

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional procedures programme manual

### 1 Introduction

NICE's interventional procedures programme assesses the efficacy and safety of interventional procedures used for treatment or diagnosis to determine whether they work well enough and are safe enough for use in the NHS. The programme can assess procedures that involve incision, puncture and entry into a body cavity, or that use ionising, electromagnetic or acoustic energy. No interventional procedure is entirely risk free, but the programme gauges the extent of uncertainties and makes recommendations on their implications for patients, clinicians and healthcare organisations.

NICE issues guidance on interventional procedures to help ensure that:

- patients and carers:
  - are reassured that new procedures are being monitored and assessed to protect patient safety
  - have access to information about new procedures (NICE produces information for the public for each procedure)
- clinicians, healthcare organisations and the NHS as a whole are supported in the process of introducing new procedures:

NICE encourages the safe introduction of innovation by:

- providing advice on the efficacy and safety of new procedures
- recommending training and other conditions for use of procedures in the NHS
- facilitating data collection and analysis.

The programme comprises the Interventional Procedures Advisory Committee (IPAC or 'the Committee'), and a team employed by NICE that carries out technical tasks

and project management. All members of the Committee are independent of NICE. The programme mostly investigates new procedures, and also examines established procedures if there is uncertainty about their efficacy or safety. It also updates interventional procedures guidance when there is a change in the evidence base to justify this.

The process and methods are designed to ensure that robust guidance is developed for the NHS in an open, transparent and timely way, with appropriate input from consultees and other stakeholders.

NICE was established in legislation as an England-only body. However, we have agreements with the devolved administrations so that interventional procedures guidance applies in Wales, Scotland and Northern Ireland.

NHS clinicians are responsible for applying NICE guidance, in their local context, in light of their duties to avoid unlawful discrimination and to promote equality. Nothing in the guidance should be interpreted in a way that would be inconsistent with compliance with these duties.

See section 22 for a glossary of terms used in this document.

## **2 Key activities of the programme**

The key activities of the interventional procedures programme are:

- receiving notifications of interventional procedures
- identifying new interventional procedures
- deciding whether notified procedures fall within the programme's remit and so should be assessed
- compiling and maintaining a list of notified procedures
- preparing procedure briefs and overviews
- obtaining specialist advice
- obtaining patient commentary

- convening meetings of the Committee, providing it with evidence and securing its preliminary recommendations
- preparing consultation documents based on the Committee's preliminary recommendations
- conducting public consultations on the preliminary recommendations
- producing interventional procedures guidance based on the final recommendations of the Committee
- ensuring all guidance addresses equalities issues
- providing a resolution process by which consultees have a mechanism for reviewing NICE's guidance for factual errors or breaches of process before it is published
- issuing interventional procedures guidance to the NHS in England, Wales, Scotland and Northern Ireland
- advising on a lay version of the guidance ('information for the public')
- advising on the production of audit tools for the guidance when these are recommended
- advising on the suitability of registers or other datasets for inclusion in the guidance
- updating guidance
- raising awareness of the programme in the NHS in England, Wales, Scotland and Northern Ireland.

### **3 Timings for developing interventional procedures guidance**

NICE is aware of the importance of timeliness when producing guidance on the efficacy and safety of novel interventional procedures. It aims to minimise how long there is uncertainty about the use of procedures before guidance is issued.

An indication of the time taken for each stage in the process is shown in table 1. The length of time between notification and agreement of the brief by the Committee is highly variable, depending on the need to get more information about the procedure.

For example, for some topics, it may be necessary to make more enquiries to find out how widely the procedure is being used in the NHS, or whether there is an evidence base with which to assess it. It is not always possible to achieve the standard times for each stage.

**Table 1. Standard timeline for NICE to develop interventional procedures guidance**

<b>Week</b>	<b>Event</b>
<b>Preparation phase</b>	
0	The procedure is notified to NICE.
8	The Committee agrees the brief. This phase can take longer than 8 weeks, for example, if NICE has to find further information on the use of the procedure, the available evidence or the licensing status of any devices that are used in the procedure.
<b>Guidance development</b>	
0–10	NICE produces the overview. Specialist advisers and patient commentators provide comments about the procedure.
13	The Committee considers the evidence and commentary on the procedure and produces draft recommendations. A consultation document is produced.
20–24	The consultation document and overview are posted on NICE’s website for a 20-working-day consultation period.
26	The Committee considers consultation comments. A final document is produced. Any late comments from patient commentators may also be considered by the Committee at this stage.
30	The final document is considered by the NICE Guidance Executive.

Week	Event
30–33	<p>The final document is open to resolution requests (15 working days).</p> <p>For procedures not needing resolution, guidance is issued to the NHS in England, Wales, Scotland and Northern Ireland. The lay version of the guidance ('information for the public') is also published. (A Welsh version is published at a later date.)</p>
37	<p>For procedures needing resolution, guidance is issued to the NHS in England, Wales, Scotland and Northern Ireland. The lay version of the guidance ('information for the public') is also published. (A Welsh version is published at a later date.)</p>

## 4 Notifications to the programme

### 4.1 Sources and timing of notifications to the programme

Clinicians and healthcare professionals are the main notifiers to the interventional procedures programme. However, anyone may notify NICE about a procedure for consideration.

Non-clinical NHS staff wanting to notify NICE about a procedure are encouraged to discuss it with a clinician first because completion of the [web form](#) is improved by clinical knowledge of the procedure.

Medical technology companies may notify NICE about procedures they believe might be within the remit of the programme. Medical technology companies should contact [medtech@nice.org.uk](mailto:medtech@nice.org.uk), to get advice from the medtech team, which collaborates with the interventional procedures programme team.

Professional organisations, the Medicines and Healthcare products Regulatory Agency (MHRA), the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme and other organisations may also notify NICE

about interventional procedures that are being done in the NHS outside a formal research setting, or about those that clinicians are considering doing. The NIHR Horizon Scanning 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.

Members of the interventional procedures team may identify new procedures, usually when investigating notified procedures. The team sometimes approaches professional organisations to invite them to notify procedures. Notifications to the programme are made using the [notification form](#) on the NICE website.

It is appropriate to notify NICE about an interventional procedure if:

- it is entirely novel, with an unknown or uncertain efficacy and/or safety profile, or
- it is a variation of an established procedure that may have a different efficacy and/or safety profile from that of the established procedure.

Sometimes practitioners make minor alterations to established procedures and these do not merit notification, for example, a small change in the length or site of an incision to improve access in an operation. Interventional procedures involving robotics are generally considered a minor modification of their non-robotic equivalent, and are therefore outside of the remit unless the procedure differs substantially because of the robotic element. Clinicians doing a well-established procedure for the first time should not notify it to the programme.

While guidance is in development, clinicians wishing to carry out the procedure, and their trusts, should ensure that special arrangements are in place for consent, governance, audit and research.

Anyone can contact the interventional procedures programme team for advice on whether it is appropriate for a procedure to be notified.

## **4.2 Surveillance**

The MHRA has the statutory function of monitoring serious device-related adverse events and is responsible for applying the European Legislation for devices. If the

MHRA gets reports of serious concerns about the safety of a procedure or device(s) it can notify the procedure to NICE. This will prompt NICE to consider assessing it; this applies whether or not the procedure has already been the subject of guidance.

### **4.3 Outcome of notifications to the programme**

If a procedure falls within the remit of the interventional procedures programme, it is assessed (see section 5).

Details of all interventional procedures notified to the programme are available on [NICE's website](#). The following information is given about each procedure within the programme's remit:

- the name of the procedure
- a procedure description
- a description of current established practice, including other procedures used for the same purpose
- the disease area
- the clinical specialty or specialties of clinicians who might do the procedure
- links to relevant documents produced by NICE (overview, consultation document, guidance, table of consultation comments including NICE's responses, External Assessment Centre report and information for the public)
- links to relevant documents produced by other agencies, like the MHRA
- links to related NICE technology appraisal guidance and NICE guidelines
- notices about changes of status to a piece of interventional procedures guidance (for example, if the guidance has been withdrawn or replaced through incorporation into a NICE guideline).

The status of the procedure is shown as 1 of 2 main categories:

- 'guidance issued' – guidance has been published and is available on NICE's website
- 'in progress' – the procedure is being assessed by the programme.

If a procedure notified to the programme appears to fall within the remit of the programme in all respects except that it is not yet being used in the NHS or independent healthcare sector, or there is no evidence base with which to assess it, the programme monitors it and assesses it at a future date if circumstances change. Such procedures are listed on [NICE's website](#), along with the reason why they are not yet being assessed.

If a procedure does not fall within the remit of the programme, it is not assessed. Notified procedures that are not within the programme's remit and the reasons for this are also listed on [NICE's website](#).

Whether the procedure is within the remit of the programme or not, NICE informs the notifier of the procedure of the outcome of their notification.

If guidance production is paused or stopped before publication, published documents remain on the website for a maximum of 6 months. After 6 months, if NICE is not going to publish guidance, the documents are removed.

## **5 Remit of the programme**

The interventional procedures programme's remit is outlined in the 'Supplemental directions to the National Institute for Care Excellence in relation to interventional procedures', which amended the NHS Act 2006.

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, with advice from specialist advisers, the Chair and members of the Interventional Procedures Advisory Committee, and others as needed. Advice is obtained primarily to establish key facts about the procedure that were unclear in the notification.

To fall within the programme's remit, a notified procedure must:

- involve an incision, a puncture or entry into a body cavity, or use of ionising, electromagnetic or acoustic energy, and

- be available within the NHS or independent sector, or be about to be used for the first time outside formal research, and
- either not yet be generally considered established clinical practice, or
- be an established clinical procedure, the efficacy or safety of which has been called into question by new information or advice
- have a CE mark specific for the notified indication if a device is involved.

When considering whether to assess a procedure, NICE also takes into account the views of specialist advisers or professional organisations on the status of the procedure and on whether they would find guidance useful.

Procedures do not fall within the programme's remit if they are considered standard clinical practice with a sufficiently well-known efficacy and safety profile. All interventional procedures carry some risks. It is the extent of uncertainty surrounding the efficacy and safety of a procedure that the programme is concerned with.

For each notified procedure, the programme team seeks advice from relevant experts about the novelty of the procedure and its use in the UK. 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 brief is prepared and presented to the Committee, which considers whether the brief contains the necessary information to proceed to develop guidance. All decisions are recorded on NICE's website.

## **5.1      *Procedures involving medical devices***

NICE assesses procedures that involve a medical device if:

- the procedure falls within the programme's remit, and
- the device has a CE mark allowing it to be used for the purpose and indication for which the procedure is intended.

If a procedure involving a specific device is notified, the programme team approaches the company or companies to ensure that at least 1 device has a CE

mark that is current and relevant to the proposed indication. NICE interventional procedures guidance does not name, or relate to, specific devices.

## **5.2 *Other information about the programme's remit***

It is not within the remit of the programme to evaluate the cost effectiveness of interventional procedures, or to advise the NHS on whether interventional procedures should be funded.

## **6 Who is involved in developing the guidance?**

### **6.1 *The interventional procedures programme team***

The interventional procedures programme 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. The team supports the Committee and is responsible for carrying out aspects of the work associated with developing guidance. This includes:

- compiling information about procedures notified to the programme and deciding whether they are within the programme's remit
- preparing evidence and commentary for consideration by the Committee
- arranging public consultation on the Committee's draft recommendations
- preparing guidance for publication by NICE
- ensuring NICE's published processes and methods for the development of interventional procedures guidance are followed in line with agreed timelines and standards of quality.

The programme team is committed to improving its practice and methods by conducting operational research and audit. Other teams at NICE also provide support to the development of interventional procedures guidance.

## **6.2      *The guidance information services team***

The NICE guidance information services team searches for evidence relevant to the procedures. This evidence is used by the programme team to prepare an overview of each procedure for the Committee.

## **6.3      *The publishing team***

The NICE publishing team reviews and edits the documents that support the development of interventional procedures guidance for publication on NICE's website. These include evidence overviews, consultation documents and guidance. The team also produces the lay version of the guidance: 'information for the public'.

