indication • proposed indication and different indications if these are thought necessary • epidemiology of the condition(s) for which the procedure is indicated, 	<p>7 Producing a scope</p>	<p>Replace with:</p> <p>Content of the scope</p> <p>The scope sets out the following information relevant to the procedure (depending on the contents of the notification and the procedure, some sections may not be relevant):</p> <ul style="list-style-type: none"> • notified procedure title, and proposed procedure title (if a different title is thought necessary) • proposed lay description • proposed procedure description, using a generic (non proprietary) description • notified indication • proposed indication and different indications if these are thought necessary • key ongoing trials • suggested search terms for the intervention and indication • epidemiology of the condition(s) for which the procedure is indicated, particularly when this

<p>particularly when this relates to NICE's equalities duties</p> <ul style="list-style-type: none"> • established alternative interventions for the condition • safety and efficacy outcomes • category of notifier • disease area(s) • specialty area(s) (according to NHS classification) • professional organisations to approach for specialist advisers • professional organisations to be informed that NICE is assessing the procedure • patient organisations to be informed that NICE is assessing the procedure • related NICE guidance • special issues relating to the procedure (NICE may be made aware of these by specialist advisers). <p>The scope also includes details of other considerations that could form part of the assessment of the procedure. These may include:</p> <ul style="list-style-type: none"> • details of specific patient subgroups • highlighting when procedures are notified for more than 1 indication • procedures that can be done with more than 1 device • information about the timing of regulatory approval of any devices involved in the procedure • identification of issues about the available evidence base (for example, emerging key trials) • related policy developments. 		<p>relates to NICE's equalities duties</p> <ul style="list-style-type: none"> • established alternative interventions for the condition • safety and efficacy outcomes • category of notifier • disease area(s) • specialty area(s) • professional organisations to approach for experts • professional organisations to be informed that NICE is assessing the procedure • patient organisations to be informed that NICE is assessing the procedure • related NICE guidance • special issues relating to the procedure (NICE may be made aware of these by experts). <p>The scope also includes details of other considerations that could form part of the assessment of the procedure. These may include:</p> <ul style="list-style-type: none"> • details of specific patient subgroups • highlighting when procedures are notified for more than 1 indication • procedures that can be done with more than 1 device • information about the timing of regulatory approval of any devices involved in the procedure • identification of issues about the available evidence base (for example, emerging key trials) • related policy developments.
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<p>Selecting the evidence to present to the Committee</p> <p>The main aim of evidence selection is to highlight the most valid and relevant studies for detailed presentation to the Committee. These studies are presented as part of the evidence summary tables in the assessment report that is prepared for the procedure. To conduct rapid assessments of novel procedures, the interventional procedures programme limits the studies presented in detail in these tables to those most likely to be relevant and informative. In general, all well-designed research studies, those reporting on large numbers of patients, those with long follow-up (if length of follow-up is relevant to outcomes of the procedure) and any reports of additional important safety outcomes are included. Typically, the number of studies in the tables is 6–8. The initial screening for eligible studies is done using abstracts downloaded from electronic databases. A study is eligible for inclusion if it includes patients with the appropriate indication, describes the relevant intervention and reports efficacy or safety outcome data, particularly if those outcomes were identified as being important in the scope. If a study cannot be reasonably excluded on the basis of the abstract alone, its eligibility is assessed using the full text of the publication.</p>	<p>8 Evidence considered by the Committee</p>	<p>Replace with:</p> <p>Selecting the evidence to present to the Committee</p> <p>The main aim of evidence selection is to highlight the most valid and relevant studies for detailed presentation to the Committee. These studies are presented as part of the evidence summary tables in the assessment report that is prepared for the procedure. To conduct rapid assessments of novel procedures, the interventional procedures programme limits the studies presented in detail in these tables to those most likely to be relevant and informative. In general, well-designed research studies, those reporting on large numbers of patients, those with long follow-up (if length of follow-up is relevant to outcomes of the procedure) and any reports of additional important safety outcomes are prioritised. Typically, the number of studies in the tables is 6–8. The initial screening for eligible studies is done using abstracts downloaded from electronic databases. A study is eligible for inclusion if it includes patients with the appropriate indication, describes the relevant intervention and reports efficacy or safety outcome data, particularly if those outcomes were identified as being important in the scope. If a study cannot be reasonably excluded on the basis of the abstract alone, its eligibility is assessed using the full text of the publication.</p>
<p>Inclusion of unpublished or non-peer-reviewed data</p> <p>Efficacy data</p> <p>Efficacy data that are unpublished or not peer reviewed are not</p>	<p>8 Evidence considered by the Committee</p>	<p>Inclusion of unpublished or non-peer-reviewed data</p> <p>While well designed relevant comparative studies are generally prioritised,</p>

