NICE National Institute for Health and Care Excellence

Interventional procedures programme manual

NICE process and methods
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www.nice.org.uk/process/pmg28

Contents

1 Introduction

This manual should be read in conjunction with the NICE HealthTech programme manual. This sets out the process for developing interventional procedures guidance.

NICE 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. Procedures that involve incision, puncture and entry into a body cavity, or that use ionising, electromagnetic or acoustic energy can be assessed. Mostly new procedures are investigated but established procedures can also be investigated if there is uncertainty about their efficacy or safety. Interventional procedures guidance can be updated when there is a change in the evidence base to justify this. No interventional procedure is entirely risk free, but the extent of uncertainties are gauged and recommendations are made 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.

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 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 10 for a glossary of terms used in this document.

2 Remit for interventional procedures

NICE's remit for interventional procedures was set out by the Department of Health in 2003, in 'Health Services Circular 2003/11 – The interventional procedures programme: working with the National Institute for Clinical Excellence to promote safe clinical innovation'.

To fall within 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 and
- have a UK Conformity Assessed (UKCA) or CE mark specific for the notified indication if a device is involved.

Procedures do not fall within 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 NICE is concerned with. All decisions about whether procedures are in remit are recorded on NICE's website.

2.1 Procedures involving medical devices

NICE assesses procedures that involve a medical device if:

- the procedure falls within remit, and
- the device has at least 1 UKCA or CE mark device 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 NICE team approaches the company or companies to ensure that at least 1 device has a UKCA or CE mark that is current and relevant to the proposed indication. NICE interventional procedures guidance does not name, or relate to, specific devices.

2.2 Other information about the remit

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

3 Notifications about interventional procedures

3.1 Sources and timing of notifications

Clinicians and healthcare professionals are the main notifiers to NICE about interventional procedures. However, anyone may notify NICE about a procedure for consideration. Notifications to the programme are made using the notification form on NICE's website.

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

Medical technology companies are encouraged to read the 'Prioritising our guidance topics' page for information on how to notify an interventional procedure to NICE and register their product on the NHS Innovation Service.

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.

Members of the NICE team may identify new procedures, usually when investigating notified procedures. The team sometimes approaches professional organisations to invite them to notify procedures that have been identified in this way.

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

- it is 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.

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

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.

Clinicians doing a well-established procedure for the first time should not notify it to NICE.

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

3.2 Notifications from the MHRA

The MHRA has the statutory function of monitoring serious device-related adverse events. If the MHRA gets reports of serious concerns about the safety of a procedure or device, it can notify the procedure to NICE. This will prompt NICE to consider assessing the procedure or, if interventional procedures guidance has already been published, updating this guidance.

3.3 On receipt of notifications

When NICE is notified of a procedure, it determines whether it falls within the remit. Notifications are scrutinised by the NICE team, the chair and members of the committee, and others as needed, to establish key facts about the procedure that were unclear in the notification. For each notified procedure, the NICE team seeks advice from experts about the novelty of the procedure, its use in the UK and whether guidance from NICE would be helpful. If there are doubts about the suitability of a procedure for guidance, the final decision is made by the associate director.

3.4 Outcome of notifications

If a procedure falls within the remit, it is assessed (see section 2).

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 (assessment report, consultation document, guidance, table of consultation comments including NICE's responses, external assessment group report for certain procedures, 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 on the NICE website.

If a notified procedure appears to fall within remit 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, it is monitored and assessed 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 remit and the reasons for this are also listed on NICE's website.

Whether the procedure is within the remit 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 relating to NICE's assessment of the procedure 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.

4 Producing a scope for interventional procedures

A scope defines the issues of interest surrounding the procedure and, for the purposes of the assessment, sets the boundaries for the work to be done. This is done by defining the procedure and indications that will be used to identify relevant evidence. Advice can be sought from relevant committee members and experts when preparing the scope.

