

The Interventional Procedures Programme

Programme Manual

September 2004

The Interventional Procedures Programme – Programme Manual

Issued: September 2004

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

This document is available from the NICE website (www.nice.org.uk) or from the NHS Response Line (telephone 0870 1555 455 and quote reference number N0712).


National Institute for Clinical Excellence
MidCity Place
71 High Holborn
London WC1V 6NA

www.nice.org.uk

ISBN: 1-84257-779-4

Published by the National Institute for Clinical Excellence
Printed by Abba Litho Sales Limited, London
September 2004

© Copyright National Institute for Clinical Excellence, September 2004. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes within the NHS. No reproduction by or for commercial organisations is allowed without the express written permission of the National Institute for Clinical Excellence.



Contents

1	Introduction	1
2	The Interventional Procedures Programme	2
2.1	The aims of the Programme	2
2.2	Implications of the Programme for patients and healthcare professionals	2
2.3	Who is involved?	3
2.4	Relationships with other organisations	3
3	How the process works	5
3.1	Key activities of the Programme	5
3.2	Notifying a procedure to NICE	5
3.3	The list of interventional procedures	6
3.4	Expressing an interest	6
3.5	Deciding whether a procedure is within the scope of the Programme	6
3.6	Producing an overview	7
3.7	Specialist Advisors' opinions	7
3.8	Provisional recommendations	8
3.9	Referral to the Review Body	10
3.10	Surveillance	10
3.11	Interventional Procedures Consultation Document	11
3.12	The consultation process	11
3.13	The production of guidance	12
3.14	Resolution of claims of factual error or breach of process	12
3.15	Publication and dissemination of guidance	13
3.16	Duration of process	14
3.17	Procedures suitable for Technology Appraisals	16
3.18	Transparency	16
4	After guidance is issued	18
5	Updating the Programme Manual	19
6	How to find more information	20
Appendix A	Glossary	21
Appendix B	Extended consultation for procedures referred to the Review Body	23
Appendix C	The resolution process	25

1 Introduction

- 1.1 The National Institute for Clinical Excellence (NICE) is part of the NHS. It is the independent organisation responsible for providing national guidance on treatments and care of people using the NHS in England and Wales. Further details about the Institute and its work programmes are available in *A guide to NICE*, which can be downloaded from the website (www.nice.org.uk).
- 1.2 In January 2003, NICE published an interim process manual describing how it prepares guidance on the safety and efficacy of interventional procedures. Since then, the process has been developed further, and guidance on specific procedures has been published monthly since July 2003. This document is the definitive Programme Manual.
- 1.3 The purpose of this document is to describe how interventional procedures are assessed. The process is designed to achieve robust guidance for the NHS, developed in an open, transparent and timely way that allows maximum understanding and input from consultees and other stakeholders.
- 1.4 Interventional procedures are those used for diagnosis or treatment that involve incision, puncture, entry into a body cavity or the use of ionising, electromagnetic or acoustic energy.
- 1.5 See page 21 for a glossary of terms used in this document.

2 The Interventional Procedures Programme

2.1 The aims of the Programme

- 2.1.1 NICE's Interventional Procedures Programme assesses the safety and efficacy of interventional procedures, with the aim of protecting patients and helping clinicians, healthcare organisations and the NHS to introduce procedures appropriately. By reviewing evidence, consulting widely, facilitating data collection and analysis, and providing guidance on the safety and efficacy of interventions, the Programme enables clinical innovation to be responsibly conducted. No interventional procedure is entirely free from risk, but the Programme gauges the extent of uncertainties and makes recommendations on their implications.
- 2.1.2 NICE issues guidance on interventional procedures to ensure that:
- ▶ patients and carers are reassured that new interventional procedures are being monitored and reviewed to protect patient safety, and that they have access to information about procedures
 - ▶ clinicians, healthcare organisations and the NHS as a whole will be supported in the process of introducing new procedures
 - ▶ NICE can foster innovation by facilitating data collection and analysis, arranging systematic reviews, recommending training and providing advice on the safety and efficacy of new procedures.
- 2.1.3 Nearly all the procedures that the Programme investigates are new, but the Programme can also scrutinise more established procedures if there is reason to be uncertain about their safety and/or efficacy.

2.2 Implications of the Programme for patients and healthcare professionals

- 2.2.1 NICE produces guidance about whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for use in the NHS. NICE makes sure that this information is available to patients, carers and the public, to people working in the NHS and to NHS organisations.
- 2.2.2 NHS healthcare professionals are responsible for notifying procedures to NICE and for applying NICE guidance to meet the needs of individual patients.
- 2.2.3 NICE guidance helps healthcare professionals to:
- ▶ provide patients with appropriate information about treatment options (NICE produces information for the public on each procedure and on consent for procedures of uncertain safety and efficacy)
 - ▶ understand the circumstances under which a procedure is safe and efficacious enough for use
 - ▶ gather further information where uncertainty exists
 - ▶ protect patients from unsuitable procedures.
- 2.2.4 The Department of Health, the Welsh Assembly Government and the Scottish Executive Health Department have issued guidance (smart codes HSC 2003/011, WHC [2003] 58 and HDL [2004] 04, respectively) to the NHS on how to engage with the Programme. These stipulate that clinicians should notify their first use of new interventional procedures and that they and NHS organisations are expected to follow the Programme's guidance. They also describe the circumstances under which a notified procedure may be used before guidance is issued.
- 2.2.5 These arrangements are underpinned by the inspections carried out by the Healthcare Commission and the requirements of the Clinical Negligence Scheme for Trusts Risk Management Standards issued by the NHS Litigation Authority. Similar arrangements exist for Scotland through NHS Quality Improvement Scotland.

- 2.2.6 Similar arrangements exist in independent hospitals because of the memoranda of understanding that NICE has agreed with the Association of British Insurers and with the Independent Healthcare Forum.

2.3 Who is involved?

- 2.3.1 The Interventional Procedures Advisory Committee (IPAC, or ‘the Advisory Committee’) makes recommendations to NICE about the safety and efficacy of interventional procedures and the other content of guidance, such as conditions under which the procedures should be used. Its 24 members, who are all independent of NICE, have a range of expertise and include clinicians who carry out interventional procedures, people who are familiar with the issues affecting patients and carers, and experts in regulation and in the evaluation of healthcare. A list of the current members is published on the NICE website (www.nice.org.uk/ip). Advisory Committee members are appointed for 3 years, as is the Committee’s Chair. This can be extended for a further 3 years by mutual agreement.
- 2.3.2 The Advisory Committee is assisted by Specialist Advisors, who are clinicians nominated or approved by professional bodies that have members involved in the use of interventional procedures. The Specialist Advisors provide advice about interventional procedures that complement findings from research. They may also be called on to provide their opinions to the Advisory Committee in person when necessary.
- 2.3.3 NICE identifies clinicians to assist the programme as Specialist Advisors in two ways.
- ▶ NICE approaches a professional body to nominate individuals able to give informed opinion about interventional procedures.
 - ▶ A current Specialist Advisor recommends another clinician to give specialist advice.
- In the latter situation, the relevant professional body is asked to ratify the clinician as a Specialist Advisor. Approved Specialist Advisors are appointed to the Programme for a term of 3 years. A list of Specialist Advisors ratified by their society is published on the NICE website.
- 2.3.4 NICE has commissioned a Review Body to provide systematic reviews of interventional procedures and to conduct collection of data. The Review Body is a consortium of two universities and an academic hospital:
- ▶ The School of Health and Related Research, University of Sheffield
 - ▶ The Institute of Applied Health Sciences, University of Aberdeen
 - ▶ Sheffield Teaching Hospitals NHS Trust.

