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# **Interventional Procedures Programme**

Process guide

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**Issued: January 2009** 

This booklet describes how NICE prepares guidance on the safety and efficacy of interventional procedures.

The booklet is available from the NICE website (www.nice.org.uk) or from the NHS Response Line (phone 0870 1555 455 and quote reference number N1761).

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#### 1 Introduction

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. Further details about NICE and its work programmes are available in 'NICE: our guidance sets the standard for good healthcare', which can be downloaded from the website (www.nice.org. uk/aboutnice/whatwedo/what\_we\_do.jsp).

NICE produces guidance on the use of new and existing medicines, treatments and procedures within the NHS, including the efficacy and safety of 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. Assessment of the efficacy and safety of interventional procedures is carried out by NICE's Interventional Procedures (IP) Programme, which comprises the Interventional Procedures Advisory Committee (IPAC or 'the Committee') and a Programme team, which carries out technical tasks and project management. The Programme team is employed by NICE. All members of the Committee are independent of NICE. Although the IP Programme mostly investigates new procedures, it may also examine an established procedure if there is uncertainty about its efficacy and/or safety.

The purpose of this guide is to describe how NICE produces its guidance on interventional procedures. The process is designed to ensure that robust guidance is developed for the NHS in an open, transparent and timely way, allowing appropriate input from consultees and other stakeholders. This guide updates the Interventional Procedures programme manual (September 2004) and is intended to be complementary to the Interventional Procedures methods guide (IP methods guide) (www.nice.org. uk/ipmethodsguide).

See Appendix A for a glossary of terms used in this document.

# 2 The IP Programme

# 2.1 The aims of the Programme

NICE's IP Programme assesses the efficacy and safety 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 efficacy and safety of interventions, the Programme enables clinical innovation to be conducted responsibly. No interventional procedure is entirely free from risk, but the Programme gauges the extent of uncertainties and makes recommendations on their implications.

NICE issues guidance on interventional procedures to help 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 are supported in the process of introducing new procedures
- NICE fosters innovation by providing advice on the efficacy and safety of new procedures, recommending training and other conditions for their use in the NHS, facilitating data collection and analysis, and arranging systematic reviews.

Nearly all the procedures that the Programme investigates are not well established in clinical practice, but the Programme can also scrutinise more established procedures if there is reason to be uncertain about their efficacy and/or safety.

NICE is committed to promoting equality and eliminating discrimination. As a public authority NICE must also comply fully with legal obligations to promote race and disability equality and equality of opportunity between men and women; and to eliminate unlawful discrimination on the grounds of race, disability, age, sex and gender, sexual orientation, and religion or belief. This is in accordance with NICE's Equality Scheme<sup>1</sup>.

<sup>&</sup>lt;sup>1</sup> www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp

# 2.2 The key activities of the Programme

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 assessed
- compiling and maintaining a list of notified interventional procedures
- preparing procedure scopes and overviews
- obtaining specialist advice and patient commentary
- convening meetings of the Committee, providing it with evidence and securing its preliminary recommendations
- preparing interventional procedures consultation documents (IP consultation documents) based on the Committee's preliminary recommendations
- consulting on IP consultation documents
- producing interventional procedure guidance (IP guidance) based on the final recommendations of the Committee
- providing a resolution process by which consultees have a mechanism for reviewing NICE's guidance for factual errors or breaches of process before it is published
- issuing IP guidance to the NHS in England, Wales, Scotland and Northern Ireland
- advising on the production of a lay version of the guidance ('Understanding NICE guidance')
- advising on the production of audit tools for the guidance when these are recommended
- reviewing and updating guidance when required
- raising awareness of the Programme in the NHS in England, Wales, Scotland and Northern Ireland.

# 2.3 Duration of the process

NICE is aware of the importance of timeliness in the production of guidance on the efficacy and safety of novel interventional procedures, and aims to minimise the period of uncertainty about the use of procedures before guidance is issued.

Indications of the times taken for stages in the process are shown below. However, it is not always possible to achieve the timings set out. The length of time between notification and the agreement of the scope by the Committee is highly variable, depending on the need to obtain further information about the procedure. For example, for some topics it may be necessary to make further enquiries to establish the extent to which the procedure is being used in the NHS, or that there is an evidence base with which to assess it.

Week	Event
	The procedure is notified to NICE.
0	The Committee agrees the scope. (The time period between notification and the Committee agreeing the scope can vary depending on the need to obtain further information about the procedure.)
0–10	NICE produces the overview. Specialist Advisers and Patient Commentators provide comments about the procedure.
13	The Committee considers the evidence and commentary on the procedure and produces draft recommendations. An IP consultation document is produced.
20–24	The IP consultation document and overview are posted on NICE's website for a 4-week consultation period.
26	The Committee considers consultation comments. A final IP document is produced.
30	The final IP document is considered by the NICE Guidance Executive.
30–33	The final IP document is open to resolution requests (3 weeks).
37	IP guidance is issued to the NHS in England, Wales, Scotland and Northern Ireland. The lay version of the guidance ('Understanding NICE guidance') is also published in English and Welsh.

# 2.4 How the Programme affects patients, clinicians and NHS organisations

NICE produces guidance about whether interventional procedures used for diagnosis or treatment work well enough and are safe 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.

NHS clinicians are responsible for notifying procedures to NICE where appropriate and for applying NICE guidance to meet the needs of individual patients. They are also 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 which would be inconsistent with compliance with those duties.

NICE guidance helps clinicians and NHS organisations to:

- provide patients with appropriate information about interventional procedures (NICE produces a lay version of the guidance for each procedure)
- understand the circumstances under which a procedure is efficacious and safe enough for use
- encourage gathering of further information where uncertainty exists (NICE produces audit support for procedures of uncertain efficacy and/or safety)
- protect patients from inappropriate procedures.

It is not within the remit of the IP Programme to evaluate the cost effectiveness of interventional procedures or to advise the NHS on whether interventional procedures should be funded. NICE assesses procedures which incorporate a device with CE marking if they fall within the remit of the Programme. NICE IP guidance does not name or relate to specific devices.

The Department of Health, the Welsh Assembly Government, the Scottish Government Health Directorates and the Northern Ireland Department of Health, Social Services and Public Safety have issued guidance<sup>2</sup> to the NHS on how to engage with the Programme. These stipulate that clinicians should notify their first use of new interventional

<sup>&</sup>lt;sup>2</sup> Smart codes and weblinks for this guidance from the Department of Health, the Welsh Assembly Government, the Scottish Executive Health Department and the Northern Ireland Department of Health, Social Services and Public Safety are: HSC 2003/011 (www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH\_4064922); WHC [2003] 58 (www.nice.org.uk/niceMedia/pdf/ip/welshhealthcircular200358.pdf); HDL [2004] 04 (www.show.scot.nhs.uk/sehd/mels/HDL2004\_04.pdf); and PPMD(NICE)1/07 (www.dhsspsni.gov.uk/ppmd\_nice\_1-07.pdf), respectively.

procedures to the Programme 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 in the period before guidance is issued. This guidance does not mean that an individual clinician performing a well-established procedure for the first time should notify it to the Programme.