4.1 Content of the scope

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

- notified procedure title, and proposed procedure title (if a different title is thought necessary)
- proposed lay description
- proposed procedure description, using a generic (non-proprietary) description
- notified indication
- proposed indication and different indications if these are thought necessary
- key ongoing trials
- suggested search terms for the intervention and indication
- epidemiology of the condition(s) for which the procedure is indicated, particularly when this relates to NICE's equalities duties
- established alternative interventions for the condition
- safety and efficacy outcomes
- category of notifier
- disease area(s)

- specialty area(s)
- professional organisations to approach for experts
- professional organisations to be informed that NICE is assessing the procedure
- patient organisations to be informed that NICE is assessing the procedure
- related NICE guidance
- special issues relating to the procedure (NICE may be made aware of these by experts).

The scope 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.

4.2 Complex notifications

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

- NICE is notified about a procedure with an imprecise name, or 1 that is atypical in UK practice. Because there is no universally recognised nomenclature for interventional procedures, the NICE team may rename the notified procedure on the advice of experts or a 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 experts 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 assessment for interventional procedures 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 NICE 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, for example when the safety or efficacy profiles are likely to be different.

Scopes involving complex notifications are likely to take longer to prepare than standard scopes.

5 Evidence considered by the committee

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

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

The evidence that the committee uses to make its draft decision is mainly from published sources. 'Commentary' refers to the variety of opinion and information from unpublished sources that may be relevant to a procedure (see section 6).

Selection of evidence for interventional procedures is influenced by the following factors:

- NICE interventional procedures guidance addresses 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 is usually insufficient.
- Randomised controlled trials (RCTs) are often not available. Non-randomised comparative studies, 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 assessment report (see section 5.3), which the committee uses as the basis for its draft recommendations on a procedure.

5.1 Literature search

The literature search is carried out by NICE or an external assessment group (EAG). 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. Developing the search strategy is an iterative process; changes are made to the strategy according to the results retrieved, based on discussions within the NICE team or between the EAG and the NICE team.

Because of the nature of procedures notified, 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. Using free-text searches (words in titles and abstracts) may therefore 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
- Euroscan International Network
- US Food and Drug Administration's 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 (ANZHSN)
- 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
- World Health Organization International Clinical Trials Registry
- National Institute for Health Research Clinical Research Network Coordinating Centre Portfolio Database.

Conference proceedings

Many of the procedures considered by the programme are very new, and therefore searching through conference proceedings can yield relevant results. The websites of the major 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 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 (morbidities) 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 limited to English-language publications. Translation into English of full articles published in languages other than English is only requested by the NICE team if the outcomes reported in the non-English-language literature differ in nature from those reported in the English-language literature, or are reported with substantially different frequency – particularly for safety outcomes. Because of resource and timing constraints, NICE may not be able to obtain English translations, even of relevant studies.

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 assessment report if they are considered to be among the most valid and relevant studies).

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.

5.2 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 assessment report that is prepared for the procedure. To conduct rapid assessments of novel procedures, the studies presented in detail in these tables is limited to those most likely to be relevant and informative. In general, well-designed research studies, those reporting on large numbers of patients, those with long follow up (if length of follow up is relevant to outcomes of the procedure) and any reports of additional important safety outcomes are prioritised. Typically, the number of studies in the tables is 6 to 8. The initial screening for eligible studies is done using abstracts downloaded from electronic databases. A study is eligible for inclusion if it includes patients with the appropriate indication, describes the relevant intervention and reports efficacy or safety outcome data, particularly if those outcomes were identified as being important in the scope. If a study cannot be reasonably excluded on the basis of the abstract alone, its eligibility is assessed using the full text of the publication.

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 evidence on the procedure and to allow all relevant studies to be listed without making the assessment report 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 assessment report 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 only on physiological outcomes) are not included in the assessment report, and therefore are 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. The newly identified studies are incorporated into the assessment report as described above.

For some procedures, selecting the studies to include in the assessment report – 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 NICE team may take the following actions:

- prioritise particular studies
- propose splitting the assessment report, 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 resources and committee time, and potential usefulness to the NHS of the resulting guidance. The NICE team refer to the scope when prioritising studies. NICE's Decision Support Unit technical support document 27 and the criteria described below provide guidance on potential prioritisation approaches.

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 experts, the notifier of the procedure, relevant committee members 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 assessment report:

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.

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 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 outcomes, 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 a key feature of the methods, 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, registers and case reports may provide valuable information, for example for procedures where 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 with procedures used to treat conditions that have little impact on quality of life or with a good prognosis.