2.4 Relationships with other organisations

- 2.4.1 NICE works closely with many professional, NHS and other organisations, including those representing patients and carers. Important partners in this Programme include:
- ▶ the Healthcare Commission
 - ▶ the Department of Health
 - ▶ the Welsh Assembly Government
 - ▶ the Scottish Executive Health Department
 - ▶ the Medicines and Healthcare products Regulatory Agency (MHRA)
 - ▶ the National Horizon Scanning Centre
 - ▶ the National Patient Safety Agency (NPSA)
 - ▶ the NHS Information Authority
 - ▶ the NHS Litigation Authority
 - ▶ the Welsh Risk Pool Scheme
 - ▶ NHS Quality Improvement Scotland
 - ▶ NHS Research and Development
 - ▶ the Association of British Healthcare Industries

- Medical Devices in Scotland
- device manufacturers
- relevant patient/carer associations
- the Royal Colleges and other professional societies and associations.

3 How the process works

3.1 Key activities of the Programme

- 3.1.1 The Programme's key activities are:
- receiving notifications of interventional procedures
 - deciding whether notified procedures fall within the Programme's remit and should therefore be investigated
 - compiling and then maintaining a list of notified interventional procedures
 - preparing procedure overviews and obtaining specialist advice
 - convening meetings of the Advisory Committee, providing it with evidence and securing its preliminary recommendations
 - preparing Interventional Procedures Consultation Documents based on the Advisory Committee's preliminary recommendations
 - consulting on Interventional Procedures Consultation Documents
 - producing Interventional Procedures Guidance based on the final recommendations of the Advisory Committee
 - issuing the guidance to the NHS in England, Wales and Scotland
 - producing information for the public relating to each piece of guidance issued
 - answering enquiries from patients, the public, clinicians, manufacturers, the NHS and the independent healthcare sector.

3.2 Notifying a procedure to NICE

- 3.2.1 Some procedures are entirely novel (for example, those that involve the use of an endoscope for a procedure previously performed through a conventional incision), and the need to assess them is obvious. Sometimes, established procedures undergo minor alterations in the hands of practitioners that clearly do not merit notification. For example, a small change in the length or site of an incision to improve access in an operation would not necessitate notification.
- 3.2.2 Thus, the necessity for notification should be judged according to whether the new procedure is likely to have a different safety and/or efficacy profile from that of the original procedure.
- 3.2.3 The main source of notifications is clinicians, who follow the guidance from the Department of Health, Welsh Assembly Government and Scottish Executive Health Department set out in Section 2.2.4.
- 3.2.4 Although clinicians most frequently notify procedures, anyone may make a notification. Non-clinical NHS staff, in particular, are encouraged to discuss the procedure with a clinician before notifying, because completion of the webform is improved by clinical knowledge of the procedure.
- 3.2.5 When notifying a procedure to the Programme, a certain amount of information is required as a minimum. This includes:
- contact details of the notifier
 - name of the interventional procedure
 - description of the interventional procedure
 - indications
 - any other procedure that the new procedure is likely to replace
 - if the notifier is not a clinician, the name of a clinician for NICE to contact in connection with the notification.
- 3.2.6 Organisations such as professional associations, specialist societies, the Royal Colleges, the

MHRA, the NPSA and NHS Research and Development may also notify NICE about interventional procedures that are being performed in the NHS outside formal research, or are likely to be performed within the next year.

- 3.2.7 Device manufacturers can also notify procedures to the Programme.
- 3.2.8 The National Horizon Scanning Centre will notify NICE of procedures likely to be used for the first time in the NHS outside a formal research setting within the next year.
- 3.2.9 NICE annually prompts Specialist Advisors and specialist societies to notify procedures.

3.3 The list of interventional procedures

- 3.3.1 The list of interventional procedures is available on the NICE website. The inclusion of a procedure on the list does not imply that it has been or will be selected for investigation, nor does it imply anything about the procedure's safety and efficacy. It simply means that NICE has been notified of the procedure.
- 3.3.2 The website provides the following information about each procedure:
 - the name of the procedure
 - other name(s) by which it is known
 - a description of the procedure, including whether it is an alternative to an existing procedure
 - the clinical specialty or specialties that might perform the procedure
 - the progress that a procedure has made through the assessment process
 - links to relevant documents produced by NICE (overview, Interventional Procedures Consultation Document, Interventional Procedures Guidance, Review Body report and *Information for the Public*)
 - links to relevant documents produced by other agencies such as the MHRA
 - links to related Technology Appraisals and Clinical Guidelines.

3.4 Expressing an interest

- 3.4.1 Individuals may express an interest in a procedure or group of procedures. They are then sent electronic updates of that procedure's progress through the Programme. These updates are triggered by significant changes to the procedure's webpage (for example, when a consultation begins). Stakeholders are encouraged to express an interest, as this is the most reliable way of ensuring awareness of a procedure's progress and of being alerted to the onset of consultation.

3.5 Deciding whether a procedure is within the scope of the Programme

- 3.5.1 Once a procedure has been notified, NICE assesses whether it falls within the scope of the Programme.
- 3.5.2 To fall within the Programme's scope, a notified procedure must:
 - involve an incision or a puncture or entry into a body cavity, or the use of ionising, electromagnetic or acoustic energy, and
 - be available within the NHS or about to be used for the first time in the NHS, outside formal research, and
 - either not yet be generally considered standard clinical practice, or
 - be a standard clinical procedure, the safety or efficacy of which has been called into question by new information.
- 3.5.3 Procedures will not fall within the Programme's scope if they are considered standard clinical practice with benefits and risks that are sufficiently well-known. All surgical procedures carry some risks. It is the extent of uncertainty surrounding the risks and benefits that the Interventional Procedures Programme investigates.

- 3.5.4 The final decision regarding the suitability of a procedure for inclusion in the Programme is made by the Programme Director and Chair of the Advisory Committee.
- 3.5.5 Individuals who notify the Programme of a new interventional procedure will be informed whether it is within the scope of the Programme. A list of notified procedures not included in the Programme is provided on the website.