<p>normally selected for presentation to the Committee. This includes conference abstracts, which are not normally considered adequate to support decisions on efficacy. If an abstract report relates to a major and potentially relevant study, then efforts are made to obtain a peer-reviewed paper of the findings as early as possible. Papers containing relevant evidence that have been accepted for publication are included, provided that the publication date is before the guidance is published.</p> <p>The programme will use unpublished data from registers if:</p> <ul style="list-style-type: none"> • they arise from a data collection exercise recommended in interventional procedures guidance and • the data collection exercise meets the register standards presented elsewhere in this manual. <p>Safety data</p> <p>Data on safety, however immature, may come from abstracts, companies, registers, specialist advisers' reports and other miscellaneous sources. The programme team always brings such data to the Committee's attention, regardless of source, when safety issues relating to serious adverse events are identified. Unpublished evidence is used when this shows safety outcomes that have not been reported in published sources.</p>		<p>unpublished and non-peer-reviewed safety or efficacy data may be considered for inclusion. Examples of unpublished or non-peer-reviewed data can include submissions from companies, papers awaiting peer-review, unpublished data from registers and conference abstracts - provided they contain sufficient detail on methods and outcomes. The inclusion of unpublished or non-peer-reviewed data will be considered on a per topic basis. Inclusion is more likely if by doing so it is probable that it will fill a gap in the evidence and add value to the Committee's decision-making process. This will particularly be the case for safety data on serious adverse events.</p> <p>Any unpublished data supplied by a company should be accompanied by sufficient details to enable a judgement as to whether it meets the same standards as published evidence and to determine potential sources of bias. Ideally, it should be structured and presented in the form of a research publication. Methodological detail should be provided in line with relevant reporting guidelines (for example those endorsed by the EQUATOR network) to allow critical appraisal of unpublished evidence.</p> <p>Unpublished data from registers is more likely to be included if:</p> <ul style="list-style-type: none"> • they arise from a data collection exercise recommended in interventional procedures guidance and • the data collection exercise meets the register
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		standards presented elsewhere in this manual.
<p>Critical appraisal of the evidence (analysis)</p> <p>The evidence summary table in the assessment report presents the efficacy and safety outcomes reported in the studies. Outcomes are grouped under subheadings where appropriate. Safety, but not efficacy, data from conference abstracts may be presented in the evidence summary table.</p>	8 Evidence considered by the Committee	<p>Replace with:</p> <p>Critical appraisal of the evidence (analysis)</p> <p>The evidence summary table in the assessment report presents the efficacy and safety outcomes reported in the studies. Outcomes are grouped under subheadings where appropriate.</p>
<p>Reasons for commissioning a systematic review</p> <p>When a systematic review is needed, NICE selects an External Assessment Group to carry it out. The systematic review normally takes 6 months to complete, and the standard timeline for developing guidance does not apply. Revised timelines for the development of guidance on the procedure are presented on NICE's website.</p>	8 Evidence considered by the Committee	<p>Replace with:</p> <p>Reasons for commissioning a systematic review</p> <p>When a systematic review is needed, NICE selects an External Assessment Group to carry it out. The standard timeline for developing guidance does not apply when a systematic review is required. Revised timelines for the development of guidance on the procedure are presented on NICE's website.</p>
<p>Structured information request</p> <p>While preparing the scope, a search is done for companies producing devices that may be used to do the procedure. Because there is no standard way of finding this information, NICE cannot do a comprehensive search. When NICE is aware that a branded device or devices are used in a procedure, it makes a structured information request to the companies involved at the beginning of the assessment of the procedure. This is normally done at the time NICE is preparing the scope for the procedure.</p> <p>The structured information request covers limited factual information on:</p> <ul style="list-style-type: none"> settings and locations in which the product is being 	9 Advice and commentary	<p>Delete.</p> <p>Replace with a sub-heading of 'Request for information' and the following text:</p> <p>"Please refer to HealthTech Programme Manual section about requests for information."</p>