## **6.4      *The implementation team***

The NICE implementation team produces audit tools for procedures when the Committee's recommendations state they are needed, and when there is no suitable register or organised system for data collection. The audit tools are developed with advice from specialist advisers and Committee members, as appropriate.

## **6.5      *The public involvement programme***

NICE's public involvement programme:

- facilitates recruitment of the Committee's lay members
- supports Committee lay members during their term of office
- identifies patient commentators (see section 6.8)
- establishes links with patient organisations with an interest in interventional procedures guidance
- encourages members of the public and patient organisations to respond to consultation.

NICE uses the terms 'patient organisation' and 'patient group' to include patient, carer, service user, community, voluntary sector and other lay organisations, including those that represent the interests of people from groups protected by equalities legislation.

## **6.6      *The Interventional Procedures Advisory Committee***

The Committee is made up of 25 members who are independent of NICE. It includes:

- clinicians who carry out interventional procedures
- lay members who are familiar with the issues affecting patients and carers
- experts in regulation and in the evaluation of healthcare
- a Chief Executive of an NHS trust
- a Medical Director of an NHS trust
- a representative from the medical device industry
- a member with knowledge of patient safety issues.

The Committee meets monthly (except in August) in public. [Agendas and minutes of Committee meetings](#) are published on NICE's website. The minutes are a contemporaneous note of the business of the meeting.

Committee members are required to submit an annual declaration of interests and declare any conflicts of interest at each Committee meeting, in line with NICE's policy on [conflicts of interest](#).

The [terms of reference and Standing Orders for the Committee](#) can be found on the NICE website.

### **The role of the Committee**

The Committee makes recommendations to NICE on the efficacy and safety of interventional procedures and on the context of guidance, such as the conditions under which procedures should be used.

### **How members are appointed**

Committee members are appointed through an open advertisement (posted on NICE's website) for a period of 3 years by a panel consisting of the Committee Chair, the centre director or appointed deputy and a senior member of the programme, usually the Associate Director. This may be extended for a further 3 years by mutual

agreement, and up to a maximum of 10 years. A list of [current members](#) is on NICE's website.

The Chair of the Committee is also appointed through an open advertisement on NICE's website. The panel consists of: the Chair of the NICE Board or a nominated deputy who is a non-executive director and chairs the panel; the chief executive or a nominated deputy from the senior management team; and the relevant centre director.

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

## **6.7 Specialist advisers**

The programme team and the Committee are assisted by specialist advisers, who are clinicians involved in the use of identified interventional procedures or in the care pathway for the condition. These specialist advisers are nominated or ratified by their professional organisations. NICE uses the term professional organisations to include royal colleges, and professional societies and associations.

### **The role of specialist advisers**

The specialist advisers provide advice about interventional procedures that complements findings from research. In addition, specialist advisers may be asked (within their area of expertise or knowledge) to advise the programme team and the Committee on related matters to enable NICE to produce the guidance and supporting materials. The advice may encompass:

- the validity of the notification and its relevance to the programme's remit
- the content of the brief
- the content of the overview
- the outcomes to be included in an audit tool for the procedure when this is recommended in the guidance
- issues relating to the collection of further data in registers or other datasets
- the content of a lay version of the guidance.

They may be called on to provide their opinions to the Committee in person when necessary, for example, when there is no Committee member present from the relevant specialty.

### **How specialist advisers are identified**

NICE identifies specialist advisers in 2 ways:

- NICE approaches a professional body to nominate individuals able to give an informed opinion about interventional procedures. NICE anticipates that, in nominating specialist advisers, professional organisations will have due regard to their responsibilities under the Equality Act 2010.
- A current specialist adviser or a Committee member recommends another clinician to give specialist advice. Then, the relevant professional body is asked to ratify the clinician as a specialist adviser.

Occasionally, and normally only if NICE cannot obtain specialist advisers by these means, the programme may approach medical device companies to ask if they know any specialists involved in using or researching the procedure. NICE seeks ratification by their professional body of specialist advisers identified in this way.

### **Once they are appointed**

Approved specialist advisers are appointed to the programme for a term of 3 years, and are given the option to renew their term every 3 years. A specialist's eligibility to advise the programme ends if they retire from NHS practice or are subject to disciplinary or legal proceedings arising from their work.

A [list of specialist advisers](#) ratified by their professional body is published on NICE's website.

## **6.8 Patient commentators**

The Committee draws on information supplied by patient commentators who have either had the procedure or are the carer of someone who has.

### **The role of patient commentators**

The process by which patient commentary is obtained is designed to produce information on patients' experience of the procedure. It is separate from, but complemented by, the information and views from patient organisations and individual patients through the usual NICE consultation process (see section 13).

Patient commentators complete a questionnaire about their personal experience of the procedure, which is given to the Committee.

### **How patient commentators are identified**

NICE approaches the notifier of a procedure to find out where the procedure is being done, and if possible the name of the clinicians doing it. This may be in the NHS or in private practice. NICE then contacts the identified clinician(s) to seek agreement for patients and/or their carers to be invited to complete a questionnaire on their experience of the procedure. If the total number of patients who have had a procedure is fewer than about 50, NICE asks the identified clinician(s) carrying out the procedure to send the questionnaire to all patients. If the figure is more than about 50, to keep administration manageable, NICE asks the clinician(s) to send questionnaires only to a sample of patients. The clinicians send their patients the questionnaires on NICE's behalf because of data protection legislation.

## **7 Registering an interest**

Both individuals and stakeholder organisations may register an interest in a procedure or group of procedures that are being assessed by the programme on NICE's website. They are then sent electronic updates of that procedure's progress through the programme. These updates are triggered by changes to the procedure's web page (for example, when consultation begins).

Interested parties are encouraged to register an interest, because this is the most reliable way of ensuring awareness of a procedure's progress and of being alerted to consultation and publication. By registering an interest, individuals acquire the status of stakeholders, with the right to return consultation comments and make a

resolution request later in the process. NICE welcomes registration of stakeholders from all sections of the community.

## **8 Producing a brief**

A brief is a short internal document covering key aspects of the procedure. It is prepared by the interventional procedures programme team. Briefs are produced in line with the [NICE equalities scheme](#).

A brief defines the issues of interest surrounding the procedure, and 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 programme's specialist advisers when preparing the brief.

Once the brief has been agreed 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.

### **8.1 *Standard approach to producing a brief***

The standard brief sets out the following information (depending on the contents of the notification and the procedure, some sections may not be relevant):

- 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, particularly when this relates to NICE's equalities duties
- established alternative interventional procedures for the condition
- relevant 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).

The brief also includes details of other considerations that could form part of the assessment of the procedure. These may include:

- 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.

## **8.2      *Complex notifications***

Sometimes a notification cannot be accepted in its original form, but the brief can suggest how useful guidance could be developed. For example:

- NICE is notified about a procedure with an imprecise name or spelling, or 1 that is atypical in UK practice. Because there is no universally recognised nomenclature for interventional procedures, the programme's technical team may rename the notified procedure on the advice of specialist advisers or the specialist Committee member. NICE aims to make the names of the procedures it assesses relevant to the clinicians who carry them out and it consults with specialist advisers when considering changes to procedure names.

- NICE is notified about a procedure with a name that is device-specific (for example, 'device X for indication Y', instead of 'procedure Z for indication Y'). Because the programme does not evaluate devices, the name of the procedure is revised to avoid reference to specific devices or trade names.
- NICE is notified about a procedure for an imprecise or atypical indication. For example, the indication might be a symptom of a disease (such as pruritus), rather than the disease itself (chronic liver disease). The programme's technical team may revise the pairing of the procedure and indication to produce appropriate guidance.
- NICE is notified about a procedure for more than 1 distinct indication. In this case, the procedure may be 'split' to produce 1 piece of guidance for each indication.

Briefs involving complex notifications are likely to take longer to prepare than standard briefs.

## **9 Evidence considered by the Committee**

Evidence and commentary are considered by the Committee at 2 stages in the assessment of a procedure:

- when formulating provisional recommendations for consultation
- when arriving at their final recommendations.

The evidence that the Committee uses to make its provisional decision is mainly, although not exclusively, from published sources. 'Commentary' refers to the variety of opinion and information from unpublished sources that may be relevant to a procedure (see section 10).

Selection of evidence for the interventional procedures programme is based on the following key principles:

- The interventional procedures process considers only efficacy and safety, not cost effectiveness.

- Depending on the circumstances, either active treatment or sham (placebo) is the preferred comparator in assessing the efficacy and safety of a procedure.
- Detailed recommendations on different indications and patient subgroups are not usually possible because the published data are usually insufficient.
- Randomised controlled trials (RCTs) are often not available. Non-RCTs, case series and case reports may therefore be the main sources of data.

The following sections describe how NICE identifies and selects the evidence for presentation to the Committee. This is done in the form of an overview (see section 9.3), which the Committee uses as the basis for its provisional recommendations on a procedure.

## **9.1      *Literature search***

The literature search is carried out by the guidance information services team. The aim is to identify as much evidence on the procedure as possible using a comprehensive and exhaustive search strategy, but on a limited number of sources in line with the rapid nature of guidance development. Development of the search strategy is an iterative process; changes are made to the strategy according to the results retrieved, based on discussions between the guidance information services team and the programme's technical team.

Because of the nature of procedures notified to the programme, there are rarely directly-relevant thesaurus headings (MeSH, EmTree). Often a given procedure has no established terminology and is referred to in a variety of ways in different publications. So, the use of free-text searches (words in titles and abstracts) may be more important, and appropriate synonyms, abbreviations and alternative spellings are sought and used extensively in the search strategy.

The search focuses on identifying relevant background information, systematic reviews, health technology assessments (rarely available) and, most importantly, primary research and ongoing or newly reported research in the form of conference proceedings.

## **Evidence included**

The following searches are conducted against the sources and methodology set out below.

### **Background information**

- NHS England [website](#)
- US Food and Drug Administration (FDA) – Manufacturer and User Facility Device Experience (MAUDE) database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S)
- Australia and New Zealand Horizon Scanning Network
- general internet search.

### **Systematic reviews and health technology assessments**

- Cochrane Database of Systematic Reviews
- Health Technology Assessment Database.

### **Primary research evidence**

- Medline
- EMBASE
- Cochrane Central Register of Controlled Trials (CENTRAL)
- Medline In-Process and other non-indexed citations (Premedline)
- PubMed
- Cumulative Index to Nursing and Allied Health Literature (CINAHL), only when appropriate.

### **Ongoing research**

Databases used include:

- [clinicaltrials.gov](http://clinicaltrials.gov)
- World Health Organization International Clinical Trials Registry
- National Institute for Health Research Clinical Research Network Coordinating Centre Portfolio Database.

**Conference proceedings**

Because many of the procedures considered by the programme are very new, searching through conference proceedings can yield relevant results. The websites of the major relevant professional organisations (UK and abroad) are searched for recent conference proceedings.

**Other sources of evidence**

Other subject-specific databases may be searched, depending on the subject area.

**Use of methodological filters**

Methodological filters such as the Cochrane Highly Sensitive Search Strategy are seldom used. This is because the evidence base is rarely large enough to warrant such restrictions and because, at the time of the programme's assessment, interventional procedures have rarely been studied in controlled trials. However, a filter based on study design may be applied for some procedures when perhaps the efficacy of an established procedure is being called into question by new information. A filter for safety outcomes may be applied for some procedures when there is a large body of evidence that includes systematic reviews, and when complications (morbidity) have been identified as a particular concern.

**Language restrictions**

Searches include publications in any language. When there is sufficient evidence available in English, selection is usually limited to English-language publications. Translation into English of full articles published in languages other than English is requested by the technical team if the outcomes reported in the non-English literature differ in nature from those reported in the English-language literature, or are reported with substantially different frequency – particularly for safety outcomes. Such translations are treated in exactly the same way as English-language studies (that is, they are included in the evidence summary table of the overview if they are considered to be among the most valid and relevant studies).

NICE may not be able to obtain English translations even of relevant studies because of resource and timing constraints.