These arrangements are underpinned by the inspections carried out by the Healthcare Commission<sup>3</sup> and the requirements of the Clinical Negligence Scheme for Trusts Risk Management Standards issued by the NHS Litigation Authority. In Scotland, NHS Quality Improvement Scotland assesses compliance with all national guidance through its clinical governance and risk management reviews of NHS Boards.

Similar arrangements also exist in independent hospitals because of memoranda of understanding between NICE and the Association of British Insurers and the Independent Healthcare Advisory Services, respectively.

<sup>&</sup>lt;sup>3</sup> The Healthcare Commission will change its name to the Care Quality Commission in April 2009.

# 3 Who is involved in developing IP guidance?

#### 3.1 The IP Programme team

The IP Programme is part of NICE's Centre for Health Technology Evaluation. The IP Programme team consists of the Director and Associate Director along with technical, project management and administrative staff who support the Committee and are responsible for carrying out aspects of the work associated with the development of IP guidance. The role of the IP Programme team includes: considering procedures notified to the Programme; preparing evidence and commentary for consideration by the Committee; arranging public consultation on the Committee's draft recommendations; preparing guidance for publication by NICE; and ensuring NICE's published processes and methods for the development of IP guidance are followed in line with agreed timelines and standards of quality. The IP Programme team is committed to improving its practice and methods by conducting operational research and audit.

In addition to the IP Programme team, other teams at NICE provide support to the development of IP guidance.

#### 3.1.1 The Editorial team

The Editorial team reviews and edits the documents that support the development of IP guidance, for publication on NICE's website. These include evidence overviews, consultation documents and guidance. The team also produces the lay version of NICE's IP guidance, 'Understanding NICE guidance'.

#### 3.1.2 The Implementation team

The Implementation team produces audit tools for procedures where the Committee's recommendations require them, and where there is no suitable register or organised system for data collection. The audit tools are developed with advice from Specialist Advisers and Committee members, as appropriate.

#### 3.1.3 The Information Services team

The Information Services team searches for evidence relevant to the procedures. This evidence is used by the IP Programme team to prepare an overview of a procedure for the Committee.

#### 3.1.4 The Patient and Public Involvement Programme (PPIP)

The PPIP recruits and supports lay members of the Committee; identifies Patient Commentators (see section 3.4 below); encourages members of the public and patient organisations to respond to consultation; and establishes links with patient organisations with an interest in IP guidance. NICE uses the terms 'patient organisation' and 'patient group' to include patients, carers and community and other lay organisations, including those that represent people from groups protected by equalities legislation.

# 3.2 The IP Advisory Committee

The Committee is made up of 25 members with a range of expertise, all independent of NICE. It includes clinicians who carry out interventional procedures, people who are familiar with the issues affecting patients, carers and trusts, experts in regulation and in the evaluation of healthcare and a representative from the medical technologies industry.

The Committee meets monthly (excluding August) in public. Agendas and minutes of Committee meetings are published on NICE's website (www.nice.org.uk/ipac). The minutes are a contemporaneous note of the business of the meeting.

#### 3.2.1 The role of the Committee

The Committee makes recommendations to NICE on the efficacy and safety of interventional procedures and the context of guidance, such as conditions under which procedures should be used. Committee members are required to submit an annual declaration of interests, and declare any conflicts of interest at each Committee meeting, in line with NICE's Code of practice for declaring and dealing with conflicts of interest<sup>4</sup>.

 $<sup>^4</sup> www.nice.org.uk/aboutnice/whoweare/policies and procedures. jsp?domedia=1\&mid=EEF24FBA-19B9-E0B5-D4ED345FBCECFBA1$ 

#### The Committee's recommendations

Depending on its judgement on the evidence, advice and commentary considered, the Committee will generally make one of the following main recommendations for use of the procedure:

- Use with normal arrangements for clinical governance, consent and audit.
- Use with special arrangements for clinical governance, consent and audit or research.
- Use only in research.
- Do not use.

(see section 6.3 below)

#### 3.2.2 How Committee members are appointed

Committee members are appointed through an open advertisement (posted on NICE's website) for a period of 3 years by a panel consisting of an Executive Director, a Non-Executive Director and the Chair of the Committee. This may be extended for a further 3 years by mutual agreement. A list of current members is published on NICE's website.

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

# 3.3 Specialist Advisers

The Committee is assisted by Specialist Advisers, who are clinicians involved in the use of identified interventional procedures. These Specialist Advisers are nominated or approved by their professional bodies such as Royal Colleges. NICE uses the term professional bodies to include Royal Colleges, specialist societies and other professional associations.

# 3.3.1 The role of Specialist Advisers

The Specialist Advisers provide advice about interventional procedures that complements findings from research. Specialist Advisers may also be asked to advise the IP Programme team and/or the Committee on the following aspects of individual procedures within their area of expertise or knowledge:

- the validity of the notification and its relevance to the Programme's remit
- preparation of the scope
- preparation of the overview
- the development of an audit tool for the procedure where appropriate (see section 9.1 below)
- the development of a lay version of the guidance.

They may be called on to provide their opinions to the Committee in person when necessary, for example in situations where there is no Committee member present with that specialism.

#### 3.3.2 The identification of Specialist Advisers

NICE identifies clinicians to assist the programme as Specialist Advisers in two ways.

- NICE approaches a professional body to nominate individuals able to give an informed opinion about interventional procedures. NICE encourages professional bodies to consider nominating Specialist Advisers from all sections of the community.
- A current Specialist Adviser recommends another clinician to give specialist advice. In such cases, the relevant professional body is asked to ratify the clinician as a Specialist Adviser.

Approved Specialist Advisers are appointed to the Programme for a term of 3 years, and are given the option every 3 years to renew their term. A specialist's eligibility to advise the Programme ends if they retire from practice.

A list of Specialist Advisers ratified by their professional body is published on NICE's website.

#### 3.4 **Patient Commentators**

The Committee draws on information supplied by Patient Commentators who: have undergone the procedure; are the carer of someone who has done so; or have been offered the procedure and declined it.

#### 3.4.1 The role of Patient Commentators

The process by which patient commentary is obtained was designed to produce information on patient views in addition to information obtained from patient

organisations and individual patients who contribute their views through the usual NICE consultation process (see section 7.1 below).

The Patient Commentators complete a questionnaire to provide information to the Committee about their personal experience of the procedure or, if relevant, the reason they chose not to have the procedure.

#### 3.4.2 The identification of Patient Commentators

NICE approaches the notifier of a procedure in order to determine where a procedure is being performed. NICE then contacts the identified hospitals to seek approval for patients and/or their parents or carers to be invited to complete a questionnaire on their experience of the procedure. If the total number of patients who have had a procedure is fewer than 60, NICE asks identified trust(s) carrying out the procedure to send the questionnaire to all patients. If the figure is more than 60 we ask trusts to send questionnaires to a random sample of 60 patients. Anonymised responses to the questionnaires are presented to the Committee to assist in formulating its recommendations (see section 6.2 below). The number of responses varies depending on the stage of development of the procedure and the type of procedure that is being performed.