3.6 Producing an overview

- 3.6.1 NICE prepares an overview for each notified procedure that falls within the Programme's scope. The overview summarises the:
 - ▶ nature and purpose of the procedure
 - ▶ results of the most valid studies found in a rapid review of the literature
 - ▶ key safety and efficacy issues that arise from review of the literature
 - ▶ opinions of the Specialist Advisors.
- 3.6.2 The overviews are prepared by an interventional procedures analyst at NICE.
- 3.6.3 The overviews are not systematic reviews, making this Programme distinct from NICE's Technology Appraisals and Clinical Guideline Programmes, which publish guidance on the basis of specially commissioned systematic reviews. By contrast, the interventional procedures overviews are brief documents, usually including an assessment of the most useful studies found by electronic literature searches. Often, there is little research available, but when selection is necessary, usefulness is decided on the basis of size, methodological soundness and suitability, recent publication and relevance to the NHS. In practice, the majority of the published experience of procedures is concentrated in the larger studies and little is gained from review of a larger number of smaller studies. If there are potentially important studies which cannot be encompassed in the overview, the procedure can be referred to the Review Body (see Section 3.9).
- 3.6.4 No formal hierarchy of evidence is used in assessing which kinds of evidence to include. The selection depends on the overall balance and quality of the evidence and its suitability for the issue under consideration. In general, studies whose design and execution minimised bias are included.
- 3.6.5 Other relevant studies not selected for full assessment are listed and briefly described within the overview. This approach means that overviews can be written within a few weeks and the guidance can therefore be produced promptly after notification. Consultation has indicated that stakeholders attached great importance to the timeliness of guidance. The interval before guidance is published is one of uncertainty and potential risk. It needs to be minimised so that patients and clinicians know as soon as possible about the safety and efficacy of a procedure and how it should be appropriately used. When significant pieces of research are not included in the overview, they often come to light during consultation on the proposed guidance, reducing the risk of judgements whose validity is compromised by the overview's limited scope.
- 3.6.6 Device manufacturers and other stakeholders can engage with the Programme before consultation, for example, by alerting NICE to the imminent publication or availability of new relevant research studies. Other non-confidential information may also be submitted at this stage. In these cases, the preparation of the overview may be delayed so that new information can be included.
- 3.6.7 In selected cases, when a systematic review is necessary, the Advisory Committee will refer procedures to the Review Body (see Section 3.9).

3.7 Specialist Advisors' opinions

- 3.7.1 NICE seeks the opinion of at least three Specialist Advisors recommended by the relevant specialist organisation(s) (see Section 2.3.2) on each procedure before it is considered by the Advisory Committee. New procedures often have potential benefits and, importantly, risks that are not yet fully described in the scientific literature. Specialist Advisors provide insight into these aspects of a procedure, sometimes supported by their accounts of clinical experience, which

complement the often limited published evidence. A list of all the current Specialist Advisors is on the NICE website.

- 3.7.2 NICE approaches the relevant professional bodies for the names of Specialist Advisors for each procedure, if the professional body has indicated it wishes to provide Advisors on that basis. The opinions of the Advisors identified by the professional body as suitable for that procedure will always be obtained if possible; however, to maintain timeliness, NICE will make use of previously approved Advisors if necessary.
- 3.7.3 The Specialist Advisors are selected because of their knowledge of the clinical field. Specialist Advisors with experience of the procedure are sought, but, to minimise bias, at least one Specialist Advisor who has not performed the procedure is selected in each case. If the procedure covers more than one specialty, at least one Specialist Advisor from each specialty is used. The Specialist Advisors complete a questionnaire and return it. Occasionally, they are interviewed by an analyst, who completes the questionnaire on their behalf and sends it to the Specialist Advisor for checking. The questionnaire includes a declaration of conflicts of interest.
- 3.7.4 Occasionally, NICE may not be able to find three Specialist Advisors with sufficient knowledge of the procedure to complete the questionnaire. This is most likely with very new procedures. If three suitable Specialist Advisors cannot be found from those approved in the relevant speciality or specialities or from the alternatives whom they suggest, the Advisory Committee may consider the opinions of two Specialist Advisors. However, if there are fewer than two available Specialist Advisors, NICE consults the Advisory Committee's Chairman before presenting to the Committee. Options in these exceptional circumstances include proceeding with one Specialist Advisor, delaying while a further search is carried out or using an overseas clinician for advice.
- 3.7.5 The names of the Specialist Advisors involved in a specific procedure are given in the overview, along with the professional body that nominated or ratified them. This is accompanied by a note explaining their function. Their responses to the questionnaire are available on written request, in accordance with the provisions of the Freedom of Information Act 2000.
- 3.7.6 Specialist Advisors are informed of which other Advisors are being approached for the procedure in question. Their responses are copied by NICE to the professional body that nominated them.
- 3.7.7 This policy did not apply early in the Programme's life, when the identity and opinions of Advisors were confidential. The change in policy is not retrospective. The identities and opinions of Specialist Advisors who gave their views under the arrangements described in the previous Programme Manuals will remain confidential.

3.8 Provisional recommendations

- 3.8.1 Having considered the procedure, the Advisory Committee makes provisional recommendations.
- 3.8.2 In doing so, the Committee considers the following questions:

Efficacy

- What are the measures of efficacy in the studies?
- How appropriate are they? Are they of importance to patients?
- How reliably are they estimated in the published literature?
 - How precisely are the benefits estimated? (Are the numbers of patients in the studies adequate?)
 - Is the estimate of benefits likely to be biased? (Is the quality of the studies adequate?)
 - How well can the estimate of benefits be generalised to the population served by the NHS?
- Is it appropriate to compare the procedure with other treatments?
- Have the benefits been shown to last long enough?
- What other outcomes need to be investigated?
- Is it possible that the apparent efficacy is a placebo response?

- Does the procedure have advantages in very ill patients in whom an alternative procedure would be too risky?
 - Are there types of units or teams to which the procedure should be limited for efficacy reasons?
- Safety**
- What risks have been reported?
 - How reliably are the risks estimated in the published literature?
 - How precisely are the risks estimated? (Are the numbers of patients in the studies adequate?)
 - Is the estimate of risks likely to be biased? (Is the quality of the studies adequate?)
 - How well can the estimate of risks be generalised to the population served by the NHS?
 - Are the risks acceptably low, taking into account the alternative treatments and the prognosis if the condition were untreated?
 - Have the Specialist Advisors (and others) noted any other potential risks, and if so, how serious are they?
 - Is the safety particularly dependent on training?
 - Are there long-term safety concerns?
 - Are the numbers of patients, their representativeness and the quality of the data high enough to exclude a modest but clinically relevant rate of serious complications?
 - Are there types of units or teams to which the procedure should be limited for safety reasons?
- 3.8.3 The Programme is concerned with safety and efficacy and this does not necessarily involve comparison with other procedures or treatments. However, some notified procedures are clearly alternatives to established treatments and, in these cases, the Advisory Committee will consider comparisons of the safety and efficacy profiles of the two treatments.
- 3.8.4 The Advisory Committee may seek further information about the impact of the condition and the procedure on patients, for example, by asking expert patients to attend the Committee or by asking the Patient Involvement Unit and/or a patient organisation to provide more detailed information.
- 3.8.5 NICE has established a Citizens Council to help in determining its approach, and that of its advisory committees, to making social-value judgements. The Council is made up of 30 men and women, broadly representative of the population of England and Wales. Over time, the Council's views are expected to influence and inform the Advisory Committee's and NICE's position on how value judgements should influence its guidance. For example, they may consider what an adequate level of safety is for a procedure and which factors should influence that judgement.
- 3.8.6 Although the Advisory Committee tailors recommendations to each procedure, guidance often takes one of a range of standard forms, depending on whether the procedure is considered to be safe and efficacious enough for routine use or to have inadequate evidence for a judgement about safety and/or efficacy.
- 3.8.7 The Advisory Committee may also make:
- recommendations on the experience, training and facilities needed by clinicians undertaking the procedure
 - recommendations for clinical audit or research, which may include the establishment of a register, the submission of information about long-term outcomes (particularly adverse events) or the provision of the treatment only within a randomised controlled trial or other formal research
 - a recommendation to the Guidance Executive that the procedure be proposed to the Advisory Committee on Topic Selection as a potential topic for a future NICE Technology Appraisal (see Section 3.17).
- 3.8.8 When specific training standards are needed, NICE asks the appropriate specialist society or Royal College to develop and publish them and send NICE a final version.
- 3.8.9 Some procedures involve the implantation or use of a medical device. The Programme usually considers the safety and efficacy of the procedure with any device which carries a CE mark and

publishes guidance which does not name specific devices. Evidence about the procedure using devices without CE marks is not considered. Devices used in individual evaluations are not normally named in the overview. When an exception is made to this, the guidance may state: 'These recommendations are based on evidence about [the procedure] using [specified devices]. There are a number of other devices that can be used in this procedure. NICE has not assessed, and is not providing guidance about, the procedure using these other devices'.