### **Date restrictions**

Date restrictions are not normally used when searching for literature on interventional procedures. They are applied only in particular situations, for example, when a technology has evolved, when there is an exceptionally large amount of literature, or when a good-quality systematic review or health technology assessment exists that has not excluded studies on the basis of study design. When a health technology assessment exists, the search is restricted to studies published after the year of publication of the most recent study included in the review or assessment.

### **Timing**

The literature search is conducted as close to the relevant Committee meeting as possible, to ensure timeliness of the search. If there are any delays to the assessment of the procedure, a further search (using the same search terms) is conducted shortly before the relevant Committee meeting in case new literature has emerged.

## **9.2 *Selecting the evidence to present to the Committee***

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 overview that is prepared for the procedure. So that the interventional procedures programme can conduct rapid assessments of novel procedures, these tables are usually limited to a maximum of 8 studies.

Typically, this limit allows inclusion of all well-designed research studies, and those reporting on large numbers of patients. 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 brief. 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.

The remaining eligible studies (those not included in the evidence summary table) are listed in an appendix, with brief details of each study and its outcomes. The aim of this appendix is to present the overall picture of the procedure and to allow the committee to consider whether the studies included in the evidence summary table are the most reliable and valid among a larger body of literature. The appendix allows all relevant studies to be listed without making the overview excessively large. It is possible, however, that other potentially relevant studies may not be included in the appendix because they were not identified by the literature search. Any anomalies normally relate to the date on which the literature search is conducted or the nature of the search terms, particularly for novel procedures. Relevant studies highlighted at consultation are incorporated into the evidence overview and consultees are encouraged to tell NICE about relevant studies during consultation.

Studies that do not contain clinical information on efficacy and safety outcomes (for example, narrative review articles, animal studies or studies reporting on physiological outcomes) are not included in the overview, and are therefore not considered by the Committee.

Once all the studies identified in the literature search have been assessed for eligibility, the reference lists of the eligible studies are checked for other studies that may not have been identified by the search strategy. If a lot of potentially eligible studies are identified through this process, the original search strategy is modified and the search is repeated.

For some procedures, selecting the studies to include for the overview – and for further appraisal in the evidence summary table – may be a complex and difficult task. This is because some studies have to take priority over others, based on a judgement about their relevance and validity. A particular difficulty arises when there are a disproportionate number of published studies in relation to:

- different subgroups of patients treated with the same procedure
- different devices used for the same procedure, or technical variations of a procedure

- different outcomes (for example, some studies reporting only efficacy and some only safety outcomes; some studies reporting quality-of-life outcomes, others not).

In this context, the programme's technical team may take the following actions:

- prioritise a particular subgroup of studies, chosen to provide a balanced view of the evidence
- propose splitting the overview, so that more than 1 piece of guidance is produced.

This approach has to be considered in the context of the need for effective use of programme resources and Committee time, and potential usefulness to the NHS of the resulting guidance. The technical team refer to the brief when prioritising studies.

In practice, subjective judgements are made, informed by these considerations. Analysts may seek a second opinion from other members of the technical team and any disagreement about the inclusion or exclusion of a particular study is resolved by consensus. If consensus is not possible, a third opinion from another member of the technical team, usually more senior, is also sought. The person offering the third opinion makes the final decision.

In general, studies that are designed and executed in a way that is most likely to minimise bias are included in the evidence summary table. A number of checks are used to establish whether the right studies have been selected for inclusion, including using the expertise and knowledge of the specialist advisers, the notifier of the procedure, the specialist Committee member and, ultimately, consultees who respond to the consultation on the draft guidance.

The treatment effect of a technology can be summarised as the difference between the health state or quality of life that would, on average, be experienced by patients having the technology, and the health state or quality of life of the same group were they to have standard or sham (placebo) treatment. The following criteria are considered when selecting evidence on safety and efficacy for the overview:

## **General quality considerations**

Quality of evidence relates to the methods used to minimise bias within a study design and in the conduct of a study.

### **Study design**

Levels of evidence are a convenient way to summarise study design according to its capacity to minimise bias. The highest value has traditionally been placed on evidence from systematic reviews or meta-analysis of RCTs, or 1 or more well-designed and executed RCT. However, the level of evidence is only 1 dimension when considering validity and relevance. Depending on the procedure and the most important outcomes being considered, non-randomised studies may be more informative, for example, for safety outcomes. In developing the brief, the programme team considers the study design that is most relevant to the outcomes of interest.

### **Study size**

Assuming that other considerations about study type and methods are equal, priority is usually given to studies that include larger numbers of patients. This is important so accurate estimates of efficacy and safety can be given, and to optimise the possibility of identifying less frequent safety outcomes.

### **Follow-up duration and completeness**

Assuming that other considerations about study type and size are equal, priority is usually given to studies with longer and more complete follow-up. This is particularly relevant for assessing efficacy and safety in the context of certain conditions (such as cancer and conditions that cause long-term disability), and for procedures relating to implantable materials or devices. Prolonged follow-up is also important to detect rare adverse events after procedures.

### **Patient-focused efficacy and safety outcomes**

Patient-focused final, as opposed to surrogate, outcomes are considered particularly important when judging the efficacy of a procedure. For example, evidence that a procedure reduces tumour size carries less weight than evidence about benefits such as enhanced survival or improved quality of life.

Because safety is an important issue, studies that systematically report adverse events are sought. Safety outcomes are often not well addressed in randomised trials. Large numbers of treated patients are needed to reliably detect uncommon yet serious adverse events. Large case series, surveys and registers may provide valuable information. Case reports of rare complications may also be useful, particularly when there is concern about the potential for rare but serious complications. Although these sources lack data to support incidence calculations, they provide information that can be highly relevant. This is particularly the case for serious adverse events that occur in the treatment of conditions with little impact on quality of life and/or with a good prognosis.

### **Procedures for which no comparator (controlled) data are reported**

Sometimes, all the evidence for a procedure is from non-comparative studies (for example, reports of case series). Selected evidence about key efficacy and safety outcomes of established practice may then be presented.

### **Procedures involving a diagnostic or monitoring test**

Some interventional procedures are carried out to obtain diagnostic or monitoring information during the procedure or to enable information to be collected subsequently (for example, carrying out a biopsy or implanting a telemetric device). Although a standard overview is produced for such procedures, there are special considerations in relation to the assessment and Committee decision-making.

Evidence about diagnostic tests relates to:

- analytical validity – whether the test detects the biomarker of interest in a laboratory setting
- clinical validity – whether the test detects changes in disease state or risk in a clinical setting
- clinical utility – whether the test improves patient outcomes.

Evidence on diagnostic tests largely consists of studies of analytical and clinical validity. Studies showing the impact of diagnostic tests on patient outcomes are less commonly available. All relevant evidence on analytical and clinical validity, and on

clinical utility, is included in the efficacy section of the overview. Specialist advice on clinical utility is collected to support the Committee's interpretation of the relevance of the evidence on analytical and clinical utility.

### **Inclusion of unpublished or non-peer reviewed data**

#### **Efficacy data**

Efficacy data that are unpublished or not peer reviewed are not 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 accepted, provided that the publication date is before the guidance is published.

A notable exception to this is efficacy data from registers, which will be included if:

- 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.

#### **Safety data**

Data on safety, however immature, may come from abstracts, companies, 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.

## **9.3      *The overview***

### **General approach to the overview**

Different terminology to report identical or similar outcomes is often used in studies included in the overview. For example, erectile dysfunction may also be described as male sexual dysfunction or impotence; insomnia might also be called sleep

disturbance. If there is no universally accepted nomenclature of signs and symptoms, the programme team may opt to 'translate' specific signs and symptoms to more widely used or reported terms. The original term is introduced, with an explanation about its subsequent substitution to improve readability and help with comparisons between studies. Symptom grading scales reported or referred to in the studies are described in the overview provided they are commonly recognised.

In the overview, a quantified outcome is usually expressed as a rate:  $x\%$  ( $r/n$ ), where  $x$  denotes a percentage value,  $r$  denotes the numerator value and  $n$  denotes the denominator value. If a denominator is less than 10, the rate is given as a fraction ( $r/n$ ), without a % value. In studies where only  $x\%$  is provided in the primary study report, the  $r/n$  is not usually calculated from assumed values.

Confidence intervals around rate values are not usually calculated; they may be included in the overview if reported in the primary report and considered relevant.

It is usually appropriate to present statistical comparisons in the overview when reporting the results of studies that contain comparative data. When a reported comparative outcome is considered important enough for inclusion in the overview, the  $p$  value reported in the primary study is also given. If no significance level is reported, it says 'not reported' or 'NR'.

Although some interventional procedures assessed by NICE involve implanting or using a medical device, the programme does not evaluate the device itself: the focus is on the procedure. The programme only considers the efficacy and safety of a procedure using devices that are CE marked. Evidence about the procedure relating to devices without CE marking is selected for the overview if the evidence meets the inclusion criteria. If proprietary names of medical devices are specified in the published studies, these names may be included in the overview of the evidence, but interventional procedures guidance does not name companies' devices or brands.

Formal submissions from device companies are not used by the programme. If the literature search shows that the published evidence for a procedure is very limited, NICE may contact the companies involved to ask for additional information. If NICE

is made aware of relevant material not in the public domain, it will consider whether to include this in the overview using the normal approach to selection of evidence for the overview.

### **Evidence summary table**

The evidence summary table included in the overview comprises:

- study details
- analysis (brief critical appraisal)
- efficacy outcomes
- safety outcomes.

### **Study details**

Study details are usually structured as follows (details are included when provided by the primary study report):

- reference (first author – surname and initials – and year)
- study type/design, that is:
  - health technology assessment or systematic review (of RCTs or non-RCT studies)
  - RCT
  - non-RCT
  - case series
  - case report.
- country (or countries) where study was done
- recruitment period
- study population and number (total number of patients and, when relevant, number of patients treated with the procedure of interest)
- age and sex of patients
- patient selection criteria
- technique (details of procedure done) and comparator (where relevant)
- length of follow-up (mean or median when stated)
- details of any conflicts of interest declared by the authors.

### **Critical appraisal of the evidence (analysis)**

The programme analyst makes critical appraisal comments to identify issues that might influence the interpretation of evidence. These normally relate to study design, quality of study and statistical analysis, effect size and relevance of the outcomes.

While a number of critical appraisal checklists exist, it is difficult to be prescriptive about using such lists because the relative importance of the issues varies according to the procedure, the indication and the available evidence.

The programme analyst may comment on the following issues when reporting on a primary study or systematic review of primary studies:

- patient selection
- patient enrolment/recruitment method (for example, whether it was continuous)
- previous operator training for the procedure
- previous volume of experience of operators or participating unit(s) with the procedure
- relevance of outcomes measured
- validity and reproducibility of measurement of outcomes (for example, blinding)
- appropriateness of analysis (for example, intention-to-treat analysis)
- completeness of follow-up, for any studies involving post-procedure follow-up
- reasons for loss to follow-up
- general considerations about validity and generalisability of the studies, when appropriate
- inclusion of the same patients in more than 1 study
- multiple reporting of a single study
- other potential sources of bias.

The evidence summary table in the overview 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.

The overview also contains advice from specialist advisers and commentary from patient commentators, which are described in section 10.

Sometimes, the volume or complexity of evidence (or the complexity of the procedure) makes it too difficult to present to the Committee in the format of an overview. In this case, NICE commissions an External Assessment Centre to produce a systematic review.

## **9.4 Systematic reviews**

### **Reasons for commissioning a systematic review**

After considering the brief and the available literature, the programme team may decide to refer the procedure to an External Assessment Centre for a systematic review. Criteria used to help identify procedures for which a systematic review might be appropriate include:

- when the size of the evidence base is too large to prepare in the format of a standard overview
- when the procedure has the potential to cause serious adverse events and the evidence therefore needs a complex statistical analysis to enable the Committee to make a decision
- when the procedure has more than 1 indication or involves more than 1 technique.