<p>used for the indication or purpose in the assessment</p> <ul style="list-style-type: none"> evidence relevant to the assessment including unpublished trials, trials in progress, registers and post-marketing data dates on which trials and other evidence are expected to become available. <p>Companies are not obliged to make this information available to NICE, and are not penalised if they do not do so. However, it helps the quality and timeliness of NICE's assessment of the procedure if they send any available information to NICE. NICE evaluates the evidence on the procedure, rather than any particular device(s) involved. Companies do not need to make a formal submission to NICE.</p>		
<p>Company attendance at the committee meeting</p> <p>NICE invites companies that it has identified in the procedure scope, and that it has approached to request information, to attend the meetings at which the Committee makes its draft recommendations and considers public consultation comments. The Committee may ask the company factual questions about their product, in the context of the procedure being assessed. Companies speak only when invited to do so, and are not invited to make a presentation on their product at the Committee meeting. Companies are present during part 1 of the committee discussions (see section 15).</p>	9 Advice and commentary	<p>Company attendance at the committee meeting</p> <p>Replace with the following text: Please refer to HealthTech Programme Manual section about committee meetings.</p>
<p>NICE has a Citizens Council to help determine its approach, and that of its Committees, to making social value judgements. The Council's views continue to influence and inform the Committee's and NICE's position on how value judgements should</p>	11 Draft recommendations	<p>Replace with: NICE Listens is a programme of deliberative public engagements. It helps NICE determine its approach, and that of its Committees, to making social value judgements. It continues to</p>

influence its guidance. For example, it may consider what an adequate level of safety is for a procedure, and which factors should influence that judgement.		influence and inform the Committee's and NICE's position on how value judgements should influence its guidance. For example, it may consider what an adequate level of safety is for a procedure, and which factors should influence that judgement.
<p>The interventional procedure consultation document</p> <p>When the Committee has made draft recommendations, NICE issues a public consultation document. This sets out:</p> <ul style="list-style-type: none"> the recommendations that NICE proposes to issue a brief description of the procedure, the indications for which it is normally used and current treatments for the condition a summary of the main efficacy and safety outcomes that were available in the published literature and which the Committee considered as part of the evidence about the procedure a summary of the opinions of specialist advisers on the efficacy and safety of the procedure any additional efficacy and safety issues raised by patient commentators other information of importance, such as details of any Medicines and Healthcare products Regulatory Agency safety notices, registers and other research in progress any other comments or observations from the Committee about the procedure and the evidence presented. 	11 Draft recommendations	Delete
Entire	12 The consultation process	Delete

Entire	13 Publication and dissemination of guidance	Delete
Entire	14 Transparency	Delete
<p>How the interventional procedures programme works with other guidance-producing programmes at NICE</p> <p>Sometimes a procedure that appears to be within the remit of the interventional procedures programme is notified to the topic selection process at another part of NICE. If this occurs, the relevant topic selection team forwards the notification to the interventional procedures programme for consideration. In particular, the medical technology evaluation programme is designed to engage with medical technology and diagnostic companies to identify innovative products with potential benefits for patients and the healthcare system. Some of these products may feature in novel interventional procedures, and the programme teams liaise to ensure that procedures fitting the programme's remit in which these products are used are assessed by the interventional procedures programme.</p>	15 Links with other NICE guidance-producing programmes	Delete
<p>Procedures suitable for medical technologies or technology appraisal guidance</p> <p>It is usually appropriate for the efficacy and safety of procedures to be considered before either the medical technologies or technology appraisals programmes address the value of the devices used in the procedure, or the procedure itself. Among the procedures considered by the interventional procedures programme to be safe and efficacious enough for routine use, there will be a small number that may be suitable for such an evaluation. This is likely to</p>	15 Links with other NICE guidance-producing programmes	Delete

involve, for example, devices that are indicated for a common health problem or where the costs to the healthcare system of introducing the device are very different from those of existing treatments. In these circumstances, the procedure is passed to NICE's Medical Technologies Evaluation Programme to consider the appropriateness of developing further NICE guidance.		
Entire	16 Reviewing and updating interventional procedures guidance	Delete
Entire	17 Stakeholder engagement	Delete
<p>Abstract (of a published study) A summary (introduction) of a published study. Abstracts of published studies can usually be retrieved through literature search engines.</p> <p>Abstract (conference) A summary of an as-yet unpublished study presented at a scientific conference. Although such abstracts may be retrievable through literature search engines, they are not peer reviewed and the study is not always subsequently published in full. If it is published in full, the content may differ from the original conference abstract.</p> <p>Adverse event An undesirable outcome experienced by a person while they are taking (a) drug(s), or having any other treatment or intervention, regardless of whether or not the event is suspected to be related to or caused by the drug, treatment or intervention.</p> <p>Assessment report A document produced by NICE to inform the Committee about an interventional procedure. It contains information on the</p>	18 Glossary	Delete these terms from the glossary as these are already included in the NICE Glossary available on the NICE website