- 3.8.10 The Advisory Committee's provisional recommendations are published as an Interventional Procedures Consultation Document (see Section 3.11). On occasion, the Committee may decide that guidance is not needed but requests that a note setting out its conclusions is placed on the website.

3.9 Referral to the Review Body

- 3.9.1 After considering the overview and the Specialist Advisors' opinions, the Advisory Committee also decides whether or not the procedure should be selected for referral to the Review Body for further investigation.
- 3.9.2 Criteria used to help select interventional procedures for referral include:
- is the procedure likely to result in a substantial health benefit to patients who undergo it?
 - are many patients potentially suitable for the procedure?
 - is the procedure significantly different from those currently used, and might it be the first in a new class of interventional techniques?
 - does the procedure have the potential to cause serious adverse events?
 - is the procedure likely to experience an inappropriate speed of diffusion (too fast or too slow) given the level of evidence for benefit or potential harm?
- 3.9.3 NICE commissions the Review Body to produce a systematic review and/or to organise the collection and analysis of data. The systematic review includes evidence on the procedure from all available sources, including published and unpublished research. Expert opinion is also sought as necessary.
- 3.9.4 The Review Body presents its review to the Advisory Committee, who may then be able to make further recommendations. The Advisory Committee also receives invited submissions from patient/carer organisations, professional bodies and manufacturers (see Appendix B).
- 3.9.5 If the systematic review is not conclusive, or is judged unlikely to be conclusive when it is begun, NICE commissions the Review Body to collect data on the outcomes of the procedure. The Review Body organises the data collection in collaboration, where possible, with the relevant specialist societies, Royal Colleges or other professional organisations. Links with established registers, controlled trials or other prospective studies of listed procedures are encouraged. The Review Body informs NICE, as a matter of urgency, of any procedure that appears to be associated with an unduly high rate of adverse events, either generally or in an individual hospital.
- 3.9.6 When sufficient data have been collected to draw conclusions, the Review Body reports to the Advisory Committee. The Committee may then be able to make further recommendations; if not, data collection will continue.
- 3.9.7 Any recommendations made as a result of the Review Body's work will be published as an Interventional Procedures Consultation Document.

3.10 Surveillance

- 3.10.1 For some procedures, NICE will become aware that potentially important research is due to be published. NICE maintains active surveillance of these procedures and brings a revised overview to the Advisory Committee when appropriate.

3.11 Interventional Procedures Consultation Document

- 3.11.1 When the Advisory Committee has made preliminary recommendations, NICE issues an Interventional Procedures Consultation Document. This sets out:
- ▶ the guidance that NICE proposes to issue
 - ▶ a description of the procedure and its indications
 - ▶ a summary of what is known of its efficacy
 - ▶ a summary of what is known of its safety
 - ▶ other information of importance, such as details of MHRA safety notices, registries and other research.

3.12 The consultation process

- 3.12.1 When consultation begins, NICE publishes the Interventional Procedures Consultation Document on its website for 4 weeks. At the same time, all those who expressed an interest are informed by e-mail that consultation has begun. During consultation, anyone may submit comments via the NICE website, by email or (less usually) by post. No person or organisation may submit comments of more than 20 pages, though 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 one side of A4.
- 3.12.2 Submissions received after the 4-week deadline but before the responses are considered by the Advisory Committee will be shown to the Committee at the discretion of the Chair and Programme Director.
- 3.12.3 NICE has the following specific arrangements for consultation with key stakeholders.

Patient organisations

- 3.12.3.1 The Patient Involvement Unit (PIU) prepares a list of patient organisations that may wish to take part in consultation on each procedure. The PIU invites each of them to participate. If an organisation wishes to respond, NICE then sends it information on the Programme and on the consultation process, as well as the Interventional Procedures Consultation Document once it is issued. The PIU is available to support patient organisations during the consultation.

Medical device manufacturers

- 3.12.3.2 NICE supplies the Association of British Healthcare Industries and Medical Devices in Scotland with a list of procedures shortly before consultation. The two organisations have agreed to alert the manufacturers of relevant devices that consultation will occur, giving them an opportunity to respond.
- 3.12.3.3 To ensure that all relevant device manufacturers are aware of consultations in which they have an interest, NICE also advertises regularly in trade publications to alert manufacturers to forthcoming consultations.

Professional groups

- 3.12.3.4 NICE has advised Royal Colleges and Specialist Societies to express an interest in the categories of procedures performed by their members and fellows in order to be alerted to consultations. NICE also alerts the relevant Specialist Advisors, shortly before consultation opens.

The notifier

- 3.12.3.5 NICE also alerts the person or organisation that notified the procedure.

Named individuals

- 3.12.3.6 NICE alerts any person named in the overview, for example, any clinician closely involved in a procedure's development.
- 3.12.4 Clinicians, patients and any other persons or groups who have expressed an interest via the NICE website will be alerted as consultation opens.

- 3.12.5 When a procedure is referred to the Review Body, several months will elapse before the Advisory Committee considers it again. This provides an opportunity for consultees who responded earlier to prepare a fuller submission than was possible during the initial 4-week consultation period, and then submit it after the submission of the Review Body report and subsequent publication of the Interventional Procedures Consultation Document. The information that NICE provides to consultees at this stage is in Appendix B.
- 3.12.6 NICE will publish alongside each piece of guidance a summary of consultation comments and NICE's response to each.

3.13 The production of guidance

- 3.13.1 The Advisory Committee reviews the consultation document in the light of the comments received during the consultation period and produces draft Interventional Procedures Guidance. An Executive Director of NICE becomes the Executive Lead for the procedure. The Executive Lead is responsible for resolving policy issues raised by the review of the procedure and, with the Programme Director, recommending publication of the guidance to the NICE Guidance Executive.
- 3.13.2 Before the Advisory Committee's consideration of responses, a further search is carried out to check for more recently published material.
- 3.13.3 What consultees include in their response to consultation is a matter for them. However, the Advisory Committee particularly welcomes the following:
- comments on the preliminary recommendation(s)
 - the identification of factual inaccuracies
 - additional relevant evidence.
- 3.13.4 Consultation responses and the replies to them are tabulated for each procedure. The table is published on the website.
- 3.13.5 If the Review Body is to conduct data collection (see Section 3.9), the draft guidance recommends that clinicians undertaking the procedure should submit data. The data collection normally continues until the Advisory Committee can reach a conclusive recommendation about the procedure.
- 3.13.6 In exceptional circumstances, comments received during consultation may prompt the Advisory Committee to refer the procedure to the Review Body for further investigation, to issue a new Interventional Procedures Consultation Document or to issue no guidance. In these circumstances, an explanatory statement will be placed on the NICE website.
- 3.13.7 The NICE Guidance Executive receives and considers the draft guidance on the Board's behalf. NICE then issues the guidance to the NHS in England, Wales and Scotland.