Occasionally, after considering the overview and specialist advice, the Committee may request a systematic review. This may occur, for example, when the Committee has found that the evidence is difficult to interpret, or considers that it leads to apparently contradictory conclusions.

When a systematic review is needed, NICE selects an External Assessment Centre to carry it out. The systematic review normally takes 6 months to complete. Revised timelines for the development of guidance on the procedure are presented on NICE's website.

### **Process for carrying out a systematic review**

A brief is prepared by an External Assessment Centre and agreed by NICE and the Committee. It describes the aims of the systematic review and the methodology to be used, including a table setting out the relevant population, intervention, comparator and outcomes (PICO).

External Assessment Centres do systematic reviews using methods proposed by [the Centre for Reviews and Dissemination](#) and [the Cochrane Collaboration](#). Systematic reviews include evidence from all available relevant scientific sources, including published research and conference abstracts, with the aim of providing the most up-to-date body of information. Unpublished sources of information are also sought. The review process incorporates a formal assessment of the methodological quality of included full-text studies, and indicates if material is unpublished.

The systematic review and related documents are published on NICE's website with the consultation document at the time of consultation.

For each systematic review, the External Assessment Centre seeks clinical advice specific to the procedure(s) under assessment. The Centre is responsible for getting this advice. In preparing the systematic review, the Centre may also need input from appropriate individuals and organisations, including:

- companies, if a medical device or devices are involved in the procedure
- patient groups, for example, in the interpretation of patient-reported outcomes
- regulators such as the Medicines and Healthcare products Regulatory Agency and the US Food and Drug Administration, in relation to the regulatory status of products and safety reports.

## **10 Advice and commentary**

In addition to the evidence in the overview, the Committee considers advice and commentary in formulating its recommendations on procedures.

## **10.1 Opinions of specialist advisers**

NICE seeks the opinion of as many specialist advisers as are deemed appropriate for the procedure. Advisers are requested from specialties involved in the procedure (sometimes more than 1 specialty) and also, when relevant, from specialties involved in the selection, referral and care of patients having the procedure. The appropriate number of professional organisations depends on the number identified in the brief. The number of questionnaires that are returned to NICE also depends on professional organisations nominating their members, and the number of individual advisers returning their questionnaire to NICE within the required timescale before it is considered by the Committee. New procedures often have potential benefits and, importantly, risks that are not yet fully described in the scientific literature. Specialist advisers provide insight into these aspects, sometimes supported by accounts of their clinical experience. They have an essential role in the process of assessing novel interventional procedures; their knowledge and opinion provides supplementary evidence that may be absent from the scientific literature. A list of all [current specialist advisers](#) is on NICE's website.

NICE approaches the relevant professional organisations for the names of specialist advisers for each procedure, and gets the opinions of these identified advisers if possible. NICE also makes use of previously approved advisers, if necessary, to maintain timeliness.

Occasionally, NICE may not be able to find specialist advisers with sufficient knowledge of the procedure to give advice. This is most likely to occur with very new procedures. If 2 specialist advisers cannot be found from those approved in the relevant specialty or specialties, NICE will normally delay developing guidance on the procedure until suitable specialist advice is available. This is because absence of advisers with any knowledge may suggest that the procedure is not currently being used. Rarely, it may be appropriate to proceed with a single specialist adviser, at the discretion of the Committee Chair and by agreement with the Programme Director, provided the Chair considers that sufficient advice is available to the Committee for it to make a sound decision.

Specialist advice is usually provided via a questionnaire. Questionnaires completed by specialist advisers are copied to the professional body that nominated them. The completed questionnaires are published on the NICE website at the same time as the overview, when the consultation period for the draft guidance starts.

A clinician who has notified NICE about a procedure cannot normally act as a specialist adviser for that procedure. However, there may be times when a notifier's expertise in, or specialised knowledge of, the procedure means that it is appropriate to ask for their advice.

All specialist advisers are asked to declare their interests in line with NICE's policy on [conflicts of interest](#). Specialist advisers' interests are available to the Chair and the Committee alongside the questionnaires.

A specialist adviser may be asked to provide more detailed assistance to the programme. This includes, but is not restricted to, attending Committee meetings (either by telephone or in person), commenting on an audit tool (if it is identified for the procedure), commenting on the suitability of registers for compiling further data on the procedure and commenting on the lay version of the guidance. The opinion of specialist advisers is sought on the following issues:

- possible controversy between specialties over the procedure
- whether they consider the procedure to be established, a minor variation on current practice, novel or the first in a new class of procedure
- interventions that could be considered as comparators
- potential adverse events associated with the procedure
- uncertainties or concerns about the efficacy or safety of the procedure
- suggested efficacy and safety outcomes for audit
- training or facilities needed to do the procedure safely
- current research or registers
- current and likely future impact of the procedure on the NHS.

## **10.2 Evidence from companies**

### **Structured information request**

While preparing the brief, 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 will make a structured information request to the companies involved at the beginning of the assessment of the procedure. This will normally be done at the time NICE is preparing the brief for the procedure.

The structured information request covers limited factual information on:

- settings and locations in which the product is being used for the indication or purpose in the assessment
- 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.

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.

### **Company attendance at the Committee meeting**

NICE invites companies that it has identified in the procedure brief, 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.

### **10.3 Contributions from patient commentators**

NICE's public involvement programme (PIP) seeks information about the impact of both the condition and the procedure on patients or their carers before the Committee meeting. Patient commentators can provide insight into outcomes not fully described in the scientific literature, such as quality of life. Their views are obtained by means of a questionnaire.

NICE tries to ensure that patient opinions are obtained by questionnaire for as many procedures as possible. However, because it relies on clinicians agreeing to send questionnaires to patients on its behalf, delays in this process or lack of response from patient commentators may mean that the questionnaires are not always available to NICE. To maintain timeliness, NICE does not delay guidance development if patient questionnaires are not available for a procedure. If patient questionnaires are not available to the Committee when it produces its draft recommendations but become available during the consultation period, the Committee considers the questionnaires when making its final recommendations.

The names of patient commentators are personal data under the Data Protection Act 1998 and are not normally released into the public domain. However, an anonymised copy of information supplied by patients about their experience of the procedure is available on request.

Occasionally, the programme is notified about procedures for which it may be inappropriate or impossible to obtain commentary from patient commentators (for example, an intraoperative diagnostic procedure that a patient may be unaware has been used during their treatment). The suitability of a topic for gaining patient commentary is discussed as part of developing each brief. Patient commentary is not sought if the Committee Chair, the programme team and the PIP all agree it would not be appropriate.

For all procedures, a statement is made in the guidance to indicate what NICE did to obtain patient commentary, and with what results. This is normally covered by 1 of the following categories:

- no commentary sought by NICE, and reasons why
- commentary sought but no replies received
- commentary received that was/was not in agreement with evidence (fewer than 10 received)
- commentary received that was/was not in agreement with evidence (10 or more received) and a summary was prepared. (This adds detail of what was noted.)

NICE is aware that patients with experience of specific procedures have a unique insight that may be of value to the Committee in formulating its recommendations. NICE is committed to taking this into account when assessing procedures.

### **Patient commentators' responses**

Patient commentators' responses to the questionnaires, which have been anonymised, are presented to the Committee to help it formulate recommendations. When responses number 10 or more, a summary is prepared for the Committee.

### **How patient commentary is used**

Commentary on patients' experiences of the procedure is considered by the Committee when it formulates its recommendations, particularly when issues are raised that are not reported in the published literature. Descriptions of the benefits or harms of procedures that may only be identified by patients are of interest, particularly those relating to quality of life, for example:

- living with the condition
- comparing life before and after the procedure
- side effects of the procedure
- experience of disease progression with and without the procedure
- outcomes that patients value most from the procedure
- the difference the procedure may make to:
  - the physical wellbeing of patients (symptoms, pain, mobility, disability)
  - lifestyles and the choices that matter to patients and carers (impact on daily activities, work, hobbies, social life, relationships)

- the psychological health of patients and carers (for example, mood, anxiety, distress)
- the balance between quality of life and length of life (if appropriate)
- the various treatment choices that matter to patients and carers.

## **11 The Committee's assessment of efficacy and safety evidence**

This section describes how the Committee weighs the evidence presented to it. In particular, it explores specific factors underpinning the Committee's consideration of efficacy (section 11.4) and safety (section 11.5). This section also describes how evidence and commentary received as part of the consultation process are considered by the Committee when producing its final recommendations.

The Committee makes recommendations about the procedure on the basis of the evidence relating to its efficacy and safety. Both efficacy and safety may be affected by certain variables about which published evidence provides little or no helpful information. For example, the individual operator and the different devices used to do procedures are often important in this context.

### **11.1 *The operator***

The outcomes of many procedures are influenced by the training, experience and aptitude of the operator. This applies particularly to procedures that need great technical skill, such as complex laparoscopic operations. Many procedures are said to have a 'learning curve'; this can affect outcomes in published series used as evidence, as well as the outcomes for clinicians who start doing new procedures.

Specialist advisers are a valuable source of advice about procedures that present technical challenges or for which special training is desirable. These considerations may influence the Committee's recommendations about the procedure, and are often translated into recommendations about training.

## **11.2     *The device***

For some procedures, a particular device must be used. This introduces important variables that need to be taken into account in NICE guidance:

- Evidence may only be available for a particular device or devices, even though others may be in use.
- New devices may be introduced into the market at any time during the development of the guidance, or after it has been published.
- The technology of devices may advance rapidly. This means that both efficacy and safety outcomes reported in the published literature may not accord with 'current practice' using more technologically advanced devices; further technological progress may further alter outcomes.

The Committee makes recommendations based on the available evidence, while bearing in mind that it is evaluating the procedure rather than a specific device. The guidance may refer to the potentially important influence of different devices on the safety or efficacy of the procedure, or to rapid technological developments described by the specialist advisers, companies or other sources.

## **11.3     *Comparisons with other procedures***

Comparison of a procedure's efficacy with that of established procedures is appropriate when they are used to treat the same condition and there are well established alternatives. This also applies to safety: the frequency and severity of complications of any established procedure are used as a benchmark against which the complications associated with a new procedure are judged.

The relevance to the Committee's decision of comparative efficacy varies, depending on what other procedures or treatments are in use for the condition. Typical scenarios are:

- There are a number of different established procedures. Judgements about efficacy are based on an overview of the available evidence on efficacy of the established procedures, but there is no need for any specific comparisons.

- The procedure is intended to replace a single, well-established, procedure. Comparative evidence is needed to show that the new procedure is equally, or more, efficacious than the existing one (also taking into account other advantages that the new procedure may have for patients).
- The procedure is an addition to an established one, intended to enhance efficacy. Comparative evidence is needed to show that adding the new procedure to the established one increases efficacy.
- No procedure or treatment exists for the condition, or those that are used do not have proven efficacy. There can be no consideration of comparative efficacy and any comparison must be against the natural history of the condition and/or sham (placebo).

Comparison of efficacy is straightforward when randomised studies comparing established and new procedures are available. The aim of such comparison is to ensure that a new procedure works at least as well as established treatments; evidence of superior efficacy is neither necessary nor usually expected. A new procedure may have other advantages, such as being less invasive or allowing faster recovery. The most important aspect of any comparison of the safety profile of the new procedure with that of established procedures is to ensure that the new procedure is not less safe.

Often, however, direct comparisons are not available, and judgements about the efficacy and safety of a new or established procedure need to be made indirectly or on the basis of the opinions of specialist advisers.

Comparison can be particularly difficult when published data about an established procedure are limited. For some common and well-established procedures, there is little evidence on their efficacy for certain indications, or on their safety profile, particularly about the incidence of uncommon but serious complications.

#### **11.4      *Decisions about efficacy***

The Committee gives precedence to outcome measures directly relevant to patients and their quality of life when making decisions relating to efficacy.

### **Consideration of benefits**

The Committee considers the nature of benefits, their magnitude, the ways in which they can be assessed and their duration. All these criteria need to be considered in the context of the natural history of the condition being treated or investigated, and compared with outcomes after established treatment options. There also needs to be evidence of sufficient benefit to justify subjecting a patient to a procedure and its risks. Minor improvements in outcome measures that do not seem to translate into real clinical improvements will not support a decision that a procedure is efficacious.