#### 3.5 The Review Body for Interventional Procedures

NICE commissions the Review Body to carry out systematic reviews of the evidence on interventional procedures if required (see section 6.4 below and Appendix B). The Review Body also provides advice on the assessment of interventional procedures to the Committee, the Committee Chair and the IP Programme team. Academic members of the Review Body attend Committee meetings in a technical advisory capacity.

# 3.6 Relationships with other organisations

NICE works closely with many professional, NHS and other organisations, including those representing patients and carers. Important partners in the Programme include:

- the Healthcare Commission
- the Department of Health
- the Welsh Assembly Government
- the Scottish Government Health Directorates
- the Northern Ireland Department of Health, Social Services and Public Safety

- the Medicines and Healthcare products Regulatory Agency (MHRA)
- the National Institute for Health Research Health Technology Assessment (HTA)
  Programme
- the National Horizon Scanning Centre
- the National Patient Safety Agency (NPSA)
- the National Specialised Commissioning Group
- NHS Connecting for Health
- the NHS Litigation Authority
- the Welsh Risk Pool Scheme
- NHS Quality Improvement Scotland
- NHS Research and Development
- NHS Technology Adoption Centre
- the Association of British Healthcare Industries (ABHI)
- device manufacturers
- patient organisations
- professional bodies, for example the Royal Colleges.

# 4 Deciding whether to notify a procedure to NICE

Procedures should be notified to NICE if:

- they are entirely novel, with an unknown or uncertain efficacy and/or safety profile; or
- they are a variation of an established procedure which is likely to have a different efficacy and/or safety profile from that of the established procedure.

Sometimes established procedures undergo minor alterations in the hands of practitioners, and these would 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 (see also section 2.1 above).

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

Stakeholders can contact the IP Programme team for advice on whether it is appropriate for a procedure to be notified to the Programme.

#### 4.1 Sources of notifications

Anyone may notify a procedure for consideration by the IP Programme, although the main source of notifications is clinicians and healthcare professionals, following the guidance from the Department of Health, Welsh Assembly Government and the Scottish Government Health Directorates set out in section 2.4 above. Notifications are normally made via NICE's website.

Non-clinical NHS staff are encouraged to discuss the procedure with a clinician before notifying, because completion of the webform (www.nice.org.uk/ipnotify) is improved by clinical knowledge of the procedure.

Professional bodies, the MHRA, the NPSA, the National Institute for Health Research HTA Programme or other organisations may also notify NICE about interventional procedures that are being performed in the NHS outside formal research, or those that clinicians are considering performing.

Manufacturers of devices may also notify procedures they believe may be within the remit of the Programme.

The National Horizon Scanning Centre notifies NICE of procedures likely to be used for the first time in the NHS outside a formal research setting within the next year.

NICE approaches professional bodies from time to time to invite them to notify procedures.

When notifying a procedure to the Programme, the information that is required includes:

- contact details of the notifier.
- name of the interventional procedure
- description of the interventional procedure
- indications for which it is to be used
- any other procedure that the new procedure is likely to replace or may be compared with
- the location where the procedure is (or is about to be) performed this may be in the NHS or the independent sector
- sources of evidence relating to the procedure
- the name of the device(s) and/or manufacturer(s) and, if known, whether the device is appropriately CE marked
- if the notifier is not a clinician, the name of a clinician for NICE to contact in connection with the notification
- any special training that might be required to carry out the procedure.

# 4.2 Deciding whether a procedure is within the remit of the Programme

Once a procedure has been notified, NICE determines whether it falls within the remit of the Programme. This is done through regular review of notifications by the IP technical team, with advice from Specialist Advisers, the IPAC members and Chair, or others, as required. Advice is taken primarily in order to establish any key facts about the procedure which were not clear from the notification, to help the technical team determine whether the procedure meets the Programme's remit.

To fall within the Programme's remit, 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 independent sector, or be about to be used for the first time, outside formal research; and
- either not yet be generally considered standard clinical practice; or
- be a standard clinical procedure, the efficacy or safety of which has been called into question by new information or advice.

Procedures do not fall within the Programme's remit if they are considered standard clinical practice with an efficacy and safety profile that is sufficiently well known. All surgical procedures carry some risks. It is the extent of uncertainty surrounding the efficacy and safety that the IP Programme investigates.

The final decision regarding the suitability of a procedure for inclusion in the Programme is made by the Director of the Centre for Health Technology Evaluation and the Chair of the Committee. All decisions are recorded on NICE's website.

#### 4.3 The outcome of notification

If a procedure falls within the remit of the Programme, it proceeds to be assessed (see section 5 below).

If a procedure notified to the Programme is not yet being used in the NHS or independent sector, or there is not an evidence base with which to assess it, the IP Programme monitors it and will assess it at a future date should the circumstances change. In the meantime, 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 set out above, it will not be assessed by the Programme. Notified procedures that are not within the remit of the Programme and the reasons for non-inclusion are listed on NICE's website. See also section 10.4 below.

Regardless of whether or not the procedure is within the remit of the Programme, the notifier of the procedure is informed of the outcome of their notification.

# 4.4 Registering an interest

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

Stakeholders are encouraged to register an interest, because this is the most reliable way of ensuring awareness of a procedure's progress and of being alerted to consultation and publication. By registering an interest in a procedure, individuals acquire the status of stakeholders, with the right to return consultation comments and make a resolution request later in the process. NICE welcomes registration of stakeholders from all sections of the community, both in the UK and internationally.

# 5 Procedure scopes and overviews

#### 5.1 Producing a scope

A scope is prepared by the IP Programme team, covering key aspects of the procedure, to enable it to be assessed. Scopes are formulated in accordance with NICE's Equalities Scheme. The scope is presented to the Committee for consideration. Once the scope has been agreed by the Committee, the procedure becomes part of the formal work of the IP Programme. At this point, NICE's website indicates that the procedure is 'in progress'.

For further details of how the IP Programme scopes procedures, see the IP methods guide.

# 5.2 Producing an overview

Interventional procedures overviews are brief documents, including an assessment of the most relevant studies found by literature searches. NICE prepares an overview for each notified procedure that falls within the Programme's remit. The overview summarises:

- the nature and purpose of the procedure
- the results of the most relevant studies found in a rapid review of the literature
- key efficacy and safety findings that arise from review of the literature
- the opinions of the Specialist Advisers
- an indication from the Patient Commentators of any outcomes not identified in the literature or by the Specialist Advisers.

Overviews are prepared by the IP Programme team on the basis of a literature search provided by the Information Services team.

Occasionally, NICE will become aware that important new evidence is due to be published on a procedure for which a scope has been agreed by the Committee. In these circumstances, NICE may delay the presentation of the overview to the Committee until that evidence is available.

Although some interventional procedures involve the use of a device, the IP Programme does not evaluate the device itself. Formal submissions from device manufacturers are not routinely requested or used unless the literature search indicates that the published evidence for a procedure is very limited. If NICE is aware of relevant material not in the

public domain it will consider whether to include this in the overview.

For further details on how the IP Programme selects evidence and prepares overviews, see the IP methods guide.

A systematic review may be deemed necessary for some procedures. This may happen if, for example, there is a large body of evidence on a procedure that would be difficult to present to the Committee in the format of an overview. NICE will refer such procedures to the Review Body (see section 6.4 below and Appendix B).