<p>indications for the procedure, a description of the procedure, a summary of key points from a rapid review of the literature, and a summary of commentary by the specialist advisers.</p> <p>Audit The evaluation of clinical performance against standards or through comparative analysis, aimed at informing service management.</p> <p>Bias Systematic (as opposed to random) deviation of the results of a study from the 'true' results caused by the way the study is designed or conducted.</p> <p>Case report An uncontrolled observational study involving an intervention and outcome in a single patient.</p> <p>Case series Reports of several patients with a given condition, usually covering the course of the condition and the response to treatment. There is no comparison (control) group of patients.</p> <p>CE Mark A CE Mark indicates that the manufacturer of a medical device complies with the relevant European Union Directive on safety, quality and performance.</p> <p>Cochrane Library A regularly updated electronic collection of evidence-based medicine databases, including the Cochrane Database of Systematic Reviews.</p> <p>Comparator An alternative treatment against which the intervention under appraisal is compared. The comparator could be standard treatment (including, on occasions, expectant management or no intervention) or a sham procedure.</p> <p>Confidence interval The confidence interval is a way of expressing how certain we are</p>		
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about the findings from a study, using statistics. It gives a range of results that is likely to include the 'true' value for the population. A wide confidence interval indicates a lack of certainty about the true effect of the test or treatment – often because a small group of patients has been studied. A narrow confidence interval indicates a more precise estimate (for example, if a large number of patients have been studied).

Consultee

An individual who, or organisation that, submits a response to an interventional procedure consultation document.

Control

An explicitly defined comparator against which the effects of an intervention are compared in a clinical study.

Critical appraisal

The process of assessing and interpreting evidence by systematically considering its validity, results and relevance.

Developer

A team set up by NICE to develop NICE guidelines for a particular area. It may be a team within NICE, or in an organisation contracted by NICE to develop guidelines. The team includes administrators, coordinators and project managers who provide administrative and management support to the Committee, plan and schedule the work, arrange meetings, and liaise with stakeholders and all other people and organisations contributing to guideline development.

Diagnostics assessment programme

The diagnostics assessment programme focuses on the evaluation of innovative medical diagnostic technologies to make sure that the NHS is able to adopt clinically- and cost-effective

technologies rapidly and consistently.

Device

A piece of equipment used for diagnostic or therapeutic purposes, sometimes along with (a) pharmaceutical agent(s).

Effectiveness (clinical)

An effective procedure is one that, compared with other interventions, produces benefits that patients value in routine use.

To be considered effective, the procedure must have been assessed in more standard clinical settings than is the case for efficacy.

Efficacy

An efficacious procedure is one that produces a desirable outcome in research conditions.

Evidence

Information on which a decision or guidance is based, from a range of sources and methodologies, but mostly from peer-reviewed publications.

Follow-up

Observation of patients taking part in a clinical study over a period of time to measure outcomes under investigation.

Guideline Committee

A group of healthcare professionals, patients, carers and technical staff who develop the recommendations for a NICE guideline. The developer responsible for the guideline recruits a Guideline Committee to work on it. They also oversee the evidence review team, who review the evidence and support the Guideline Committee. The Committee writes draft guidance, and then revises it after a consultation with organisations registered as stakeholders.

Guidance Executive

The Executive and Centre Directors of NICE, delegated by the NICE Board to issue guidance on its behalf.