### **Outcome measures**

Evidence of improved survival, reduced morbidity or improved quality of life carries more weight in decision-making than surrogate outcomes (such as those shown by imaging or biochemical markers). The Committee may identify outcome measures that it considers to be particularly appropriate and suggest these for future research and audit.

### **The absence of comparative studies**

IPAC often considers evidence from single-arm studies such as case reports and case series. Occasionally, the Committee may decide that more information is needed from studies that compare an active treatment against a sham procedure or standard treatment. Then, guidance may recommend that comparative studies are done.

### **Consideration of efficacy of procedures that provide diagnostic or monitoring information**

There are particular considerations when NICE develops guidance on a diagnostic procedure because it is important to ensure that the assessment encompasses the value to patients of the diagnostic information generated by the procedure under consideration. The programme does not have the remit or methods to evaluate subsequent treatment in the management pathway, which may be influenced by the results of a diagnostic test. However, to arrive at a reasonable view of the efficacy of the diagnostic test used in the procedure, the Committee must take into account whether it can reasonably be considered to change clinical decision-making and subsequent management in a way that is likely to benefit patients.

The scientific literature for diagnostic tests consists largely of studies of analytical and clinical validity. Evidence on the impact of diagnostic technologies on final patient outcomes (clinical utility) is generally limited. To conduct an assessment for interventional procedures guidance, NICE seeks specialist advice on the clinical utility of the diagnostic procedure so it can provide information on whether the diagnostic procedure can plausibly inform clinical decision-making and so benefit patients. The Committee considers analytical and clinical validity data on the diagnostic procedure only in the context of advice that it has plausible clinical utility.

### **Short-term efficacy**

This is almost always important. A procedure that does not provide benefit in the short term is unlikely to be considered efficacious. Short-term efficacy may sometimes be the only requirement. For example, for a new procedure to treat an acute illness such as appendicitis, the expectation of long-term benefit is implicit once the appendix has been removed (or other acute condition treated) and the patient has recovered.

### **Long-term efficacy**

This can be a problem for procedures that have not been used long enough to allow for lengthy follow-up studies, and can mean the evidence on long-term efficacy is small in quantity or of poor quality. Examples of procedures that must have durable results to be considered efficacious are insertion of prosthetic joint components, procedures to relieve urinary or faecal incontinence, and procedures intended to cure cancers.

## **11.5      *Decisions about safety***

No procedure is completely safe; all interventions are associated with risks.

Decisions relating to safety need to be made in the context of the natural history of the condition being treated or investigated, and the alternative treatments available.

It is important to point out the difference between a recommendation based on the Committee's assessment that the evidence on safety is adequate and the concept that a procedure is safe. If the Committee considers that evidence on safety is adequate in quantity and quality, this means that there were sufficient data to inform

a decision about safety. A procedure may nevertheless be associated with significant risks of serious complications, but it is considered that enough is known about those complications and their frequency to construct recommendations for the procedure's use.

### **Seriousness and frequency of reported adverse events**

When assessing safety, both the seriousness and frequency of adverse events are considered. A low risk of very damaging complications is generally considered to be a more significant safety issue than a high risk of minor complications. Most importantly, patients (or their parents or carers, when appropriate) should be informed and should understand the risks when offered the procedure. This always means telling them the known risks, and it may also mean telling them that there is uncertainty about the frequency of complications – in particular uncommon and serious ones. This consideration informs the Committee's recommendations on consent.

### **Quantity of evidence on safety outcomes**

The number of reported cases considered adequate to make or support a decision relating to the safety of a procedure is influenced by:

- the natural history of the condition
- the prevalence of the condition
- the expectation of likely adverse events.

For a procedure that is used to treat a rare but rapidly fatal condition, safety data based on only a few reported cases may be considered adequate. In contrast, for a procedure for a common condition that is not a serious threat to health, and about which theoretical concerns have been raised about a possible uncommon, but serious, complication very large numbers of well-reported cases may be needed to adequately assess its safety.

### **Quality of evidence on safety outcomes**

Decisions relating to safety are strongly influenced by the completeness with which adverse events appear to have been reported in the available studies and case

series. Some studies make clear that safety outcomes have not been reported at all, whereas other studies present complications in great detail (to the extent that some of these outcomes may be judged as expected sequelae of the procedure).

Particular difficulties arise in making decisions about safety when:

- studies do not report any adverse events but fail to make clear whether none occurred, or whether events were simply not recorded or reported
- specialist advisers refer to specific theoretical complications as matters for concern (and even cite anecdotal complications known to them), but there are no reports of these complications in the published literature
- the frequency of adverse events varies markedly between studies
- several different devices may be used for the procedure and these are examined differently in the available evidence; that is, different devices may have been examined in different studies and there may be no data on others.

In making decisions relating to safety, the Committee generally adopts a proportionate risk-averse approach, preferring to take account of higher complication rates and advice that raises concerns rather than low complication rates (when studies vary) and more optimistic advice. The Committee will also take into account the quality of the evidence base because variation in safety findings between studies may be related to study quality. A precautionary approach is particularly important when considering procedures for chronic conditions with good overall prognosis.

### **Impact of adverse events on patients' quality of life**

The Committee takes account of the impact of complications on patients' quality of life, informed by advice from both patients and specialists. Lay members of the Committee in particular are able to make contributions on this matter.

### **Short-term safety**

This is always important and includes complications (morbidity and mortality) during the procedure and shortly afterwards. Interventional specialties commonly use the first 30 days after the procedure as the interval for 'postoperative complications' in reported series.

### **Long-term safety concerns**

Some procedures pose risks of adverse events that only become apparent in the longer term. The likelihood of these occurring may either be suggested by the nature of the procedure (for example, insertion of a prosthesis) or raised by specialist advisers on the basis of their experience (advisers are questioned about adverse events when providing advice on a procedure). Lack of long-term safety data is a frequent problem. If there is uncertainty or concern about long-term safety in the context of the severity of the condition being treated, the Committee may decide that the safety data are altogether inadequate. If the risk of delayed adverse events is only theoretical or sufficiently remote, the decision may be simply to advise reporting of these if and when they occur, to inform future practice.

## **12 Provisional recommendations**

The Committee makes its provisional recommendations on the efficacy and safety of the procedure, taking into account the overview, specialist advice, patient commentary and factors related to equalities. Provisional recommendations are formulated in accordance with the [NICE equalities scheme](#).

For each procedure, the Committee makes recommendations on conditions for the safe use of the procedure. These include details of the arrangements that should be made for consent, audit and clinical governance. Recommendations take into account efficacy and safety in both the short and the longer term. The relative importance of either short- or long-term outcomes may vary according to the nature of the condition (for example, whether it is acute or chronic). Often, explicit statements are made about each of these 4 aspects (that is, efficacy in the short and long term, and safety in the short and long term). However, sometimes specific reference to each is implicit or unnecessary on the basis of the clinical knowledge, or because long-term follow-up considerations may, by their nature, be inapplicable for certain procedures and conditions.

The Committee does not have a remit to determine the place of a procedure in the pathway of care for the condition or disease in question, or to consider the cost effectiveness of procedures.

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 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.

### **12.1 *Main types of recommendations made by the Committee***

The main recommendations made by the Committee are intended to address the practical steps that clinicians should take to carry out the procedure safely in relation to their hospital's clinical governance arrangements, the patient consent process and the collection of data. The Committee may include comments in the guidance describing its judgement of the evidence, and the balance between risks and benefits, or other important factors affecting their decision.

Sometimes, it is appropriate to make 2 different recommendations in the same piece of guidance. This normally happens when, for example, there are 2 different patient groups for whom the risks and benefits of the procedure differ.

#### **'Standard' arrangements**

For a procedure to be recommended for use with standard arrangements for clinical governance, consent and audit, the evidence should be adequate in the following respects.

- It should be valid, relevant and of good quality.
- It should be available in sufficient quantities for the Committee to make a positive decision.
- It should be sufficiently consistent in nature.
- It should show benefits within an appropriate time of the procedure (short- or long-term efficacy). It may not be practical to obtain long-term efficacy evidence for some recently introduced procedures, so specific recommendations may be made about the need for more data on long-term outcomes. When long-term safety issues seem relevant, data on these should be adequate or the need for reporting on long-term safety outcomes may be stipulated.

- It should be shown that the frequency and severity of adverse effects of the procedure are similar to, or less than, those of any comparable and established procedures. In exceptional circumstances, the frequency and severity of adverse events may be greater, but this would normally only lead to a recommendation for standard arrangements if the procedure has a much greater benefit: that is, in reasonable proportion to the severity of the condition being treated and the size of clinical benefit obtained; and acceptable in the context of the natural history of the condition.

### **‘Special’ arrangements**

A special arrangements recommendation states that clinicians using the procedure must inform the clinical governance lead in their trust, tell the patient about the uncertainties regarding the safety and efficacy of the procedure and collect further data by means of audit or research. The Committee recommends these arrangements when using a procedure because there are significant uncertainties in the evidence on efficacy or safety, or an inadequate quantity of evidence. The Committee may also consider the balance of risks and benefits of the procedure is such that special arrangements should be in place. This recommendation is often made when the procedure is considered to be emerging practice in the NHS.

When the Committee recommends special arrangements and audit is needed, and there is no data collection facility in place, NICE prepares an audit tool containing audit criteria for use with the procedure, drawing on advice from specialist advisers and Committee members. NICE publishes the audit tool with the guidance.

### **‘Research only’**

Sometimes the Committee recommends that the procedure should be carried out only in the context of formal research studies approved by a research ethics committee. This recommendation is normally made when at least 1 of the following is the case:

- the procedure is still considered to be experimental in nature
- the level of uncertainty about the efficacy or safety evidence is such that it is considered to be in the best interest of patients to recommend controlled

investigation of the procedure under the scrutiny and protection of research ethics committees

- resolution of substantial uncertainties about its efficacy or safety would be fundamental to its routine use.

In guidance that recommends research only, the Committee normally makes specific research recommendations, stating the areas of uncertainty that the research should address, and sometimes referring to outcomes or other details that should be addressed in studies. The NICE Research and Development (R&D) team monitors all published NICE guidance and extracts these research recommendations. They are added to the NICE research recommendation database and made publicly available on the NICE website. This database is monitored by research funders such as the National Institute for Health Research (NIHR). For example, the NIHR National Evaluation, Trials and Studies Coordinating Centre (NETSCC) actively reviews all NICE research recommendations and considers for funding those that are within the remit of the programmes that they manage.

For a pilot phase starting in 2015, NICE is able to designate specific research recommendations as a 'NICE Key Priority'. These are fast-tracked through the NETSCC development and review processes. Such a designation may only be made when the Committee Chair and the Centre Director agree that it is appropriate. Then, NICE consults NIHR NETSCC about the proposed priority designation before the guidance is finalised. Further information on this process is provided in the [NICE Research Recommendations Process and Methods Guide](#).

#### **'Do not use'**

When the evidence suggests that a procedure has no efficacy or poses unacceptable safety risks, the Committee recommends that it should not be used.

## **12.2 Additional recommendations to support effective use of procedures**

### **Clinical teams and specialised units**

The Committee sometimes recommends that a procedure should only be done by a specific type of clinical team or unit. Recommendations of this kind are usually based on the views of specialist advisers or comments received during consultation, and take into account the following:

- Appropriate team members and adequate facilities can be important for some procedures.
- Specialist teams may need members to help with patient selection, counselling, doing the procedure, dealing with unexpected problems, care during recovery, adjuvant treatments and rehabilitation.
- Some procedures can be skilfully done by clinicians of more than 1 specialty.

Recommendations may stipulate that specific team members are considered essential. They may state that the team 'should include' particular specialists, but recognise that the make-up of an appropriate team may vary between units. Recommendations sometimes refer to supporting services needed to deal with potential problems arising from a procedure.