# 6 The development of provisional recommendations

The Committee meets to develop provisional recommendations on the efficacy and safety of interventional procedures. In doing so it considers the overview of evidence along with commentary from Specialist Advisers and Patient Commentators. Provisional recommendations are formulated in accordance with NICE's Equalities Scheme.

# 6.1 Contributions from Specialist Advisers

NICE seeks the opinion of at least two Specialist Advisers (see section 3.3 above) on each procedure before it is considered by the Committee. New procedures often have potential benefits and, importantly, risks that are not yet fully described in the scientific literature. Specialist Advisers provide insight into these aspects of a procedure, sometimes supported by accounts of their clinical experience, which complement the published evidence, particularly when this is limited. A list of all current Specialist Advisers is on NICE's website.

The Specialist Advisers are selected because of their knowledge of the clinical field in question. NICE approaches the relevant professional bodies for the names of Specialist Advisers for each procedure. The opinions of these identified Advisers will always be obtained if possible; however, to maintain timeliness NICE will make use of previously approved Advisers if necessary. To minimise bias, NICE seeks Specialist Advisers who have performed the procedure and those who have not. If the procedure covers more than one specialty, at least one Specialist Adviser from each specialty is used where possible.

Occasionally, NICE may not be able to find Specialist Advisers with sufficient knowledge of the procedure to give advice. This is most likely to occur with very new procedures. If two Specialist Advisers cannot be found from those approved in the relevant specialty or specialties, the development of guidance on the procedure will normally be delayed until suitable specialist advice is available. In exceptional circumstances it may be appropriate to proceed with a single Specialist Adviser, at the discretion of the Chair of the Committee.

Specialist advice is normally provided in the format of a questionnaire. The names of the Specialist Advisers who provided advice for a specific procedure are given in the overview, along with the professional body that nominated or ratified them. Their responses to the questionnaire are available on written request, in accordance with the provisions of the Freedom of Information Act 2000. Questionnaires completed by Specialist Advisers are copied by NICE to the professional body that nominated them.

A clinician who has notified a procedure to NICE cannot normally act as a Specialist Adviser for that same procedure. However, there may be times when a notifier's

expertise in or specialised knowledge of the procedure means that it is appropriate that they are asked for advice.

All Specialist Advisers are asked to declare any conflicts of interest in line with NICE's Code of practice on declaring and dealing with conflicts of interest<sup>5</sup>. These conflicts are presented to the Chair and the Committee at the time the Advisers' questionnaires are considered.

A Specialist Adviser may be asked to provide more detailed assistance to the Programme. This includes but is not restricted to attending Committee meetings (either by telephone or in person), commenting on an audit tool (if it is identified for the procedure) and commenting on the lay version of the guidance (see also section 3.3 above).

#### 6.2 Contributions from Patient Commentators

NICE's PPIP seeks further information about the impact of the condition and the procedure on patients and/or their carers or parents before it is considered by the Committee. 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.

The PPIP approaches NHS hospitals and requests that they send a questionnaire to patients (or their carers or parents). NICE endeavours to ensure that patient opinions are obtained by questionnaire for as many procedures as possible, but since it relies on hospitals to agree to sending 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 development of guidance if patient questionnaires are not available for a procedure.

The names of Patient Commentators are personal data under the Data Protection Act 1998 and these would not normally be released into the public domain. However, an anonymised copy of information supplied by them about their experience of the procedure is available upon request.

Occasionally procedures are notified to the IP Programme for which it may be inappropriate or impossible to obtain commentary from Patient Commentators (for example, an intraoperative diagnostic procedure which a patient may be unaware has been used in the course of their treatment). By agreement between the IPAC Chair, the IP Programme team and the PPIP, contributions from Patient Commentators are not sought in these cases.

<sup>&</sup>lt;sup>5</sup> www.nice.org.uk/aboutnice/whoweare/policiesandprocedures/policies\_and\_procedures. jsp?domedia=1&mid=EEF24FBA-19B9-E0B5-D4ED345FBCECFBA1

#### 6.3 Provisional recommendations

The Committee makes its provisional recommendations on the efficacy and safety of the procedure, taking account of the overview, specialist advice and patient commentary. For each procedure it 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. The Committee does not have a remit to determine the placement of a procedure in the pathway of care for the condition or disease in question.

When the Committee makes recommendations about specific training standards, NICE may ask the appropriate professional body to develop and publish them.

When the Committee recommends that special arrangements be in place for audit, and there is no register or data collection facility in place, NICE prepares an audit tool containing audit criteria to be developed for the procedure. The criteria are developed with advice from Specialist Advisers and IPAC members, as appropriate.

Some procedures involve the implantation or use of a medical device. Where this is the case, the Programme considers the efficacy and safety of procedures using devices that are already CE marked. Evidence about the procedure relating to devices without CE marking may also be considered in the course of assessing a procedure if it meets the inclusion criteria, and may be included in the overview presented to the Committee. This includes relevant evidence from countries outside the European Union. If proprietary names of medical devices are specified in the published studies, such names may be included in the overview of the evidence, but NICE's guidance does not name or relate to specific manufacturers' devices.

The Committee's provisional recommendations are published as an IP consultation document (see section 6.6 below).

NICE has a Citizens Council to help in determining its approach, and that of its Committees, to making social value judgements. The Council's views continue to influence and inform the Committee's and NICE's position on how value judgements should influence its guidance. For example, it may consider what an adequate level of safety is for a procedure, and which factors should influence that judgement.

Further information on the approach taken by the Committee, the considerations it takes into account and the standard wording of recommendations are in the IP methods guide.

# 6.4 Referral to the Review Body

After considering the overview and the Specialist Advisers' opinions, the Committee may decide to refer the procedure to the Review Body for development of a systematic review. In these circumstances, the Committee may decide to issue interim guidance on the procedure. For details of how the Review Body prepares a systematic review, see Appendix B.

Criteria used to help identify interventional procedures for referral to the Review Body may include:

- the evidence base being too large to be presented in the standard format of the overview
- the available body of evidence being difficult to interpret or leading to apparently contradictory conclusions
- the procedure having the potential to cause serious adverse events
- the procedure having more than one indication.

NICE commissions the Review Body to produce a systematic review. The systematic review includes evidence on the procedure from all available sources, including published and unpublished research. A scope is produced and presented to the Committee. Following this, the systematic review usually takes 6 months to complete. Expert advisers are identified by the Review Body, either through relevant professional bodies or through contact with known clinical experts in the field, who assist in all stages of the systematic review process.

The Review Body presents its systematic review to the Committee, which then makes recommendations based on the evidence in the systematic review, and an IP consultation document is issued (see section 6.6 below). In making its recommendations, the Committee may make use of specialist advice and patient questionnaires used in the development of interim guidance on the procedure, or the Committee may request new advice. Following consultation, guidance is published in line with NICE's standard process. If interim guidance was published, the guidance based on the evidence in the systematic review supersedes it, and the interim guidance is cancelled.

In some circumstances it will be appropriate for the IP Programme team to commission a systematic review before the procedure is presented to the Committee. This will be done by the Committee Chair on the advice of NICE.

When a procedure is referred to the Review Body to produce a systematic review, several months will elapse before the Committee considers it again.