3.14 Resolution of claims of factual error or breach of process

- 3.14.1 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 exists to prevent the publication of guidance containing factual errors or being developed other than in accord with this document.
- 3.14.2 The resolution process is described in detail in Appendix C. Its key elements are as follows:
- 3.14.2.1 After Guidance Executive authorises publication, all those who responded to the consultation document will be alerted electronically and given access to the text of the revised guidance document. However, any request for resolution that falls within the scope of the resolution process and is made before the onset of publication will be investigated, whatever the source.
- 3.14.2.2 It is therefore important that any organisation or individual who may wish to make use of the resolution process later submits a consultation response at the appropriate stage. Individuals and organisations should bear in mind that the guidance distributed as described in section 3.14.2.1 may be significantly different from the Interventional Procedures Consultation Document as a

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

- 3.14.2.3 Individuals and organisations then have 15 working days after the alert to request a resolution on one or both of the grounds of factual inaccuracy and breach of process. Those making requests must specify the remedy that they seek so that NICE can fully understand the nature for their concern and provide an appropriate remedy if there has been an error or breach of process.
- 3.14.2.4 If no request is received, the guidance is published as soon as possible thereafter.
- 3.14.2.5 If a request that is within the scope of the resolution process is received, the Programme Director will investigate the matters referred to in the request.
- 3.14.2.6 The Programme Director then reports on his/her findings to a panel consisting of a non-executive director, the Advisory Committee Chair and an Executive Director previously uninvolved in the procedure, making a recommendation of a remedy if he/she believes that there has been an error or breach of process. The panel, conferring with the Programme Director as required, then decides whether there has been an error or breach of process, and if so, what remedy is appropriate. The Programme Director informs the individual or organisation that initiated the resolution process and all other consultees on that procedure of its result and implements the panel's decision.
- 3.14.2.7 Claims of factual inaccuracy received after the closure of the resolution period, including after publication of the guidance, will be investigated. However, the investigation will include an updated literature search, the results of which are likely to be better considered by the Programme Director and the Advisory Committee Chair, and possibly by the Committee itself.

3.15 Publication and dissemination of guidance

- 3.15.1 The guidance is published on the NICE website and disseminated to the following.
 - Consultants in relevant specialities
 - Specialist Registrars in relevant specialities
 - NHS Trust chief executives in England and Wales
 - Chief executives of NHS Boards in Scotland
 - Medical and nursing directors of hospital trusts in England and Wales
 - Directors of public health, medical and nursing directors of NHS boards in Scotland
 - Clinical governance leads
 - Audit leads
 - NHS libraries
 - Patient advice and liaison coordinators in England
 - Primary Care Trust chief executives in England
 - Local Health Board chief executives in Wales
 - Strategic Health Authority chief executives in England
 - Chief Executive of the NHS in England
 - Chief Executive of the NHS in Scotland
 - Director of the NHS in Wales
 - Chief medical, nursing and pharmaceutical officers in England, Scotland and Wales
 - Chief Executive of NHS Quality Improvement Scotland
 - Director of the NHS Performance, Quality and Regulation Division, Welsh Assembly Government
 - Healthcare Commission
 - National Patient Safety Agency
 - NHS Litigation Authority
 - NHS Clinical Governance Support Team

- Patient advocacy groups invited to be consultees on that procedure
 - Representative bodies for health services, professional organisations and statutory bodies, and the Royal Colleges
 - All those who expressed an interest in the procedure (via email notification that guidance has been issued).
- 3.15.2 NICE publishes information for the public relating to each piece of guidance in easily understandable language. Information for the public is published in English and Welsh.
- 3.15.3 For procedures considered insufficiently safe and/or efficacious for use, the guidance will include reference to any advice that NICE has given to the Department of Health, Welsh Assembly Government, NHS Quality Improvement Scotland, NPSA and MHRA about proscribing the procedure.

3.16 Duration of process

- 3.16.1 NICE is aware of the particular importance of timeliness in the production of guidance on the safety and efficacy of interventional procedures, and has put in place a process that aims to minimise the period of uncertainty before guidance is issued.
- 3.16.2 Indications of the time taken for the process are shown in Figures 1 and 2. However, it is not always possible to achieve the timings set out.

Figure 1 Process of assessment for procedures not referred to the Review Body (Timelines are indicative only and may be subject to change)