It is not within the remit of the interventional procedures programme to make recommendations on the number of procedures (or similar procedures) that should be carried out regularly, or should have been done previously by a clinician or unit, even though this is sometimes suggested during consultation. It is the role of commissioners of health services to set these types of standards for the hospitals that provide their services. It is recognised that some units will be starting to use a procedure de novo, and that they may not initially be able to do the procedure in substantial numbers. The important issues to be considered are access to appropriate training and thorough audit within a clinical governance framework, both during and after the introduction phase of the procedure.

## **Training**

It is expected, without being stated in the guidance, that consultants should be adequately trained to do procedures within their specialty. Similarly, it is expected that consultants involved in the delivery of a diagnostic or therapeutic intervention that involves radiation exposure are accredited in its use. Special knowledge and training may also be needed to use certain devices, including those that deliver energy such as laser, radiofrequency or ultrasound. Therefore, specific recommendations about training are made only when particular training issues have been raised by specialist advisers, comments from consultation or publications. Most often these issues relate to difficult technical challenges that may necessitate an above normal level of training, expertise or experience for a specialist in the relevant discipline.

Consultants are, by definition, fully trained in their own specialty. The term 'training', as used in the Committee recommendations, is intended to encapsulate all ways of acquiring knowledge and skills from others, such as mentoring and supervising, for the procedure in question.

When possible, the Committee seeks to identify procedures that need an enhanced level of training or experience and to reflect this in their recommendations.

Specifying the kind of training needed is not possible unless published standards exist, or there are training courses that have been recognised and supported by the appropriate professional organisations. Training or standards that are already provided by professional organisations are referenced in the guidance. If specialist advisers advise the Committee that specific training is essential, and if no published standards exist, then NICE may approach professional organisations with a request to publish standards that can be referred to in the guidance.

For some procedures, specialist training for members of the operating theatre team, other than the clinician doing the procedure, may also be needed and this is specified in the guidance.

### **Other information**

Other information may be included in the guidance, for example, on whether evidence suggests that certain patient subgroups may derive a greater or lesser benefit, or be at a greater or lesser risk, from a procedure and about regulatory issues, such as off-label use of pharmaceutical products. These issues are normally addressed in the 'committee comments' or the 'further information' section of the guidance.

### **12.3 Data collection to address uncertainty**

When data on efficacy or safety are inadequate, the recommendations usually refer to the need for further evidence generation to enable NICE to review and update the guidance. The outcomes that are most needed are specified, for example, quality-of-life measures or long-term outcomes. The guidance may recommend either research in formal clinical studies or through routine data collection through a register. The considerations for recommending a specific type of research design are:

#### **Formal clinical studies**

If an appropriate research study is in progress or is nearing the stage of recruitment, a recommendation may be made for clinicians to enter patients into that study. This involves the Committee judging that the study is viable and that its main outcomes are relevant to the guidance. In these circumstances, a recommendation to enter patients into the study is considered likely to benefit recruitment and to lead to more rapid data collection. The Committee considers whether the trial is open to recruitment of patients by clinicians who are not already involved. The consultation document refers to the trial by name.

The situation is more difficult when additional formal clinical research would clearly be of value but there are no ongoing studies into which clinicians might be recommended to enter patients. This is a common situation. The practical and procedural obstacles and resource needs for setting up new clinical research projects are considerable, and the delay between deciding to address a research question and starting to recruit patients may be lengthy. In these circumstances, the Committee may comment on the desirability of further evidence on the procedure,

referring to the outcomes for which improved evidence would enable NICE to update the guidance.

## Registers

When the data on the efficacy or safety of a procedure are inadequate in quantity or quality, the Committee may recommend that data be collected on all patients having the procedure. The aims are:

- to accrue evidence for future update of the guidance
- to monitor the use and dissemination of the procedure
- to encourage audit of outcomes.

A recommendation for data collection through a register may specify sending data to:

- an established register specific to the procedure
- an established register that includes several related procedures
- an established register that is to be modified to enable data collection on the procedure
- a new register, created as a result of the guidance.

Before an established register is recommended, the programme team confirms that the standards in table 2 are met, using the criteria outlined.

Patient Reported Outcome Measure (PROMS) data are used if collected through a national register that meets the standards in table 2.

**Table 2. Register standards and criteria**

Standards	Criteria
All procedures (all devices), without exception, are recorded in the database	<p>Raw anonymised data available for secondary analysis and validation.</p> <p>Denominator data available to assess data coverage, such as sales figures and routine health service information.</p>

<p>The data recorded address relevant efficacy and safety outcomes</p>	<p>Medicines and Healthcare products Regulatory Agency/NICE and professional representatives involved in dataset design and agree final protocol.</p> <p>Data include details of modifications or evolution of procedure/device and numbers done for the original indication (and respective outcomes).</p>
<p>Independent oversight</p>	<p>Independent steering group responsible for design, data monitoring and analysis.</p> <p>Register recorded on national database of registers.</p> <p>Explicit intent to publish results whatever the outcome.</p> <p>Process for data collection, storage and analysis independent of any company.</p>

In some cases, NICE commissions an External Assessment Centre to establish a national register to collect observational data on procedures for which the Committee has identified a need for further evidence. This usually relates to the long-term safety and efficacy of a procedure.

#### **12.4      *The interventional procedure consultation document***

When the Committee has made preliminary recommendations, NICE issues a public consultation document. This sets out:

- 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 of the Committee about the procedure and the evidence presented.

## **13 The consultation process**

When consultation begins, NICE publishes the consultation document for comment on its website for 4 weeks. It also informs, by email, everyone who registered an interest that consultation has begun. During consultation, anyone may submit comments via [NICE's website](#) using a structured web form, or by email, fax or post. NICE only accepts comments submitted as part of the consultation process. It does not accept comments that are posted by third parties on other organisations' websites as consultation responses.

No person or organisation may submit comments of more than 20 pages, although this may be waived in exceptional circumstances at NICE's discretion. If a submission is longer than 10 pages, it should contain an executive summary of no more than 1 side of A4.

NICE is committed to promoting the values of equality and diversity through its guidance, and to eliminating discrimination. NICE encourages comments on its draft guidance from all sections of the community. Consultees are asked to highlight any

ways in which draft guidance fails to promote equality or avoid discrimination, and how it might be improved.

Late comments received after the 4-week deadline are shown to the Committee only at the discretion of the Chair, on the advice of the programme team. Late comments are usually considered if they highlight substantial new information, or are sent by ratified specialist advisers or professional organisations directly involved in patient care. The programme is not obliged to accept or note comments unless they are formally made during the consultation period.

It is up to consultees what they include in their response to consultation. However, the Committee particularly welcomes the following:

- comments on the preliminary recommendation(s)
- the identification of possible factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

All consultation responses are potentially important to, and potentially influence, the development of the guidance, including those that are entirely supportive of the proposed guidance.

During consultation, stakeholders submitting consultation comments are invited to complete a confidentiality statement enabling them to be involved in the programme's resolution process (see section 15).

### **13.1 Patient organisations and members of the public**

For each procedure considered by the Committee, the public involvement programme (PIP) contacts national patient organisations, if they exist, that represent the interests of patients affected by the condition(s) relevant to the procedure, including those that have a specialist interest in issues relating to equalities. The patient organisations are asked if they would like to contribute to the consultation process. Anyone wishing to receive alerts about the progress of a procedure can register as a stakeholder with the programme. Stakeholders (groups and individuals) are alerted at the start of the consultation process.

NICE only seeks expressions of interest proactively from national patient organisations. However, local branches of patient organisations and individual patients and carers are also encouraged to contribute to the consultation. Anyone interested in contributing from a patient or carer perspective can contact the PIP during the consultation if they need help to participate in the process.

NICE encourages consultees to include the following in their responses:

- views on the provisional recommendations
- views on how well the procedure works, including benefits or drawbacks to the patient that have been overlooked
- views on how safe (or unsafe) the procedure is, including any pain, side effects or complications.

### **13.2     *Medical device companies***

NICE encourages companies with products that are used to do the procedure to respond to the draft guidance.

NICE supplies the Association of British Healthcare Industries (ABHI) with a list of procedures that have briefs approved, and a list of procedures before public consultation. The ABHI alerts the companies whose devices it knows to be involved in doing a procedure to inform them of relevant consultations, giving them the opportunity to make consultation comments, directly to NICE.

### **13.3     *Professional organisations***

NICE encourages professional organisations to register an interest in the procedures done by their members in order to be alerted to consultation. Before consultation opens, NICE also alerts the relevant specialist advisers, their professional organisations and those with members who refer patients for the procedure, as listed in the brief.

### **13.4 Other stakeholders**

NICE informs the person or organisation that notified the procedure of the forthcoming consultation.

NICE also informs any person it recognises to be closely involved in a procedure's development. For example, if a procedure is named after the person who developed it, they are invited to comment on the draft recommendations. This includes developers who live outside the UK.

### **13.5 Stakeholders who register an interest**

Clinicians, patients and any other people or groups who have registered an interest in the procedure via NICE's website are alerted when consultation opens.

## **14 The production of guidance**

At a further Committee meeting, the Committee reviews the consultation document. It considers all the comments received during consultation and makes appropriate changes to the draft guidance. The Committee makes its final decision on the recommendations in the closed part of the meeting (discussion is divided into a Part 1: open and a Part 2: closed, in accordance with Section 1(2) of the Public Bodies (Admission to Meetings) Act 1960).

During the consultation period, an updated literature search is done by the guidance information services team to look for any further evidence that has been published since the overview was prepared. Any studies that meet the initial inclusion criteria are presented to the Committee when the consultation comments are discussed at the post-consultation Committee meeting, and are considered for inclusion in an updated overview. Also, the programme team investigates any relevant evidence highlighted by consultees and presents it to the Committee. This evidence, along with that in the overview, forms the final body of evidence on which the Committee's recommendations are based. The overview is then updated by the programme team before final publication of the guidance.

Consultation comments and NICE's responses to them are tabulated for each procedure. The table is published on NICE's website at the same time as the guidance. Individual consultees' comments are anonymised. NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all when, in the reasonable opinion of NICE, the comments are voluminous, or publication would be unlawful or otherwise inappropriate.

From time to time, comments received during consultation may prompt the Committee to:

- issue a new consultation document (typically, because the recommendations or the evidence base have changed substantially such that another public consultation is necessary), or
- refer the procedure to an External Assessment Centre for a systematic review (see section 9.4), or
- issue no guidance.

An explanatory statement is then placed on NICE's website.

NICE may decide to pause the development of guidance on a procedure, if important 'in press' or unpublished data are identified at consultation, until the new information is available.

The NICE Guidance Executive receives and considers the final guidance on behalf of the NICE Board. At this stage, the final guidance is subject to the resolution process.

## **15 The resolution process**

The resolution process is a final quality assurance step, intended to ensure that NICE acts fairly, follows its own processes and produces clear, accurate guidance. It is a final quality and content check for those stakeholders who have taken part in guidance development. The resolution process takes place after the Guidance Executive has approved the guidance for publication and before it is published. When resolution requests are received, publication of the guidance is delayed.

The resolution process is not needed when no consultation comments are received or if stakeholders who provided consultation comments do not return their confidentiality statement.

### **15.1      *Grounds for resolution***

The resolution panel (see section 15.5) only considers resolution requests that meet 1 or both of the following grounds:

**Ground 1:** breach of NICE's published process for the development of interventional procedures guidance. This would encompass, for example, a failure to refer new evidence to the Committee even though it is relevant.

**Ground 2:** factual errors in the proposed guidance. This encompasses cases in which there is an objective error of material fact in the proposed final guidance. It does not include disagreements surrounding scientific or clinical interpretation, or judgement, whether this refers to the appropriateness of guidance itself, or to the weight given to 1 piece of research or evidence over another. For example, if a consultee argues that a statistic quoted in the guidance is incorrect, NICE will establish whether the proposed final guidance misquoted the statistic or whether there were 2 or more pieces of evidence available and 1 piece was preferred because the Committee considered it to be the more reliable. The latter would not constitute a factual error, but a difference of scientific or clinical judgement.