# 6.5 Registers, data collection and research

When the data on the efficacy and/or safety of a procedure are inadequate in quantity or quality, the Committee may recommend that data be collected on all patients who undergo the procedure. The aims of this are: to accrue data for future review of the guidance; to monitor the use and dissemination of the procedure; and to encourage audit of outcomes.

A recommendation for data collection may stipulate submission to:

- an established register specific to the procedure
- an established register which includes a number of related procedures
- a new register, created as a result of the IP guidance.

Before an established register is recommended, the IP Programme team confirms that:

- its dataset is adequate for relevant details of the procedure to be submitted, to inform future review of guidance
- all data required for future review of the guidance will be made available to NICE
- the register has independent clinical supervision (that is, it is independent of commercial concerns, and is clinically supervised by a body that has the recognition and support of its clinical community)
- data submission is likely to be practical for all clinicians who wish to use the procedure, under the circumstances recommended in the guidance.

The dataset required for any register is defined with reference to the audit criteria for the procedure, which are informed by specialist advice. These criteria guide the judgement as to how suitable an established register is to collect data on a procedure, as well as the development of a new register.

# 6.5.1 The development of new registers

NICE is committed to exploring processes for easier creation of new registers in the future. Important principles in creating new registers for interventional procedures include close collaboration with the relevant professional bodies.

Another important principle is that it should be easy to access the data in the register. Plans are made for the review of data after predetermined intervals or after collection of data on specified numbers of procedures. Arrangements are also put in place for an alert to be issued if any procedure appears to be associated with an unduly high rate of adverse events, either generally or in an individual hospital.

#### 6.5.2 Referral to the HTA Programme

From time to time, procedures assessed by the IP Programme may be referred by NICE to the HTA Programme for consideration of the potential for their inclusion in a formal research proposal.

#### 6.6 The IP consultation document

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

- the recommendations that NICE proposes to issue
- a brief description of the procedure, the indications for which it is normally used and current treatments for this condition
- a summary of the main efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about the procedure
- a summary of the opinions of Specialist Advisers on the efficacy and safety of the procedure
- any additional efficacy and safety issues raised by Patient Commentators
- other information of importance, such as details of MHRA safety notices, registries and other research
- any related NICE guidance that has been published or is in development
- any other comments or observations of the Committee about the procedure and the evidence presented.

# 7 The consultation process

When consultation begins, NICE publishes the IP consultation document on its website for 4 weeks. At the same time, all those who registered an interest are informed by email that consultation has begun. During consultation, anyone may submit comments via NICE's website, by email, fax or 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. Consultation comments are accepted from international organisations and individuals outside the United Kingdom.

NICE is committed to promoting the values of equality and diversity through its guidance, and to eliminating discrimination. NICE encourages comments on its draft guidance from all sections of the community. Consultees are asked to highlight any ways in which draft guidance fails to promote equality or avoid discrimination, and how it might be improved.

Late comments received after the 4-week deadline will be shown to the Committee at the discretion of the Chair on the advice of NICE.

Points that consultees include in their response to consultation are a matter for them. However, the Committee particularly welcomes the following:

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

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.

Only stakeholders who respond at consultation are eligible to be involved in the Programme's resolution process (see section 8.2 below).

NICE has specific arrangements for consultation with key stakeholders.

# 7.1 Patient organisations and members of the public

For each procedure considered by the Committee, the PPIP contacts national patient organisations that represent patients affected by the condition(s) relevant to the procedure, including those that have a specialist interest in issues relating to equalities. The patient organisations are asked if they would like to contribute to the consultation

process and those that express an interest in being involved are contacted by the IP Programme team. Interested groups receive information on the IP Programme and the consultation process, and are sent the IP consultation document once it is issued. A lay description of the procedure is included in this document to help consultees understand whether the procedure is relevant to them.

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

NICE welcomes consultation responses from patients, their parents or carers and patient organisations, and encourages consultees to include the following in their responses:

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

#### 7.2 Medical device manufacturers

NICE supplies the ABHI with a list of procedures before consultation. They have agreed to alert the manufacturers of relevant devices that consultation will occur, giving them the opportunity to respond.

NICE advertises regularly in trade publications to alert manufacturers to forthcoming consultations. This ensures that all relevant device manufacturers are aware of consultations in which they have an interest. NICE also contacts manufacturers of devices referred to in the evidence summarised in the overview.

#### 7.3 Professional bodies

NICE has advised professional bodies to register an interest in the categories of procedure performed by their members and fellows in order to be alerted to consultations. Before consultation opens, NICE also alerts the relevant Specialist Advisers, their professional bodies and the professional bodies whose members may be responsible for referring patients for a particular procedure.

#### 7.4 Other stakeholders

#### 7.4.1 The notifier

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

#### 7.4.2 Named individuals

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

#### 7.4.3 Stakeholders who register an interest

Clinicians, patients and any other persons or groups who have registered an interest in the procedure via NICE's website will be alerted as consultation opens.

# 7.5 The production of guidance

The Committee reviews the consultation document in the light of the comments received during the consultation period and makes changes to the draft guidance.

During the consultation period, an updated literature search is conducted by the Information Services team to find any further evidence that may have been published since the overview was prepared. Studies that meet the initial inclusion criteria are presented to the Committee to be considered for inclusion in an updated overview. The Committee may decide to include any such studies in the final overview, which is updated by the IP Programme team before final publication of the guidance. In addition to the updated literature search, any relevant evidence highlighted by consultees is investigated by the IP Programme team and presented to the Committee. This then forms the final body of evidence on which the Committee's recommendations are based.

NICE may decide to delay development of guidance on a procedure if important 'in press' or unpublished data are identified at consultation.

Consultation comments and NICE's responses to them are tabulated for each procedure. The table is published on NICE's website at the same time as the guidance. Individual consultees' consultation comments are anonymised.

NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where, in the reasonable opinion of NICE, the comments are voluminous, or publication would be unlawful or otherwise inappropriate.

The consultation process

In exceptional circumstances, comments received during consultation may prompt the Committee: to refer the procedure to the Review Body for further investigation; to issue a new IP consultation document; or to issue no guidance. In these circumstances, an explanatory statement will be placed on NICE's website.

The NICE Guidance Executive receives and considers the draft guidance on the NICE Board's behalf. NICE then issues the guidance to the NHS in England, Wales, Scotland and Northern Ireland. The guidance is also adopted in the UK in the independent sector via memoranda of agreement (see section 2.4 above).

# 8 The resolution process

The resolution process is a final quality assurance step, intended to ensure that NICE acts fairly, follows its own processes and produces clear, accurate guidance. It exists to prevent the inadvertent publication of guidance that contains factual errors or is developed other than in accord with this document.

The resolution process takes place after the Guidance Executive has approved the guidance for publication and before it is published.

# 8.1 Resolution grounds

The Resolution panel (see section 8.5 below) will only consider resolution requests that meet one or both of the following grounds:

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

Ground 2: factual errors in the proposed guidance. This encompasses cases in which there is an objective error of material fact in the proposed final guidance. It does not include disagreements surrounding scientific or clinical interpretation or judgement, whether this refers to the appropriateness of guidance 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 was more than one piece of evidence available, one being preferred because the Committee considered it to be more reliable evidence. If it is the latter, there is no factual error, but a difference of scientific or clinical judgement.