Procedures for which no comparator (controlled) data is 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 assessment report 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 (diagnostic and therapeutic yield) – 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 assessment report. 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

While well-designed relevant comparative studies are generally prioritised, unpublished and non-peer-reviewed safety or efficacy data may be considered for inclusion. Examples of unpublished or non-peer-reviewed data can include submissions from companies, papers awaiting peer review, unpublished data from registers and conference abstracts, provided they contain sufficient detail on methods and outcomes. The inclusion of unpublished or non-peer-reviewed data will be considered on a topic-by-topic basis. Inclusion is more likely if it is likely to fill an evidence gap and add value to the committee's decision-making process. This is particularly likely for safety data on serious adverse events.

Any unpublished data supplied by a company should be accompanied by sufficient details to enable a judgement as to whether it meets the same standards as published evidence and to determine potential sources of bias. Ideally, it should be structured and presented in the form of a research publication. Methodological detail should be provided in line with relevant reporting guidelines (for example, those endorsed by the EQUATOR network) to allow critical appraisal of unpublished evidence.

Unpublished data from registers is more likely to be included if:

- it arises from a data collection exercise recommended in interventional procedures guidance, and
- the data collection exercise meets the register standards presented elsewhere in this manual.

5.3 The assessment report

General approach to the assessment report

Different terminology to report identical or similar outcomes is often used in studies included in the assessment report. 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 NICE 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 assessment report provided they are commonly recognised. No pooling or meta-analysis of data is done by the NICE team.

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 assessment report if reported in the primary report.

It is usually appropriate to present statistical comparisons in the assessment report when reporting the results of studies that contain comparative data. When a reported comparative outcome is considered important enough for inclusion in the assessment report, 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 device itself is not evaluated: the focus is on the procedure. Only the efficacy and safety of a procedure using devices that are UKCA or CE marked is considered. Evidence about the procedure relating to devices without UKCA or CE marking is selected for the assessment report 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 assessment report of the evidence, but interventional procedures guidance does not name companies' devices or brands.

Formal submissions are not used. However, a search is done for companies producing

devices that may be used to do the procedure, so that NICE can make a request for information at the beginning of the assessment of the procedure (see section 6.2).

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

Evidence summary table

The evidence summary table included in the assessment report 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 conflicts of interest declared by the authors.

Critical appraisal of the evidence (analysis)

The critical appraisal of the studies in the assessment report identifies issues that might influence the interpretation of the evidence. The critical appraisal addresses key features of the evidence relating to study design, the quality of the study, statistical analysis, effect size and relevance of the outcomes. While several 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 NICE team or the EAG may comment on the following issues when reporting on a primary study or systematic review of primary studies:

- patient selection
- patient enrolment or recruitment method (for example, whether it was continuous)
- previous operator training for the procedure
- previous volume of experience of operators or participating units 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 assessment report presents the efficacy and safety outcomes reported in the studies. Outcomes are grouped under subheadings where appropriate. The assessment report also contains advice from experts and commentary from patient commentators, which are described in section 6.

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 assessment report. In this case, NICE commissions an EAG to produce a systematic review.

5.4 Systematic reviews

Reasons for commissioning a systematic review

After considering the scope and the available literature, the NICE team may decide to refer the procedure to an EAG 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 assessment report
- 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 assessment report 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 EAG to carry it out. The standard timeline for developing guidance does not apply when a systematic review is required. Revised timelines for the development of guidance on the procedure are presented on NICE's website.

Process for carrying out a systematic review

A scope for the review is prepared by an EAG and agreed by NICE and the committee, if required. 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).

EAGs 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 and, if they are used, this is stated clearly in the report. 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 EAG seeks clinical advice specific to the procedure(s) under assessment. The EAG is responsible for getting this advice. In preparing the systematic review, the EAG 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.

6 Advice and commentary

In addition to the evidence in the assessment report, the committee considers advice and commentary in formulating its recommendations on procedures.

6.1 Opinions of experts

NICE seeks the opinion of as many experts as are deemed appropriate for the procedure. Experts 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 scope. The number of questionnaires that are returned to NICE also depends on professional organisations nominating their members, and the number of individual experts 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. Experts 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.