The resolution panel does not consider a resolution request unless the grounds for resolution are clearly identified and meet either 1 or both of the grounds set out above. Resolution requests concerning the scientific judgement of the Committee are not permissible.

### **15.2      *Eligibility to make a resolution request***

After the Guidance Executive authorises publication, all consultees who responded to the consultation document and completed a confidentiality statement are alerted electronically to the start of resolution. They are given access to the revised

guidance document, updated literature search and anonymised consultation comments with NICE's responses to them.

Only consultees who responded to the consultation process are eligible to make a resolution request. It is therefore important that any organisation or individual who may wish to make use of the resolution process submits a consultation response at the appropriate stage. Individuals and organisations should bear in mind that the prepublication guidance may be significantly different from the consultation document because of consultation responses received and considered by the Committee when formulating its final recommendations.

### **15.3      *Resolution requests***

Individuals and organisations have 15 working days after the alert to request resolution on 1 or both of the grounds of breach of process and factual accuracy. Requests may be made by email, fax or letter to the Associate Director of the programme. Those making requests should specify the remedy that they seek, so that NICE can fully understand the nature of their concern and provide an appropriate remedy.

If a request is received, publication of guidance is paused pending an investigation of the points raised. When no requests are received, the guidance is published as soon as possible after the deadline for receipt of resolution requests has passed.

### **15.4      *Initial scrutiny of resolution requests***

All resolution requests are subject to an initial scrutiny process. If a request is received, the programme team investigates the matters raised and reports the findings to the Centre Director who, as part of the initial scrutiny process, decides whether the request falls within the scope of the resolution process. The initial scrutiny process will be completed within 15 working days of the close of the resolution period.

If, on initial scrutiny of a resolution request, the Centre Director considers that the breach of process ground (ground 1) does not appear to have been met, or does not

have a reasonable prospect of success, the programme team relays this decision to the organisation or individual requesting resolution and the guidance proceeds to publication. If the Centre Director considers that the breach of process ground (ground 1) appears to have been met, the programme team convenes the resolution panel (see section 15.5).

If the Centre Director considers that the factual error ground (ground 2) does not appear to have been met, or does not have a reasonable prospect of success, the programme team relays this decision to the body or individual requesting resolution and the guidance proceeds to publication.

If the Centre Director considers the guidance contains a minor factual error or a point that needs clarification, new wording is produced and signed off by the Committee Chair without being referred to the resolution panel. An example of a minor factual change in this context would be one that would not have had an impact on the recommendations of the Committee had it been known when they considered the procedure, for example, a minor amendment to the description of the way in which the procedure is carried out. The guidance then proceeds to publication.

If the Centre Director considers that a major factual error appears to have been made, the programme team convenes the resolution panel. The resolution panel would need to meet, for example, if the consultee raises a substantial challenge to the contents of the guidance document that could not be remedied by minor amendment.

Sometimes more than 1 resolution request is received for a procedure, but not all requests are referred to the resolution panel. Then, the consultees whose requests have not been referred to the panel are informed that the panel is to be convened, and that they will be told of the outcome of their request at a later date when the outcome of the panel is made known. This is to avoid pre-empting the outcome of resolution.

**Table 3 Initial scrutiny of resolution requests**

<b>Outcome of initial scrutiny</b>	<b>NICE action</b>
Ground 1 not met	Guidance is published
Ground 1 met	Resolution panel is convened
Ground 2 not met	Guidance is published
Ground 2 met, minor factual error	Guidance is amended and published
Ground 2 met, major factual error	Resolution panel is convened

### **15.5     *The resolution panel***

The resolution panel consists of 2 NICE Board members (a Non-Executive Director and an Executive Director not previously involved in the development of guidance on the procedure). The resolution panel decides whether there has been a breach of process or factual error and, if so, what action is appropriate.

#### **Meeting**

If the initial scrutiny process finds that the resolution grounds have been met, the resolution panel will normally meet within 20 working days of the conclusion of the initial scrutiny process.

The programme team prepares a briefing for the resolution panel, which forms the basis for its consideration of the resolution request. In the case of ground 1, this means establishing what process was followed in the development of the guidance and what events or omissions have been alleged by the party requesting resolution. In the case of ground 2, this involves setting out what evidence and judgements lay behind the parts of the guidance that are alleged to contain errors.

The Committee Chair and Programme or Associate Director attends meetings of the resolution panel to provide clarification to the panel members if needed. The Chair is not a member of the panel and does not formulate the outcome of resolution.

Members of the programme team may also attend to answer questions from the resolution panel members.

### **The outcome of resolution**

- Ground 1: breach of process

With requests for resolution under ground 1, the resolution panel will find either that there has been no breach of process (so the guidance is published as proposed); or that there has been a breach of process.

If there has been a breach, the resolution panel decides what action is appropriate to remedy the breach. This is likely to mean repeating the process from a certain point, and may include referral back to the Committee or reopening consultation when necessary.

- Ground 2: factual error

With requests for resolution under ground 2, the resolution panel will find either that there are no factual errors and that the guidance will be published as proposed; or that there were factual errors (or elements to be clarified), in which case an amended version of the guidance is produced.

When a factual error is identified in the guidance, the resolution panel considers whether the error can be corrected before publication or whether the Committee should review the wording of the guidance document in light of the error identified.

If it is decided under ground 2 that the wording of the guidance should be changed, the programme team, in consultation with the Centre Director, considers whether there is a need for further consultation or whether to publish the guidance containing the amended wording without further consultation. Further consultation would normally be needed if there is a proposal from resolution to review or revise a recommendation in the guidance. Other changes to the guidance not involving the actual

recommendations could also result in further consultation before the guidance is published if these changes are significant.

**Table 4 Outcome of resolution panel meeting**

<b>Outcome of resolution panel meeting</b>	<b>NICE action</b>
Ground 1 not met	Guidance is published
Ground 1 met	Appropriate action as decided by resolution panel
Ground 2 not met	Guidance is published
Ground 2 met	Appropriate action as decided by resolution panel

## **15.6      *Communicating the outcome of resolution***

The programme team implements the panel's decision and informs the individual or organisation that initiated the resolution process, and all other consultees who made a resolution request on that procedure, of the outcome of resolution. This normally occurs 2 days before the guidance is due for publication. This does not apply if the Committee needs to reconsider the guidance.

The decision reached by the resolution panel and communicated to the person who requested the resolution is final in terms of NICE's process.

It is essential that NICE interventional procedures guidance is factually accurate and supports safe practice. Occasionally, questions of factual accuracy or safety are raised after resolution has closed or after the guidance has been published. The programme team may then investigate any factual inaccuracies or issues of safety, irrespective of timing. This may involve NICE making changes to items published on the website, including the guidance itself.

## **16 Publication, dissemination and surveillance of guidance**

Guidance is published in electronic form. Each piece of guidance is explained in a lay version of the guidance produced by NICE called 'information for the public'. This is developed in consultation with specialist and lay Committee members, and specialist advisers as needed. The final document is published in English and, at a later date, in Welsh.

Also, new guidance is considered in terms of appropriate inclusion and presentation in [NICE Pathways](#). Pathways are an online tool accessed through the NICE website that provide access, topic by topic, to the range of guidance available, including quality standards, technology appraisals, clinical, public health and social care guidelines and NICE implementation tools.

When the Committee recommends that special arrangements be in place for audit, and there is no existing register or data collection facility in place, NICE also develops a specific audit tool for the procedure, to help and encourage good auditing practice for the procedure. The tool is developed with advice from specialist advisers and Committee members, as appropriate.

When guidance recommends that a procedure should not be used, the programme team advises the Department of Health, Welsh Government, Healthcare Improvement Scotland and the Northern Ireland Department of Health, Social Services and Public Safety, along with the device regulator if appropriate, of the contents of the guidance.

## **17 Transparency**

NICE is committed to transparency in the process of developing its interventional procedures guidance for the public and its stakeholders.

## **17.1 Freedom of Information Act 2000**

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).

## **17.2 Public access to Committee meetings**

Holding Committee meetings in public supports NICE's commitment to openness and transparency, and allows NICE to show that its processes are rigorous. It helps consultees and stakeholders to understand the basis for the acceptance or rejection of the various forms of evidence that are considered, and illustrates how the Committees that advise NICE take account of the totality of the evidence submitted by stakeholders and consultees.

Public access to meetings of the Committee will be granted in accordance with [NICE policies](#) and subject to the standing orders of the Committee.

### **Arranging Committee attendance**

NICE publishes a notice on its website announcing each Committee meeting, at least 20 working days in advance of the meeting. The notice includes:

- the date, time and place of the meeting
- a list of agenda items, showing whether each will be discussed in the open or closed session of the meeting
- the name, address and telephone number of the administrator responsible for providing administrative support to the meeting.

Members of the public may apply to observe a meeting via the NICE website. NICE also accepts enquiries by post or fax. Up to 20 places are available for each meeting.

If attendance at any meeting is oversubscribed, attendees are selected according to NICE's allocation procedure. To allow wide public access, NICE reserves the right to limit attendees to 1 representative per organisation.

When the meeting agenda has been finalised, NICE contacts applicants to let them know whether a place is available to them. The invitation includes information on Committee procedures and admission to the building where the meeting is to be held. All efforts are made to follow the meeting agenda, but all agendas can be subject to change because of availability of Committee members and specialist advisers. Attendees should allow for this.

If a meeting is cancelled, NICE will try to provide as much notice as possible.

### **How meetings are conducted**

Scheduled meetings of the Committee are typically held in London, at venues for which access to members of the public is available.

As per NICE policy, each item on the agenda may either be held entirely in public or split into a part 1 session for which the public and additional experts are present and a part 2 session from which the public and additional experts are excluded. The reasons for holding a part 2 session include when:

- the decisions made by the Committee are commercially sensitive.
- the Committee is considering commercial- or academic-in-confidence information
- the Committee is considering patient commentator submissions when these have been submitted under conditions of confidentiality.

The decision not to hold a part 2 session is at the discretion of the Chair in consultation with the Centre Director or their nominated deputy, and is taken when no confidential or personal data or information is being considered, and when the matters under consideration are not commercially sensitive.

### **17.3 Access to documents used in guidance development**

So that the process is as transparent as possible, all non-confidential evidence relevant to the Committee's decisions is made publicly available. The following documents are published on NICE's website:

#### **Documents available at consultation:**

- consultation document

- overview
- systematic review and related documents, if commissioned for the procedure
- specialist advice questionnaires.

**Documents available at resolution:**

- final draft guidance
- consultation comments table with anonymised comments and responses
- updated literature search.

**Documents available on publication of the guidance:**

- the guidance
- overview, updated to include any new evidence since it was first prepared
- anonymised consultation comments and responses
- audit tool, if needed
- information for patients ('information for the public')
- equality impact assessment.

The Committee agendas and minutes are also published.

## **17.4 Using confidential data**

Normally, the assessment of procedures by the programme is based on published evidence. However, occasionally it may be necessary for the Committee to review confidential data to assess a procedure. This may happen at any stage in the process. When a data owner considers that unpublished data should be marked as either 'commercial-' or 'academic in confidence', the rationale for doing so should be clearly stated and should be consistent with the following principles:

- Information and data that are in the public domain anywhere in the world may not be marked as confidential.
- When confidential results from a research study are used during preparation of an overview, publication of NICE documentation quoting these results will be delayed until the study has been accepted for publication.

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

## **18 Links with other NICE guidance-producing programmes**

### ***18.1 How the interventional procedures programme works with other guidance-producing programmes at NICE***

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.

### ***18.2 Procedures suitable for inclusion in NICE guidelines***

NICE guidelines place established treatments in the care pathway, and it is therefore generally only appropriate for them to include interventional procedures when a recommendation has been made for use with standard arrangements and there is a degree of clinical interest in the procedure.

#### **Procedures with recommendations for standard arrangements**

If a committee decides that a procedure for which interventional procedures guidance recommends standard arrangements is relevant to a guideline but does not merit full assessment, the interventional procedures guidance is referred to in the 'related NICE guidance' section of the guideline.