The resolution panel will not consider a resolution request unless the grounds for resolution are clearly identified and meet either one or both of the grounds set out above.

# 8.2 Eligibility to make a resolution request

After the Guidance Executive authorises publication, all consultees who responded to the consultation document and completed a confidentiality form before the resolution process opens are alerted electronically. They are given access to the text of the revised guidance document and anonymised consultation comments, with NICE's responses to them. The purpose of this is to enable them to raise instances of what they believe to be errors or breaches of process, before publication.

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

# 8.3 Resolution requests

Individuals and organisations have 15 working days after the alert to request resolution on one or both of the grounds of breach of process and factual inaccuracy. Requests may be made by email, fax or letter to the Associate Director of the IP Programme. Those making requests should specify the remedy that they seek so that NICE can fully understand the nature of their concern and provide an appropriate remedy if there has been a breach of process or a factual inaccuracy in the guidance.

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

It is essential that NICE IP guidance is factually accurate and supports safe practice. Occasionally questions of factual accuracy or safety are raised after resolution has closed or after IP guidance has been published. In such circumstances the IP Programme team will investigate factual inaccuracies or issues of safety whatever their source. The remedy may include changes to NICE's website and/or the guidance itself.

# 8.4 The initial scrutiny process for resolution requests

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

If on initial scrutiny of a resolution request the Centre Director considers that the breach of process ground (ground 1) does not appear to have been met, or does not have a reasonable prospect of success, the Associate Director relays this decision to the body or individual requesting resolution and the guidance proceeds to publication. If the Centre Director considers that the breach of process ground (ground 1) appears to have been met, the Associate Director convenes the resolution panel (see section 8.5 below).

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

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

If the Centre Director considers that a major factual error ground appears to have been met, the Associate Director convenes the resolution panel. The resolution panel would be required to meet, for example, if the consultee raises a substantial challenge to the contents of the guidance which could not be remedied by minor amendment.

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

# 8.5 The resolution panel

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

#### 8.5.1 Meetings of the resolution panel

If the initial scrutiny process finds that the resolution grounds have been met, the Associate Director convenes the resolution panel to meet within 20 working days of the conclusion of the initial scrutiny process.

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

references in the guidance that are alleged to be errors.

The Committee Chair and Associate Director are in attendance at meetings of the resolution panel to provide clarification to the panel members if required. The Committee Chair is not a member of the panel and does not formulate the outcome of resolution. Members of the IP Programme team may also be required to attend to answer questions from the resolution panel members.

#### 8.5.2 The outcome of resolution

#### 8.5.2.1 Ground 1 – breach of process

In relation to requests for resolution under ground 1, the resolution panel will find either that there has been no breach of process and that the guidance will be published as proposed; or that there has been a breach of process.

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

#### 8.5.2.2 Ground 2 – factual error

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

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

If it is decided under ground 2 that the wording of the guidance should be changed, NICE will consider whether to publish the guidance containing the amended wording, or whether there is a need for further consultation. The need for further consultation would normally arise if there were a substantive change to a recommendation in the guidance. Other changes to the guidance not involving the recommendations could also give rise to the need to carry out further consultation before the guidance is published if these changes are significant, or are likely to be of interest to consultees.

#### 8.5.3 Communicating the outcome of resolution

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

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

# 9 Publication, dissemination and surveillance of guidance

## 9.1 Publication and dissemination

The guidance is published on NICE's website and disseminated to the following:

- consultants in relevant specialties
- specialist registrars in relevant specialties
- NHS and foundation trust chief executives in England and Wales
- chief executives of NHS boards in Scotland
- medical and nursing directors of NHS and foundation trusts in England and Wales
- directors of public health and medical and nursing directors of NHS boards in Scotland
- clinical governance leads
- audit leads
- NHS libraries
- ABHI
- 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
- the Chief Executive of the NHS in England
- the Chief Executive of the NHS in Scotland
- the Director of the NHS in Wales
- chief medical, nursing and pharmaceutical officers in England, Scotland and Wales
- the Chief Executive of NHS Quality Improvement Scotland

- the Director of the NHS Performance, Quality and Regulation Division, Welsh Assembly Government
- the Healthcare Commission
- the NPSA
- the NHS Litigation Authority
- the NHS Clinical Governance Support Team
- patient organisations invited to be consultees on that procedure
- representative bodies for health services, professional and statutory bodies, and the Royal Colleges
- all those who expressed an interest in the procedure (via email notification that guidance has been issued).

NICE publishes information for patients ('Understanding NICE guidance') relating to each piece of guidance. This information is a lay version of the guidance, and is developed in consultation with specialist and lay Committee members and Specialist Advisers as required. The final document is published in English and Welsh.

When the Committee recommends that special arrangements be in place for audit, and there is no register or data collection facility in place, NICE develops a specific audit tool for the procedure. The tool is developed with advice from Specialist Advisers and IPAC members, as appropriate.

Where guidance recommends that a procedure should not be used, the IP Programme team advises the Department of Health, Welsh Assembly Government, NHS Quality Improvement Scotland and the Northern Ireland Department of Health, Social Services and Public Safety, along with the device regulator if appropriate, of the contents of the guidance.

## 9.2 Surveillance

The NPSA is responsible for monitoring patient safety incidents (adverse events) in the NHS in England and Wales. The MHRA have the statutory function of monitoring serious device-related adverse events. If the NPSA or MHRA receives reports that give rise to serious concerns about the safety of a procedure or the device(s) used in carrying it out, they may notify the procedure to NICE, which will prompt NICE to consider assessment of it; this applies whether or not the procedure has already been the subject of guidance.

# 10 Transparency

NICE is committed to making the process of developing its interventional procedures guidance transparent to its stakeholders.

## 10.1 Public access to meetings of the IPAC

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

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

## 10.1.1 Arranging attendance

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

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

At the same time NICE supplies the ABHI with a copy of the draft agenda.

Members of the public may apply to attend a meeting through NICE's website. NICE will also accept enquiries by post or fax. Up to 20 places will be available for each meeting.

In the event that attendance at any meeting is oversubscribed, attendees will be selected according to NICE's allocation procedure. To allow wide public access, NICE reserves the right to limit attendees to one representative per organisation.

When the meeting agenda has been finalised, NICE will contact applicants to let them know whether a place has been made available to them. The invitation will include information on Committee procedures and admission to the building where the meeting is to be held.

In the event that a meeting is cancelled, NICE will endeavour to provide as much notice as possible.

## 10.1.2 How meetings are conducted

Most meetings of the Committee will be held at NICE's offices in London, which are accessible to the public, including those with limited mobility.

Each item on the agenda may either be held entirely in public or split into a part 1 session, for which the public are present, and a part 2 session, from which the public are excluded. The reasons for holding a part 2 session include situations where:

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

The decision not to hold a part 2 session will be at the discretion of the Chair and Centre Director, and will be taken when no confidential or personal data or information will be considered, and when the matters under consideration are not commercially sensitive.

## 10.2 Access to documents used in guidance development

To ensure that the process is as transparent as possible, NICE considers it desirable that all evidence relevant to the Committee's decisions should be publicly available. The following documents are therefore published on NICE's website.