<p>Healthcare Improvement Scotland Healthcare Improvement Scotland is the body responsible for improving the quality of healthcare in Scotland by setting standards, monitoring performance and providing advice, guidance and support to NHS Scotland on effective clinical practice and service improvements.</p> <p>Health technology assessment Independent research about the effectiveness, costs and broader impact of healthcare (treatments and tests) for people who plan, provide or have care in the NHS. The Health Technology Assessment (HTA) programme is part of the National Institute for Health Research (NIHR).</p> <p>'In confidence' material Information (for example, the findings of a research project) defined as 'confidential' because its public disclosure could affect the commercial interests of a particular company ('commercial in confidence') or the academic interests of a research or professional organisation ('academic in confidence').</p> <p>Information for the public A document issued by NICE for patients and carers that summarises the recommendations in NICE guidance in everyday language.</p> <p>Interventional Procedures Advisory Committee (IPAC) The Committee is responsible for advising NICE on the safety and efficacy of interventional procedures.</p> <p>List of notified procedures The list of interventional procedures notified to NICE, posted on NICE's website.</p> <p>Medicines and Healthcare products Regulatory Agency (MHRA) The MHRA is the national</p>		
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competent authority responsible for regulating medical devices on the UK market. It has a statutory responsibility to investigate incidents involving medical devices and powers to prosecute manufacturers when it can be shown that there has been a serious breach of the Medical Devices Regulations. Because some new interventional procedures involve devices, the work of the MHRA and NICE may occasionally overlap. The MHRA's senior officer responsible for medical aspects of device regulation is a member of the Committee and the 2 organisations are in regular contact.

Medical technologies evaluation programme

The medical technologies evaluation programme aims to promote the timely and consistent adoption of new or novel medical technologies that have the potential to offer benefits to patients or the NHS. It does this by identifying technologies, producing NICE advice or guidance, and helping generate evidence.

MeSH

Medical subject headings; the controlled vocabulary used for indexing content in Medline and certain other databases.

Meta-analysis

A statistical technique for combining (pooling) the results of more than 1 study addressing the same question and reporting on the same outcomes to produce a summary result. The aim is to derive more accurate and clear information from a large data pool. Meta-analysis is generally more likely than the individual trials to reliably confirm or refute a hypothesis.

NIHR Horizon Scanning Research & Intelligence Centre
The [NIHR Horizon Scanning](#)

[Research & Intelligence](#)

[Centre](#) aims to provide advance notice of new and emerging technologies that might need urgent evaluation, consideration of clinical and cost effectiveness, or modification of clinical guidance.

Non-randomised controlled study

Any study of an intervention compared with another intervention (whether looking at harm or benefit) that does not use randomisation to allocate patients to comparison groups.

p value

The p value is a statistical measure that is used to indicate whether or not an effect is statistically significant.

PICO (population, intervention, comparator, outcome)

A structured approach for developing review questions about interventions. The PICO framework divides each question into 4 components: the population, the intervention(s), the comparator(s) and the outcome(s).

Placebo (sham procedure)

An inactive substance or interventional procedure that the effects of an active drug or interventional procedure is compared against in a study.

Randomised controlled trial (RCT)

A comparative study in which patients are allocated randomly to intervention and control groups, and are followed up to examine differences in outcomes between the groups.

Specialist adviser

A person nominated by a relevant professional organisation to advise the interventional procedures programme about notified procedures.

Stakeholder

An individual or organisation with

<p>an interest in the interventional procedures programme's activities and outputs.</p> <p>Systematic review A review that summarises the evidence on a clearly formulated review question according to a predefined protocol, using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, analyse, collate and report their findings. It may or may not use statistical meta-analysis.</p> <p>Technology appraisal programme The technology appraisal programme at NICE makes recommendations on the clinical and cost effectiveness of new and existing medicines and treatments within the NHS in England, such as medicines, medical devices, diagnostic techniques, surgical procedures and health promotion activities.</p> <p>Validity Whether a test or study actually measures what it aims to measure. Internal validity shows whether study or test is appropriate for the question, for example, whether a study of exercise among gym members measures the amount of exercise people do at the gym not simply whether people join. External validity shows whether findings can be generalised to other settings or populations.</p>		
<p>New additions to glossary</p>	<p>18 Glossary</p>	<p>Add the following items:</p> <p>Assessment report An assessment report is generated to support guidance development. This report can either be produced by NICE or an External Assessment Group (EAG). When produced by an EAG, this is an external assessment report, and the EAG is responsible for the content and quality of the report.</p>

		<p>HealthTech programme The NICE HealthTech programme combines the former NICE Diagnostics Assessment programme, Interventional Procedures programme and Medical Technologies Evaluation programme.</p> <p>Patient reported outcome measures (PROMs) Patient Reported Outcome Measures (PROMs) measure a patient's health status or health-related quality of life at a single point in time, and are collected through short, self-completed questionnaires.</p>
Interventional procedures programme	Throughout	Amend to 'interventional procedures guidance'
Specialist advisers	Throughout	Amend to 'experts'