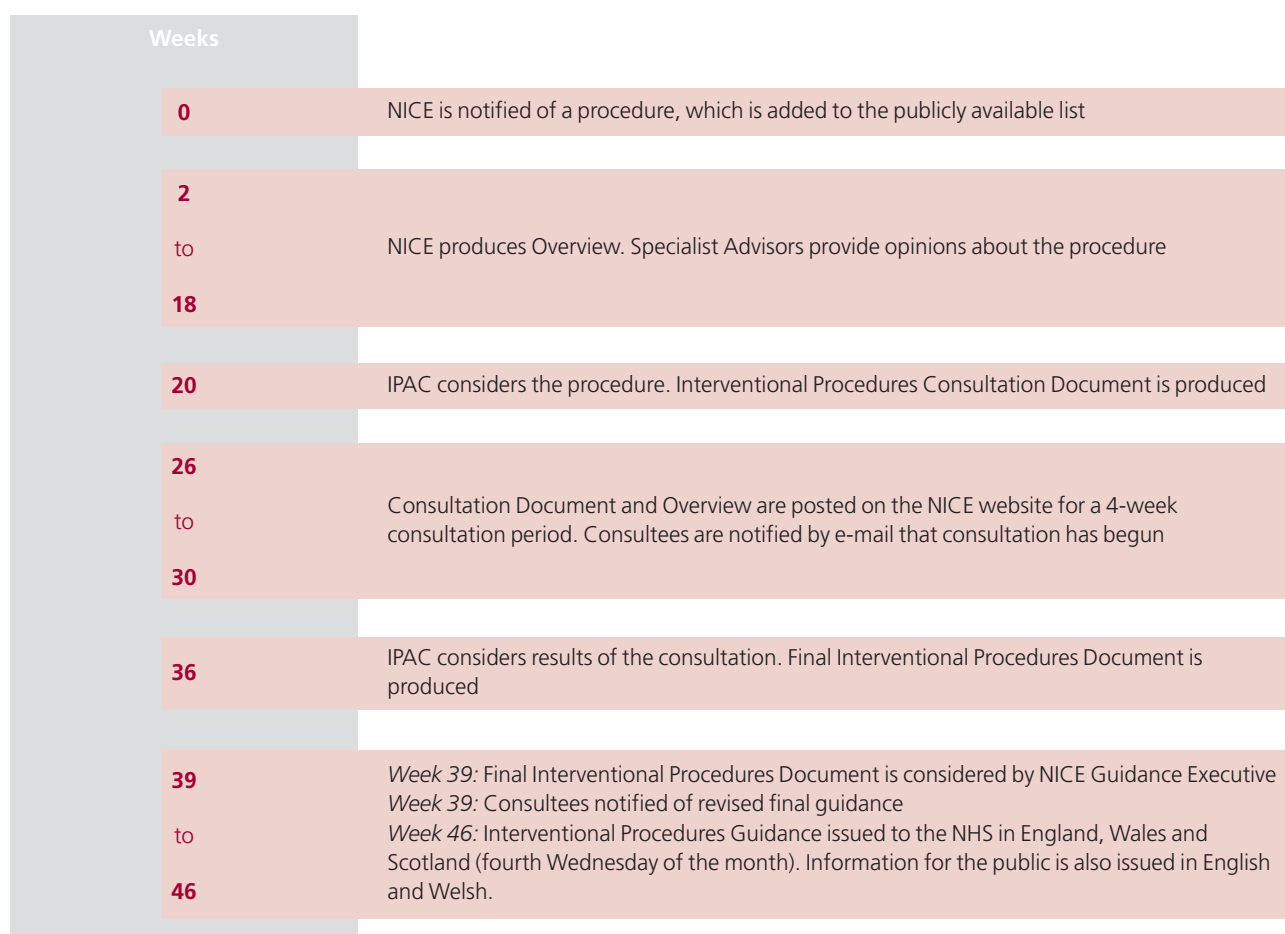
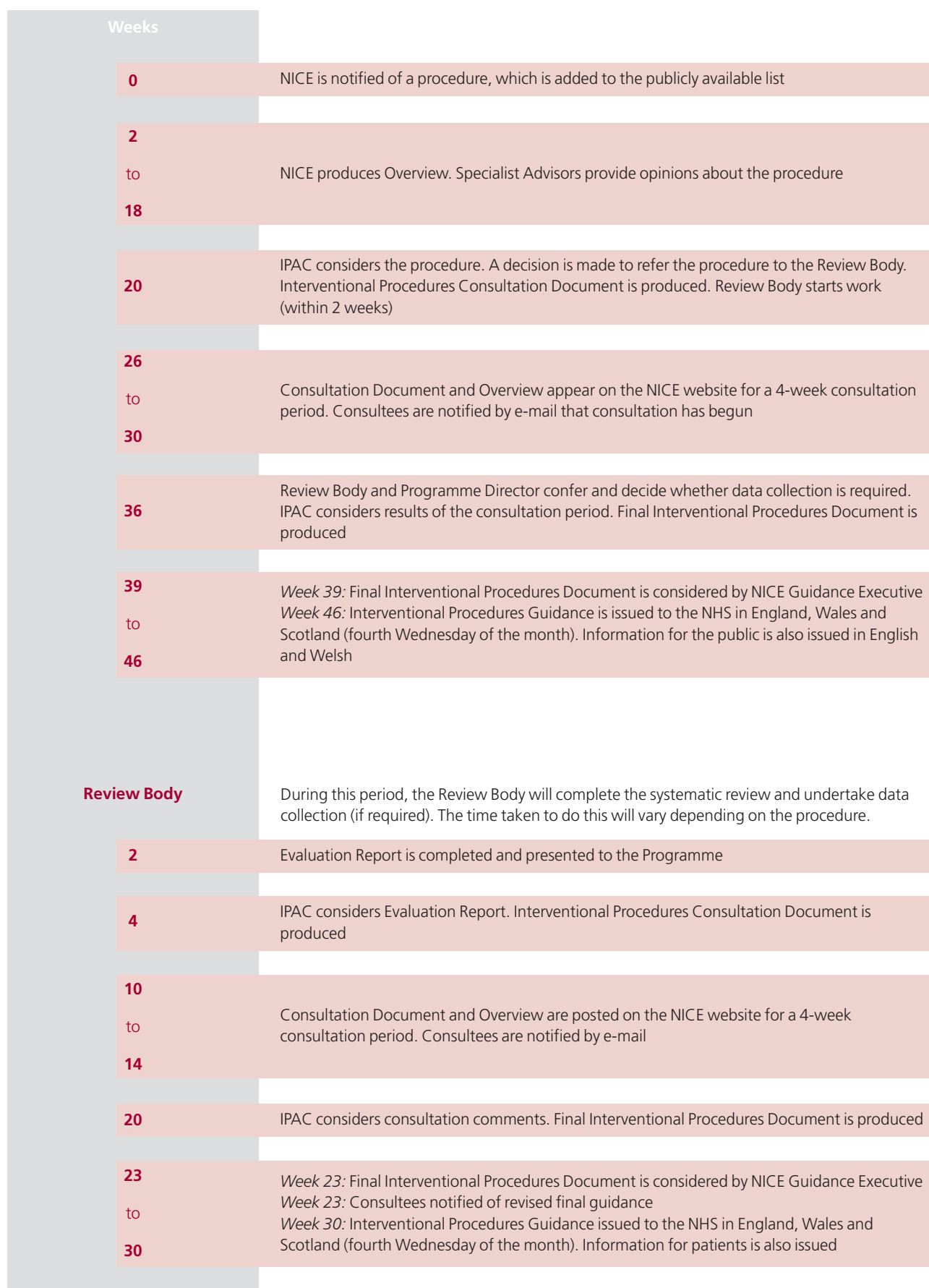


Figure 2 Process of assessment for procedures referred to the Review Body
(Timelines are indicative only and may be subject to change)



3.17 Procedures suitable for Technology Appraisals

- 3.17.1 Some interventional procedures may be referred to NICE by the Advisory Committee on Topic Selection. It is usually appropriate for consideration of safety and efficacy to occur before the Technology Appraisals Programme addresses clinical and cost effectiveness.
- 3.17.2 If NICE concludes that a procedure's safety and efficacy are uncertain, it will not be subject to an Appraisal while the uncertainty persists. This uncertainty and the imprecision in estimating benefits and harms mean that any appraisal would be premature.
- 3.17.3 Among the procedures considered by the Interventional Procedures Programme to be safe and efficacious enough for routine use will be a small number that are suitable for the Technology Appraisal Programme. They are likely to have many of the following characteristics:
- ▶ they are indicated in a common health problem
 - ▶ there are important patient-perspective and clinical advantages over existing treatment(s)
 - ▶ there is no existing treatment, and/or
 - ▶ there is potential for rapid diffusion (for example, the procedure needs no new skill or equipment, and/or is likely to appeal to patients and/or their clinicians)
 - ▶ there are very different costs from existing treatment(s)
 - ▶ there is a connection to a Government priority.
- 3.17.4 The value of referral for an Appraisal will be assessed at various stages in the development of Interventional Procedures Guidance, including the two meetings of the Interventional Procedures Advisory Committee at which the procedure is considered. The Programme Director and Executive Lead may then recommend to Guidance Executive that a Technology Appraisal should be considered. If the recommendation is accepted, the procedure will be referred to the Advisory Committee on Topic Selection.
- 3.17.5 The Institute will notify manufacturers when a procedure in which it has an interest is referred to the Advisory Committee on Topic Selection with a view to a technology appraisal.

3.18 Transparency

- 3.18.1 The minutes of Advisory Committee meetings are published on the NICE website after the Committee has approved them. The overview is also published on the website at the same time as the Interventional Procedures Consultation Document. It includes a summary of the Specialist Advisors' opinions (see Section 3.7). Reports from the Review Body are published when they have been accepted by the Advisory Committee.
- 3.18.2 To ensure that the process is as transparent as possible, the Institute considers it desirable that all evidence pivotal to the Advisory Committee's decisions should be publicly available. Ideally, any of the evidence seen by the Advisory Committee should be disclosable in the consultation documents and in the final guidance. In exceptional circumstances, unpublished evidence can be accepted, under agreement of confidentiality. Such evidence includes data marked 'commercial in confidence', and information and data awaiting publication (marked 'academic in confidence').
- 3.18.3 Where 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 principles set out below:
- ▶ Information and data that has been put into the public domain anywhere in the world may not be marked as confidential.
 - ▶ When it has been decided that release of trial results will occur through journal publication at a date later than the first release by the Institute of documentation quoting data from the trial, a structured abstract should be made available for disclosure, as a minimum. The content of the structured abstract should have a synopsis derived from a recognised format for a full trial report, such as that provided by the CONSORT statement (www.consort-statement.org).
- 3.18.4 The Institute will ask data owners to reconsider restrictions on release of data when either there

appears to be no obvious reason for the restrictions, or such restrictions would make it difficult or impossible for the Institute to show the evidential basis for its guidance.