Documents available at consultation:

- IP consultation document
- overview, including aggregated opinions of Specialist Advisers and any additional efficacy and safety issues raised by Patient Commentators
- systematic review, if commissioned for the procedure.

Documents available on publication of IP guidance:

- IP guidance
- overview, updated to include any new evidence since it was prepared initially
- anonymised consultation comments and responses
- audit tool, if required
- information for patients ('Understanding NICE guidance').

The Committee agendas and minutes are also published.

## 10.3 Use of confidential data

Normally, the assessment of procedures by the IP Programme is based on published evidence; however, occasionally it may be necessary for the Committee to review confidential data in order to assess a procedure. This may happen at any stage in our processes. 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 have 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 NICE of documentation quoting data from the trial, a structured abstract should be made available for disclosure, as a minimum.

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

# 10.4 Information about procedures notified to the Programme

A list of all interventional procedures notified to the Programme is available on NICE's website. The website provides the following information about each procedure that is within the Programme's remit:

- the name of the procedure
- a description of the procedure, including its major comparator (if there is one)
- the clinical specialty or specialties that might perform the procedure
- links to relevant documents produced by NICE (overview, IP consultation document, IP guidance, table of consultation comments including NICE's responses, Review Body report and 'Understanding NICE guidance')
- links to relevant documents produced by other agencies such as the MHRA
- links to related technology appraisals and clinical guidelines
- notices concerning changes of status to a piece of IP guidance (for example, if the guidance has been withdrawn or superseded through incorporation into a clinical guideline).

The status of the procedure is also included. There are two main categories:

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

Some procedures fall within the remit of the Programme but their assessment is delayed (see section 4.3 above). The reasons for this include:

- the procedure is only being carried out in a research setting
- the procedure does not have an evidence base
- the procedure does not have appropriate CE marking.

These procedures are listed separately on the website along with a rationale for the delay.

Procedures that are not considered to be within the remit of the Programme are listed separately along with an explanation of this decision.

The criteria by which it is determined whether a procedure is within the remit of the Programme are detailed in section 4.2 above.

## 10.5 Freedom of Information Act 2000

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

# 11 Links between the IP Programme and other NICE guidance-producing programmes

## 11.1 Topic Selection at NICE

Occasionally, a procedure is notified to Topic Selection that appears to be within the remit of the IP Programme. In these instances, the Topic Selection team will forward the notification to the IP Programme for consideration.

# 11.2 Procedures suitable for technology appraisal guidance

It is usually appropriate for consideration of efficacy and safety to occur before the Technology Appraisal Programme addresses clinical and cost effectiveness. Among the procedures considered by the IP 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)
  - costs are very different from those of existing treatment(s)
  - there is a connection to a Government priority.

In these circumstances, the procedure will be passed to NICE's Topic Selection team to consider its appropriateness for referral into the Technology Appraisal Programme.

# 11.3 Procedures suitable for inclusion into clinical guidelines

Clinical guidelines focus on placing established treatments in the care pathway, and it will therefore generally only be appropriate for them to include interventional procedures published under 'normal' arrangements. During the guideline scoping phase, published IP guidance may be identified that is relevant to a guideline.

# 11.3.1 Procedures with recommendations for 'normal' arrangements

If a Guideline Development Group (GDG) decides that a procedure for which the guidance recommends 'normal' arrangements is relevant to a guideline but does not merit full assessment, the IP guidance will be referred to in the 'related NICE guidance' section of the guideline.

If the GDG considers that a procedure published under 'normal' arrangements merits assessment as part of the development of the clinical guideline, the procedure's clinical and cost effectiveness will be assessed using the Clinical Guidelines Programme's normal assessment methods and processes. The IP Programme Associate Director will be added as a stakeholder to enable the IP Programme to comment on the scope and to review the relevant sections of the guideline.

If a procedure is found to be clinically and cost effective, the GDG will recommend its use in practice. In such cases, use of the procedure will become a guideline recommendation, but the existing IP guidance will remain active. This is because the IP guidance may contain other more detailed information about the procedure that may be of value to patients and clinicians. Importantly, the IP guidance may also specify conditions for use of the procedure, for example, that the surgeon should have training, or that the procedure should be carried out within the context of a multidisciplinary team. The clinical guideline will contain a footnote referring to the IP guidance and a note will be inserted on the NICE webpage for the IP guidance referring to the clinical guideline.

When a procedure is found to be not clinically and cost effective, the clinical guideline will recommend that it should not be used. In such cases the IP guidance for that procedure will be withdrawn. In some cases the clinical guideline and the IP guidance may address different but overlapping indications. This will mean that sometimes IP guidance will need to remain current even if it is superseded by a clinical guideline for one or some indications. A separate decision will be made for each piece of IP guidance affected in this way.

In circumstances when there is considerable uncertainty about the clinical or cost effectiveness of an interventional procedure, a decision should be made about whether the IP guidance stands, whether it should be updated, or whether it should be withdrawn.

The GDG may decide to make a 'research only' recommendation. The decision to make a 'research only' recommendation for a procedure where 'normal' arrangements guidance has been published will be taken by the GDG in consultation with NICE. In this instance, the relevant IP guidance will be withdrawn.

## 11.3.2 Procedures with recommendations for 'special' arrangements

If, in the opinion of the GDG, an IP published under 'special' arrangements has become part of mainstream practice and it would be appropriate for it to be assessed as part of the clinical guideline, the GDG will formally notify the procedure to the IP Programme to allow for potential review of the IP guidance. If, on reassessment, the procedure changes to 'normal' arrangements status, its clinical and cost effectiveness will be assessed as part of the guidelines process. If after reassessment via the Committee the procedure retains its 'special arrangements' status, the clinical guideline will refer to the procedure as 'related NICE guidance'.

## 11.3.3 IP guidance published with other recommendations

Sometimes IP guidance will recommend that the procedure should be carried out only in research, where the Committee deems the evidence base insufficient to make recommendations for even conditional use. Sometimes the guidance recommends that the procedure should not be used, where there is no evidence of efficacy/safety, or evidence of no efficacy/safety. The evidence base for such procedures reflects the fact that they are not established treatment, and they would not normally form part of a clinical question in a clinical guideline.

## 11.3.4 Concurrent development of a clinical guideline and IP guidance

The national collaborating centres will check the IP guidance publication list during the guideline development phase. If a clinical guideline is already in development when a relevant notification is received, the IP Programme will pass the finalised scope(s) for the relevant procedure(s) to the Clinical Guidelines Programme to enable appropriate planning and cross-referencing between the two programmes.

If IP guidance in development has not been finalised at the time of the guideline consultation, the guideline should cross-refer to the interventional procedure consultation document.

# 11.3.5 Newly notified procedures

When a newly notified procedure has been scoped and it has been agreed that it will be assessed by the IP Programme, and a clinical guideline is already being developed in this area, the IP Programme team will inform the national collaborating centre and the NICE Guideline Commissioning Manager that the notified procedure is relevant to the guideline.