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

Occasionally, NICE may not be able to find experts with sufficient knowledge of the procedure to give advice. This is most likely to occur with very new procedures. If 2 experts cannot be found from those approved in the relevant specialty or specialties, NICE will normally delay developing guidance on the procedure until sufficient advice is available. The absence of experts with any knowledge may suggest that the procedure is not currently being used. Rarely, it may be appropriate to proceed with a single expert, 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.

Expert advice is usually provided using a questionnaire. Questionnaires completed by experts are copied to the professional body that nominated them. The completed questionnaires are published on NICE's website at the same time as the assessment report, when the consultation period for the draft guidance starts.

A clinician who has notified NICE about a procedure cannot normally act as an expert 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.

For each procedure, experts are required to declare their interests in line with NICE's policy on declaring and managing interests for NICE advisory committees. Experts' interests are available to the chair and the committee alongside the questionnaires.

An expert may be asked to provide more detailed assistance to the programme. This includes, but is not restricted to, attending committee meetings (either virtually or in person), commenting on an audit tool for the procedure (if NICE is producing one), 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 experts is sought on the following issues, which are mainly encompassed in the questionnaire:

- 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 (including theoretical and anecdotal adverse events)
- 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.

6.2 Evidence from companies

Request for information

Details on requests for information are in section 1.3 of the NICE HealthTech programme manual.

Company attendance at the committee meeting

Details on the participation of company representatives at the committee meeting are in sections 1.3.5 and 1.3.6 of NICE technology appraisal and highly specialised technologies guidance: the manual.

6.3 Contributions from patient commentators

NICE's people and communities team 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 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 scope. Patient commentary is not sought if the committee chair, the NICE team and the people and communities team 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.

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 there are 10 or more responses, 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
- experience of having the procedure.

7 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 7.4) and safety (section 7.5). 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 can 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.

7.1 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.

Experts 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.

7.2 The device

Some procedures need to be carried out with a particular device or involve implanting a device. 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 experts, companies or other sources.

7.3 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 assessment report 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 at least as efficacious as 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 experts.

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.

7.4 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 for the procedure that it considers to be particularly informative and suggest these for future research and audit.

The absence of comparative studies

The committee 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

When NICE develops guidance on a diagnostic procedure it is important to ensure that the assessment encompasses the value to patients of the diagnostic information generated by the procedure. It is out of remit for the evaluation of interventional procedures 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 considers 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 do an assessment for interventional procedures guidance, NICE seeks expert advice on the clinical utility of the diagnostic procedure, so that it can provide information on whether the diagnostic procedure can plausibly inform clinical decision making and therefore 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. For some procedures, evidence of short-term efficacy may be the only requirement. For example, for a new procedure to treat an acute illness, the expectation of long-term benefit is implicit once the condition has been 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.

7.5 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, if a procedure is for a common condition that is not a serious threat to health, and 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
- experts 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.

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 especially important when considering procedures for long-term 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 experts on the basis of their experience. 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 is 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.

8 Draft recommendations

The committee makes its draft recommendations on the efficacy and safety of the procedure, taking into account the assessment report, expert advice, patient commentary and factors related to equalities. Draft 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 Listens is a programme of deliberative public engagements. It helps NICE determine its approach, and that of its committees, to making social value judgements. It continues to 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.

8.1 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.

Can be used (previously 'standard arrangements')

For a procedure to be recommended for use with 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 use 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.

Can be used with evidence generation (previously 'special arrangements')

A recommendation with evidence generation states that clinicians using the procedure must 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 additional 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 evidence generation and audit is needed, and there is no data collection facility in place, NICE provides an interventional procedures guidance audit tool template. This tool is used to support the use of NICE guidance and monitor the safety and efficacy outcomes of interventional procedures.

More research is needed (previously 'research only')

Sometimes the committee recommends that the procedure should only be done as part of formal research 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 more research is needed, the committee's research recommendations state the areas of uncertainty that the research should address, and sometimes refer to outcomes or other details that should be addressed in studies. The NICE Science Policy and Research 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.

Should not be used (previously '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.

8.2 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 experts or comments received during consultation, and take into account the following considerations:

- 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 evaluation 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 experts, 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 the 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 experts 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.