If a committee considers that a procedure published under standard arrangements merits assessment as part of the development of a guideline, the procedure's clinical and cost effectiveness is assessed using the NICE guideline programme's normal assessment methods and processes.

### **Procedures with recommendations for special arrangements**

If the committee opinion is that a procedure with a recommendation for use with special arrangements has become part of mainstream practice and it is appropriate to assess it as part of the NICE guideline, the committee formally notifies the procedure to the interventional procedures programme to allow for potential update of its guidance. If, on reassessment, the procedure changes to a recommendation for use with standard arrangements, its clinical and cost effectiveness can be assessed as part of the guidelines process. If, after reassessment by the Committee, the procedure retains its special arrangements recommendation, the NICE guideline will refer to the procedure as 'related NICE guidance'.

### **Interventional procedures guidance published with other recommendations**

Sometimes, when the Committee deems the evidence base insufficient to make a recommendation for use even with special arrangements, the guidance recommends that the procedure should be carried out only in research. Where there is evidence of no efficacy or the procedure is judged to be unsafe, the guidance recommends that the procedure should not be used. Such procedures will not form part of a clinical question in a NICE guideline.

## **18.3 *Procedures suitable for technology appraisal guidance***

It is usually appropriate for consideration of efficacy and safety of procedures to occur before the technology appraisal programme addresses clinical and cost effectiveness. 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 the technology appraisal programme. They are likely to have many of the following characteristics: that they are indicated for a common health problem; that there is no existing treatment; that costs are very different from those of existing treatment(s); and that there is a connection to a Government

priority. In these circumstances, the procedure is passed to NICE's Medical Technologies Evaluation Programme to consider its appropriateness for the technology appraisal programme.

## **19      Reviewing and updating interventional procedures guidance**

When reviewing guidance in the interventional procedures programme, NICE finds out if there is any new evidence or information to suggest that the guidance recommendations would be likely to change. If so, NICE updates the guidance.

### **19.1      *Principles for guidance review***

There are 4 main categories of recommendation within interventional procedures guidance:

- standard arrangements for clinical governance, consent and audit
- special arrangements for clinical governance, consent and audit or research
- only in research
- do not use.

The approach to reviewing guidance depends on the category of recommendation made in the guidance.

NICE does not proactively review standard arrangements guidance. So, it is not updated unless a stakeholder or organisation alerts NICE to significant new evidence that casts doubt on the validity of the original recommendations, for example, because of emerging new safety concerns. The relevance of safety alerts issued by national or international regulators (for example, the Medicines and Healthcare products Regulatory Agency or the US Food and Drug Administration) or any other serious safety concerns brought to NICE's attention are considered, and may trigger an update of guidance.

Guidance on procedures with 'special' or 'research only' arrangements is proactively reviewed after 3 years, and the guidance is updated if important new evidence is available.

Guidance with a 'do not use' recommendation is not proactively reviewed, and so would not be updated unless there is a significant change in the evidence base.

If there is more than 1 patient group in a piece of guidance, NICE may partially update the guidance if the evidence base changes for 1 group of patients but not the other. In these circumstances, the guidance on the patients in whom there has been no change in the evidence base remains current.

### **19.2      *Key steps in proactive guidance review***

In proactive reviews of guidance, the guidance information services team carries out a literature search to identify new evidence published since the literature searches were done for the original guidance. The search strategies developed for the original guidance are updated (if necessary) and rerun. Specialist advisers' opinions are obtained on the validity and relevance of any new evidence identified in this way, and they are asked if any new issues have emerged around use of the procedure. A new brief is produced for the procedure.

If it is deemed that there is sufficient new published evidence and that the opinions of specialist advisers support the reassessment of the procedure, a request to update the guidance is submitted to the NICE Guidance Executive for approval.

### **19.3      *Guidance update***

Once the NICE Guidance Executive has approved the proposal to update the guidance, the update is scheduled into the programme's work processes, and follows the standard timelines and process for guidance development.

### **19.4      *The status of guidance being updated***

Guidance on a procedure that is reassessed is withdrawn when the new guidance is published. While the update of the guidance is in progress, the existing guidance

continues to apply. If extreme safety concerns such as reports of serious adverse events are raised, NICE will consider suspending current guidance pending update of the guidance.

## 20 Updating the programme manual

NICE will review the need to update this document 3 years after its publication.

It may be necessary to make minor changes to the process of developing interventional procedures guidance before 3 years. Changes will be made in accordance with NICE’s policy. Minor changes that may be made without consultation are those that:

- do not add or remove a fundamental stage in the process
- do not add or remove a fundamental methods technique or step
- will not disadvantage 1 or more stakeholder(s)
- will improve the efficiency, clarity or fairness of the process or methodology.

Changes meeting these criteria will be published on NICE’s website 4 weeks before their implementation. Any other changes will only be made after the 12-week public consultation.

## 21 Stakeholder engagement

### 21.1 Relationships with other organisations

NICE works closely with many professional, NHS and other organisations, including those representing patients and carers. Important partners in the interventional procedures programme are given in Table 5.

**Table 5 Stakeholders**

<b>Professional organisations</b>	Professional societies and associations, Royal College of Physicians, Royal College of Surgeons, Royal College of Nursing, Academy of Royal Colleges
<b>Chief executives/directors</b>	NHS trusts chief executives in England and Wales, local health board chief executives in Wales.

	Medical and nursing directors of NHS and foundation trusts in England and Wales, directors of public health and medical and nursing directors of NHS boards in Scotland.
<b>Clinical governance</b>	Clinical governance and audit leads
<b>NHS bodies</b>	NHS England, NHS Classifications Service (Coding Centre), NHS Litigation Authority
<b>Regulators</b>	Medicines and Healthcare products Regulatory Agency, Human Tissue Authority, NHS Blood and Transplant, Care Quality Commission
<b>Industry groups</b>	Association of British Healthcare Industries
<b>Academic bodies</b>	External assessment centres, National Institute for Health Research
<b>Government bodies</b>	Welsh Government, NHS Scotland, Wales and Northern Ireland, Department of Health
<b>Patient and public groups</b>	Patient Advice and Liaison Service in England, Patients Involved in NICE
<b>Independent sector</b>	Independent insurers, independent/private hospitals, surgeons and other healthcare professionals.

## 22 Glossary

### **Abstract (of a published study)**

A summary (introduction) of a published study. Abstracts of published studies can usually be retrieved through literature search engines.

### **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.

### **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.

**Audit**

The evaluation of clinical performance against standards or through comparative analysis, aimed at informing service management. When a piece of interventional procedures guidance recommends special arrangements for audit, NICE issues audit criteria when the guidance is published.

**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.

**Case report**

An uncontrolled observational study involving an intervention and outcome in a single patient.

**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.

**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.

**Cochrane Library**

A regularly updated electronic collection of evidence-based medicine databases, including the Cochrane Database of Systematic Reviews.

**Commentary**

Commentary obtained by the public involvement team that refers to patient opinion about an interventional procedure.

**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.

**Confidence interval**

The confidence interval is a way of expressing how certain we are 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.

### **Decision-making 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 Guidance Development Group (GDG) to work on it. National collaborating centre staff review the evidence and support the GDG. The centre writes draft guidance, and then revises it after a consultation with organisations registered as stakeholders.

### **Developer**

A group set up by NICE to develop NICE guidelines for a particular disease area. Each centre is based at 1 of the Royal Colleges. The evidence is reviewed for a guideline and presented to a decision-making Committee.

### **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.

### **EMBASE**

Excerpta Medica database. A European database of medical and health research.

**EmTree**

The controlled vocabulary used for EMBASE and other similar databases.

**Evidence**

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

**Evidence summary table (in overview)**

A summary in a tabular format of the design, methods, results and brief critical appraisal of the studies judged to be most valid and relevant in relation to the interventional procedure of interest.

**External Assessment Centres**

NICE commissions 4 External Assessment Centres to help develop its guidance. They help the interventional procedures programme develop systematic reviews when they are needed.

**Follow-up**

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

**Generalisability**

The extent to which the results of a study relating to a particular patient population or context hold true for other patient populations or different contexts.

**Guidance Executive**

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

**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).

**Indication**

A condition or disease that may make a patient eligible for a particular treatment or procedure.

**Inclusion criteria (literature review)**

Explicit criteria used to decide which studies should be considered as potential sources of evidence.

**Information for the public**

A document issued by NICE for patients and carers that summarises the recommendations in NICE guidance in everyday language.

**Interventional procedure**

A procedure used for diagnosis or treatment that involves incision, puncture or entry into a body cavity, or the use of ionising, electromagnetic or acoustic energy.

**Interventional Procedures Advisory Committee (IPAC)**

The Committee is responsible for advising NICE on the safety and efficacy of interventional procedures.

**Interventional procedures guidance**

Guidance on the use of an interventional procedure based on current evidence of its safety and efficacy, issued by NICE after consultation has ended and the Committee has met to discuss comments received at consultation.

**Learning curve**

The process by and time during which an individual surgeon or surgical team achieves proficiency in a particular surgical procedure. It relates mostly to complex and difficult procedures that need subspecialty expertise and skills.

**List of notified procedures**

The list of interventional procedures notified to NICE, posted on NICE's website.

**Medicines and Healthcare products Regulatory Agency (MHRA)**

The [MHRA](#) is the national 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.

### **Medline**

An online, open-access, searchable electronic database produced by the United States National Library of Medicine (NLM).

### **Medical technology 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.

### **National Institute for Health Research Horizon Scanning Centre**

The [National Horizon Scanning 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.

## **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.

## **NICE Pathways**

NICE Pathways are interactive topic-based diagrams that aim to provide users with a way to quickly navigate all NICE guidance recommendations on a particular topic.

## **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.

## **Operator**

The individual clinician who does a procedure – s/he may be a surgeon, interventional radiologist, radiotherapist, interventional physician, etc.

## **Outcome (clinical)**

The clinical effect that results from exposure to a healthcare intervention.

## **Overview**

A document produced by NICE to inform the Committee about an interventional procedure. It contains information on the 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 value**

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

## **Patient commentary**

The written information patient commentators provide about their personal experience of a procedure.

### **Patient commentator**

Patient commentators are individuals who have either had a procedure or are the carer of someone who has. Patient commentators complete a questionnaire to provide information to the Committee about their personal experience of a procedure.

### **Patient group, patient organisation**

Terms used to cover patient, carer, community and other lay organisations, including those that represent people from groups protected by equalities legislation.

### **Patient-focused outcome**

Any health outcome that is directly meaningful to the patient (for example, survival, mortality, morbidity, quality of life). Such outcomes should be distinguished from surrogate outcomes.

### **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.

### **Public involvement programme**

The public involvement programme advises NICE on patient and carer involvement, and identifies patient and carer organisations interested in contributing to its work programme. It promotes effective patient and carer input by providing training and

support to patient organisations and individual patients, carers and lay members who contribute to NICE's work.

**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.

**Rapid review**

A review of the literature that is systematic but not exhaustive (for example, not including direct contact with study authors, or manual searches of journals).

**Register**

A type of database for observations and related information about a group of patients, a disease or an intervention for the purpose of analysis.

**Risk**

The proportion of participants experiencing the adverse event of interest.

**Search strategy**

The combination of terms used to identify studies in an electronic database such as Medline.

**Serious adverse event**

An adverse event resulting in death, hospitalisation, prolongation of a hospital stay or long-term loss of function.

**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 an interest in the interventional procedures programme's activities and outputs.

**Surrogate outcome**

An outcome measure that is not of direct clinical importance but may be associated with patient-focused clinical outcomes, such as 1 based on imaging findings or measurement of a biochemical marker. It should be distinguished from a patient-focused outcome.

**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.

**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.

**Technical team**

Members of the interventional procedures programme team with responsibility for the technical aspects of the assessment process, including scoping of the topic, selecting and analysing the evidence that forms the basis of the overview and advising on technical aspects in the consultation documents.

**Validity**

The degree to which a result (of a measurement or study) is likely to be true and free of bias (systematic errors).

## 23 Overall process for development of guidance