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

4 After guidance is issued

- 4.1 The NPSA is responsible for monitoring patient safety incidents (adverse events) in the NHS in England and Wales. If the NPSA receives reports that give rise to serious concerns about the safety of a procedure, an assessment of the procedure may be prompted; this applies whether or not the procedure has already been the subject of guidance.
- 4.2 If the adverse event arose from problems with a medical device, its instructions for use, labelling or device/user interface issues, the event should be reported to the MHRA and the NPSA.
- 4.3 Suggestions for review of guidance from any source will be considered when there is new information that calls into question the validity of the current guidance. NICE would like to be informed of new and significant evidence that might prompt reconsideration of a procedure.
- 4.4 NICE does not routinely reconsider Interventional Procedures Guidance. The increasing volume of procedures would make this unsustainable. However, NICE identifies procedures that may need to be reconsidered because of new information discovered by surveillance (see Section 3.10) or submitted by a stakeholder. In this case, a new overview is prepared for Advisory Committee consideration, and further Specialist Advisor comments are also provided.

5 Updating the Programme Manual

- 5.1 NICE will review and update this document 3 years after its publication.
- 5.2 It may be necessary to make small changes to the process before 3 years. Changes to the Programme Manual will be made in accordance with NICE's policy. Minor changes that can 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 one or more stakeholders
 - will improve the efficiency, clarity or fairness of the process or methodology.
- 5.3 Changes meeting these criteria will be published on the NICE website 4 weeks before their implementation. The electronic version of this document will also be updated at that time and a note to this effect placed on the opening page.
- 5.4 Any other changes will only be made after 3 months' public consultation.

6 How to find more information

- 6.1 More information about the Interventional Procedures Programme can be found on the NICE website (www.nice.org.uk/ip). This includes:
- common questions about the Programme, and their answers
 - the list of notified procedures
 - the list of Specialist Advisors
 - the list of members of the Advisory Committee
 - minutes of Advisory Committee meetings
 - Review Body reports
 - Overviews
 - Interventional Procedures Consultation Documents
 - Interventional Procedures Guidance
 - information for the public relating to each piece of guidance issued
 - information for patients whose consent is being sought in regard to a procedure of uncertain safety and efficacy.

APPENDIX A Glossary

Advisory Committee on Topic Selection (ACTS)

This is the Government committee that advises Ministers on the topics for NICE's Technology Appraisals and Clinical Appraisals guidance.

Consultee

A consultee is an individual or organisation who submits a response to an Interventional Procedures Consultation Document.

CE Mark

CE Marking indicates that the manufacturer of a medical device complies with the relevant European Union Directive on safety, quality and performance.

Effectiveness

An effective procedure is one that 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. The Advisory Committee considers procedures only in terms of safety and efficacy; it does not examine clinical or cost effectiveness.

Guidance Executive

The Executive Directors and Programme Directors of NICE, acting on behalf of the Board.

Interventional procedures

Interventional procedures are those used for diagnosis or treatment that involve incision, puncture, entry into a body cavity or the use of ionising, electromagnetic or acoustic energy.

Interventional Procedures Advisory Committee (IPAC)

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

Interventional Procedures Consultation Document (IPCD)

This is a provisional decision about the safety and efficacy of an interventional procedure. The Advisory Committee is responsible for producing the Interventional Procedures Consultation Document after considering the overview and the views of Specialist Advisors, and sometimes a report from the Review Body.

Interventional Procedures Guidance (IPG)

This is guidance on the use of an interventional procedure based on current evidence of its safety and efficacy, issued by NICE to the NHS in England, Wales and Scotland. The Advisory Committee is responsible for producing Interventional Procedures Guidance after the Interventional Procedures Consultation Document has been available for consultation over a 4-week period. The Advisory Committee produces the guidance in light of the comments received during the consultation.

List of notified procedures

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

Medicines and Healthcare products Regulatory Agency (MHRA)

The MHRA (www.mhra.gov.uk) is responsible for the licensing system for medical devices. It has a statutory responsibility to investigate incidents involving medical devices and powers to prosecute manufacturers where 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 Advisory Committee and the two organisations are in regular contact.

National Horizon Scanning Centre

The National Horizon Scanning Centre aims to provide advance notice of new and emerging technologies that might require urgent evaluation, consideration of clinical and cost effectiveness, or modification of clinical guidance.

National Institute for Clinical Excellence (NICE)

NICE is a special health authority set up to promote clinical excellence and the effective use of resources within the NHS. It is responsible for providing national guidance on treatment and care for people using the NHS in England and Wales. Its guidance is for healthcare professionals and patients and their carers to help them make decisions about treatment and healthcare.

National Patient Safety Agency (NPSA)

The NPSA (www.npsa.org.uk) is responsible, among other things, for monitoring long-term adverse events of procedures in use.

NHS Quality Improvement Scotland

The role of NHS Quality Improvement Scotland (www.nhshealthquality.org) is to improve the quality of healthcare in Scotland. This is done by setting standards, monitoring performance and providing advice, guidance and support to NHS Scotland on effective clinical practice and service improvements. By agreement with NHS Quality Improvement Scotland and the Scottish Executive Health Department, NICE's Interventional Procedures Programme covers Scotland.

Overview

NICE produces this document to inform the Advisory Committee about a procedure. It contains information on the indications for and a description of the procedure, its probable frequency of use, a summary of key points from a rapid review of the literature, and a summary of the views of the Specialist Advisors. It is used by the Advisory Committee as the basis for its decisions.

Patient Involvement Unit (PIU)

The PIU advises NICE on patient and carer involvement and identifies patient and carer organisations interested in contributing to its work programme. The PIU 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.

Programme

This refers to the Interventional Procedures Programme.

Review Body

This is the consortium of three British universities and an academic hospital commissioned by NICE to undertake systematic reviews, to facilitate data collection by clinicians and to report to NICE.

Specialist Advisor

A person nominated or ratified by a relevant professional body to provide the Programme with advice about procedures that have been notified.

Stakeholder

A stakeholder is an individual or organisation with an interest in the Programme's activities and outputs.

Systematic review

A systematic review is a summary of a number of individual research reports. It is prepared by comprehensive searching for reports eligible for inclusion, unbiased assessment of their validity and methodical comparison of their methods and findings.

APPENDIX B Extended consultation for procedures referred to the Review Body

Introduction

This appendix sets out arrangements for extended consultation for procedures referred to the Review Body.

Patient/carer organisations

What does NICE need from patient/carer organisations?

From patient/carer organisations, NICE needs an understanding of what it is like to undergo the procedure and what difference the procedure makes to patients' lives.

The following provides examples of the views and information that organisations might wish to include in their submissions:

- the aim of the organisation and who it represents
- the benefits of having had the procedure
- the risks or disadvantages of the procedure (for example, side effects and complications)
- meaningful outcomes for patients and/or carers
- the difference the procedure makes or could make to:
 - physical well-being (for example, symptoms such as pain)
 - quality of life and well-being for the patient and/or carer
 - physical functioning (for example, preventing or improving mobility and other physical disabilities)
- comments on whether the views submitted are widespread in the patient/carer group (even though they may not be widespread, they may still be important)
- the source of the views raised, that is, how and where views were gathered
- the names of any advisors that the group used to support the preparation of their submission
- any other information that the organisation feels is relevant.