8.3 Data collection to address uncertainty

When data on efficacy or safety is 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 routine data collection through a register. The considerations for recommending a specific type of research design are:

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 the committee considers that additional formal clinical research would 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 is 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 NICE team confirms that the standards in table 1 are met, using the criteria outlined.

Patient Reported Outcome Measure (PROMs) data is used if collected through a national register that meets the standards in table 1.

Table 1 Register standards and criteria for recommending a register in interventional procedures guidance

Standards	Criteria
All known procedures (all devices), without exception, are recorded in the database	Raw anonymised data available for secondary analysis and validation. Denominator data available to assess data coverage, such as sales figures and routine health service information.
The data recorded address relevant efficacy and safety outcomes and important patient characteristics	Medicines and Healthcare products Regulatory Agency/NICE and professional representatives involved in dataset design and agree final protocol. Data includes details of modifications or evolution of procedure/device and numbers done for the original indication (and respective outcomes).

Standards	Criteria
Independent oversight	Independent steering group responsible for design, data monitoring and analysis. Register recorded on national database of registers. Explicit intent to publish results whatever the outcome. Process for data collection, storage and analysis independent of any particular company or any commercial interest.
The Register must comply with the data protection principles laid out in the UK Data Protection Act 1998 and any other relevant legislation	Data is: • used fairly and lawfully • used for limited, specifically stated purposes • used in a way that is adequate, relevant and not excessive • accurate • kept for no longer than is absolutely necessary • handled according to people's data protection rights • kept safe and secure • not transferred outside the European Economic Area without adequate protection.

In some cases, NICE commissions an external assessment group 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.

9 Links with other NICE guidance-producing programmes

9.1 Procedures suitable for inclusion in NICE guidelines

Section 8 of Developing NICE guidelines: the manual describes how NICE guidelines link to NICE interventional procedures guidance.

10 Glossary

See also the glossary on the NICE website.

Assessment report
An assessment report is generated to support guidance development. This report can either be produced by NICE or an external assessment group (EAG). When produced by an EAG, this is an external assessment report, and the EAG is responsible for the content and quality of the report.

Commentary
Commentary obtained by the people and communities team that refers to patient opinion about an interventional procedure.

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

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

EmTree
The controlled vocabulary used for EMBASE and other similar databases.

Evidence summary table (in assessment report)
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.

Expert
A person nominated by a relevant professional organisation to advise NICE about notified procedures.

External assessment group
NICE commissions 4 external assessment groups to help develop its guidance. They help the interventional procedures programme develop systematic reviews when they are needed.

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.

HealthTech programme
The NICE HealthTech programme combines the former NICE Diagnostics Assessment programme, Interventional Procedures programme and Medical Technologies Evaluation programme.

Inclusion criteria (literature review)
Explicit criteria used to decide which studies should be considered as potential sources of evidence.

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

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 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.

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

Operator
The individual clinician who does a procedure. They may be, for example, a surgeon, interventional radiologist, radiotherapist or interventional physician.

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

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-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.

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 Reported Outcome Measures (PROMs)

Patient Reported Outcome Measures (PROMs) measure a patient's health status or health-related quality of life at a single point in time, and are collected through short, self-completed questionnaires.

People and communities team
The people and communities team 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.

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, a prolonged hospital stay or long-term loss of function.

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.

UK Conformity Assessed (UKCA) mark
A UKCA mark shows that a medical device is fit for its intended purpose, meets requirements in legislation relating to safety, and can be freely marketed in England, Wales and Scotland.

Update information

November 2025: This manual has been updated to remove Scotland from the devolved nations that NICE interventional procedures guidance applies to.

October 2025: This manual has been updated to further align with the NICE HealthTech programme manual, which covers the processes for interventional procedures.

For interventional procedures topics that started development before 14 July 2025, the previous version of the manual applies.

July 2025: This manual has been updated to align with the NICE HealthTech programme manual, which covers the methods and processes that NICE follows when evaluating health technology products (such as diagnostics, medical devices, digital technologies) and the processes for interventional procedures.

Minor changes since publication

December 2024: Minor updates were completed throughout detailing the main types of recommendations that can be made by the interventional procedures advisory committee.

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