What is of lower priority for patient/carer organisations to provide?

The Review Body will conduct on behalf of NICE a systematic review of research on the procedure. NICE will also review technical and clinical data received from manufacturers. NICE does not expect to receive this data from patient/carer organisations.

However, patient/carer organisations may wish to provide NICE with their views on the nature of the existing scientific evidence, for example, the outcome measures used and how they relate to patients and/or carers.

Healthcare professional groups

What does NICE need from healthcare professional groups?

The Review Body concentrates on evidence from all available scientific sources, including published research and conference abstracts. Expert opinion is also sought as necessary. NICE welcomes comments on the quality of the literature. It is particularly helpful for the professional organisations to highlight specific issues of interpretation, for example, concerns over the quality of the literature in general or specific studies. Professional groups will be aware of discrepancies between outcome measures used in research and those that are of most value to them and patients in routine practice.

Professional groups should be able to assess the relative role of the procedure compared to what

is currently available, and likely to become available, in the NHS, and on the importance professionals place on the procedure. They should comment on the consensus, or lack of it, amongst the professional groups on the procedure's safety and efficacy. They may be aware of the potential for adverse events that may not be identified in a research setting. They should also identify any personnel, education and training issues that will need to be addressed.

What is of lower priority for healthcare professional groups to provide?

A formal scope is agreed between NICE and the Review Body, setting out the questions that need to be addressed, and an appropriate search strategy is agreed. It is therefore not necessary for the organisation to undertake a detailed review of the literature.

Medical device manufacturers

What does NICE need from medical device manufacturers?

The Review Body concentrates on evidence from all available scientific sources, including published research and conference abstracts. Expert opinion is also sought as necessary. NICE welcomes comments on the quality of the literature that is likely to be available. It is particularly helpful for the manufacturers to highlight specific issues relating to the safety and efficacy of the procedure.

What is of lower priority for manufacturers to provide?

A formal scope is agreed between NICE and the Review Body. This scope sets out in detail the questions that need a response, and an appropriate search strategy is agreed. It is therefore not necessary for the organisation to undertake a detailed review of the literature.

The Review Body may, during the course of conducting the systematic review, contact manufacturers for technical and clinical data of the procedure. It is therefore not necessary for manufacturers to submit detailed data of this kind.

Format of submissions

What should the submission look like?

This is up to the consultee. NICE does not expect all submissions to be the same. There is no minimum length and it is not usually necessary to provide more than 20 pages. If a submission is longer than 10 pages, it should contain an executive summary of no more than one side of A4.

NICE would like to receive submissions electronically (by email or disk) and using Microsoft software packages and Rich Text Format (rtf) documents. On occasion, however, NICE will also accept submissions in paper format.

What is the time frame for submission?

The Institute will specify a deadline that will be notified to all organisations who responded to the first consultation, all identified patient/carer organisations, professional associations and relevant device manufacturers.

Further material for submission

Some organisations may want to develop new material for their submission. Please note this is not a requirement. Examples of some work that groups undertake are:

- commissioned research, for example, focus groups
- membership surveys/questionnaires
- workshops and subsequent reports
- analysis of patient/carer views.

Declaration of interests

Consultees should explain if they receive financial support or formal advice, or collaborate in other ways with companies or commercial interests associated with the procedure under assessment. Declaring these interests does not invalidate the submission.

APPENDIX C The resolution process

Introduction

The resolution process enables those who have been involved with and/or have an interest in the development of Interventional Procedures Guidance to remedy concerns about its development prior to its publication. It is intended to assist NICE in ensuring that it acts fairly, follows its own processes and produces clear, accurate guidance.

How the resolution process fits into the Programme

The consultation stage

The Programme includes a consultation stage, at which NICE publishes a consultation document that contains provisional recommendations and is linked to an overview of published evidence. This is the means by which comments on the proposed guidance are elicited for consideration by the Advisory Committee and disagreement with the Committee's judgements expressed and taken into account. Because the resolution process does not provide direct access to the Advisory Committee and does not consider matters of interpretation of evidence or scientific judgement, its use is not an alternative to engagement during consultation.

The resolution stage

After Guidance Executive authorises publication, all those who responded to the consultation document will be alerted electronically and given access to the text of the revised guidance document. However, any request for resolution that falls within the scope of the resolution process and is made before the onset of publication will be investigated, whatever the source. Requests for resolution must be made in the 15 working days following the alert. Publication of guidance will not occur until either the period for activating the process has passed without any resolution requests being submitted, or the resolution process had been completed.

Any resolution request submitted is then considered as set out in the section below. If the request for resolution does not claim breach of process or factual error, or it is concluded that there has been no breach of process and that there are no errors in the guidance, then the guidance is published. Otherwise, the next steps will depend on the nature of the problem found.

Grounds for resolution

The grounds for invoking the resolution procedure are:

- 1 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 Advisory Committee even though it is relevant.
- 2 Ground 2: factual errors in the proposed guidance. This encompasses cases in which there is an objective error of 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 to be given in Section 1 of the guidance document, or to the weight given to one piece of research or evidence over another. For example, if a consultee argues that a statistic quoted in the guidance is incorrect, NICE will establish whether the proposed final guidance misquoted the statistic or whether there were two different sets of evidence available, one being preferred because the Advisory Committee considered it to be more reliable evidence. If it is the latter, there is no factual error, but a difference of scientific judgement.

Where a factual error is identified in the guidance, the resolution panel will consider whether the error can simply be corrected by Guidance Executive before publication or whether the Advisory Committee should review the appropriateness of the remainder of the guidance document in light of the error identified.

The nature of the resolution process

Requests for a resolution are dealt with as follows:

The Programme Director investigates the subject matter of the request for the resolution and reports on it to the resolution panel. In the case of ground 1, this means establishing what process had been followed in the particular case and the position in terms of events or omissions alleged by the party requesting the resolution. In the case of ground 2, this involves investigating what evidence and judgements lay behind the references in the guidance that are alleged to be errors.

The request for a resolution is then considered by a resolution panel comprising a non-executive director, the Advisory Committee Chairman and an Executive Director previously uninvolved in the procedure – conferring with the Programme Director as required.

The outcome of the resolution panel's consideration is one of the following.

- ▶ In relation to requests for resolution under ground 1, a finding either that there has been no breach of process 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 assessment process from a certain point, including, where necessary, re-opening consultation and/or referral back to the Advisory Committee.
- ▶ In relation to requests for resolution under ground 2, a finding 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) so that an amended version of the guidance will be produced (as indicated in 'Grounds for resolution'), the amended version of the guidance may be produced either by the Guidance Executive or by the Advisory Committee, depending on the nature of the error identified and its impact on the remainder of the guidance document.

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

However, if it is decided under ground 2 that the wording of the guidance should be changed, NICE considers whether to publish the guidance containing the amended wording, or whether there is a need for further consultation with other interested parties. This depends on the nature of the changes, the nature of the different interests in the guidance and on other circumstances.



*National Institute for
Clinical Excellence*

**National Institute for
Clinical Excellence**

MidCity Place
71 High Holborn
London WC1V 6NA

www.nice.org.uk

£10.50