# 12 Reviewing IP guidance

# 12.1 Principles for IP guidance review

There are four main categories of recommendation within IP guidance:

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

The approach to reviewing IP guidance depends partly on the category of recommendation made in the guidance. Procedures with 'normal' arrangements guidance will not normally be reassessed unless significant new evidence casts doubt on the validity of the original recommendations, for example because of the emergence of new safety concerns. Guidance on procedures with 'special' arrangements will be reviewed after 3 years and the procedure will be reassessed if important new evidence is available. Procedures with 'research only' guidance may be reassessed when relevant research is published. There is no intention to review 'do not use' guidance unless there is a significant change in the evidence base.

Safety alerts issued by national or international regulators (for example, the MHRA, NPSA or the US Food and Drug Administration) and brought to NICE's attention are considered for their relevance and may trigger a review of IP guidance.

Review proposals for IP guidance are submitted to the NICE Guidance Executive for approval.

The process of reviewing guidance and submitting review proposals to the Guidance Executive forms part of the normal workload of the IP Programme. Guidance updated as a result of the review process is included in the Programme's annual target for guidance production.

# 12.2 Key features of the process for IP guidance review

Taking advice from the IPAC Chair and specialist IPAC members and Specialist Advisers as necessary, the IP Programme team prepares guidance review proposals for submission to the Guidance Executive.

The Information Services team carries out a literature search to identify new evidence published in the period since the literature searches were undertaken for the initial guidance. If available, the search strategies developed for the initial guidance are rerun.

A new scope is also produced for the procedure.

If there is deemed to be sufficient new evidence to warrant reassessment of the procedure a proposal is presented to the Guidance Executive.

Once the Guidance Executive has approved the proposal to reassess the procedure, the reassessment is scheduled into the IP Programme's workload and follows the standard timelines and process for development of IP guidance.

# 12.3 The status of IP guidance being reviewed

IP guidance on a procedure that is reassessed is withdrawn when the new IP guidance is published. While the reassessment of the procedure is in progress, the existing guidance applies.

IP guidance that has been superseded by a clinical guideline is withdrawn (see section 11.3 above).

Some pieces of IP guidance are put on a static list, which means that NICE does not intend to review them in the foreseeable future. This may be because the procedure is no longer being used in the NHS or because no relevant new evidence has been published for a long time. Procedures on the static list may be transferred back to the active list for further assessment if new evidence becomes available that is likely to have a material effect on the last guidance issued.

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.

If extreme safety concerns are raised, NICE will consider suspending current guidance pending a reassessment of the procedure.

# 13 Updating the process guide

NICE will review and update this document 3 years after its publication.

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

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

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

Any other changes will only be made after 3 months' public consultation.

# 14 How to find more information

More information about the IP Programme can be found on NICE's website (www.nice.org.uk/ip). This includes:

- common questions about the Programme, and their answers
- a link to the IP methods guide
- the list of notified procedures
- the list of Specialist Advisers
- the list of members of the Committee
- minutes of Committee meetings
- Review Body reports
- overviews
- IP consultation documents
- IP guidance
- 'Understanding NICE guidance' relating to each piece of guidance issued
- 'Consent procedures for which the benefits and risks are uncertain': information for patients whose consent is being sought regarding a procedure of uncertain efficacy and safety.

# **Appendix A: Glossary**

#### Consultee

A consultee is an individual or organisation who submits a response to an interventional procedures consultation document.

## **CE** marking

CE marking is a declaration by the manufacturer that a medical device or product meets the safety, quality and performance requirements of the relevant legislation implementing certain European Directives.

#### **Effectiveness**

An effective procedure is one that produces benefits compared with other interventions 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.

#### **Guidance Executive**

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

# **Guideline development group (GDG)**

A group of healthcare professionals, patients, carers and technical staff who develop the recommendations for a clinical guideline. The national collaborating centre responsible for developing the guideline recruits a GDG to work on the guideline. National collaborating centre staff review the evidence and support the GDG. The group writes draft guidance, and then revises it after a consultation with organisations registered as stakeholders.

## Interventional procedure

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

## **Interventional Procedures Advisory Committee (IPAC)**

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

# Interventional procedures consultation document (IP consultation document)

A provisional decision about the efficacy and safety of an interventional procedure. The Committee makes a provisional decision after considering the overview, commentary from Specialist Advisers and Patient Commentators, and, sometimes, a report from the Review Body.

## Interventional procedures guidance (IP guidance)

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

## List of notified procedures

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

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

The MHRA is the national competent authority responsible for the regulation of medical devices on the UK market. 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 Committee and the two organisations are in regular contact (www.mhra.gov.uk).

# National collaborating centre

A group set up by NICE to develop clinical guidelines for a particular disease area. Each centre is based at one of the Royal Colleges. Staff at the national collaborating centre review the evidence for a guideline and present it to a GDG.

## **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 (www.pcpoh.bham.ac.uk/publichealth/horizon).

## **National Patient Safety Agency (NPSA)**

The agency responsible for monitoring all patient safety incidents and producing learning from these incidents for the NHS (www.npsa.nhs.uk).

## **NHS Quality Improvement Scotland**

The body responsible for improving the quality of healthcare in Scotland by setting standards, monitoring performance and providing advice, guidance and support to NHS Scotland on effective clinical practice and service improvements (www.nhshealthquality.org).

#### **Overview**

A document produced by NICE to inform the Committee about an interventional procedure. It contains information on the indications for the procedure, a summary of key points from a rapid review of the literature, a summary of the advice of Specialist Advisers and a summary of any patient commentary if it raises any concerns not previously identified in the literature or by Specialist Advisers.

# Patient and Public Involvement Programme (PPIP)

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

#### **Patient Commentator**

A patient or carer, identified through a trust, who provides details of their own experience of the procedure to the IP Programme.

# 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.

## **Review Body**

A consortium of two UK universities, commissioned by NICE to undertake systematic reviews of the efficacy and safety of interventional procedures.

## **Specialist Adviser**

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

#### Stakeholder

An individual or organisation with an interest in the IP Programme's activities and outputs.

## **Systematic review**

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 the study quality and findings.

# **Technology Appraisal Programme**

The Technology Appraisal Programme at NICE makes recommendations on the clinical and cost effectiveness of new and existing medicines and treatments within the NHS in England and Wales, such as medicines, medical devices, diagnostic techniques, surgical procedures and health promotion activities.

# **Appendix B: Development of systematic reviews**

This appendix sets out the process for undertaking a systematic review for the IP Programme. There are four stages to the development of a systematic review:

- 1 A scope is prepared by the Review Body and agreed by NICE and the Committee. It details 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).
- 2 The Review Body conducts the systematic review using the methodology developed by the Centre for Reviews and Dissemination<sup>6</sup> and the Cochrane Collaboration<sup>7</sup>. The systematic review includes evidence from all available relevant scientific sources, including published research and conference abstracts, with the aim of providing the most up-to-date body of information. Unpublished sources of information are also sought. The review process incorporates a formal assessment of the methodological quality of full-text included studies, and indicates if material is unpublished.
- **3** The systematic review is presented to the Committee by members of the Review Body.
- **4** The systematic review is published on NICE's website at consultation with the IP consultation document.

For each systematic review, the Review Body seek clinical advice specific to the procedure(s) under assessment. The Review Body are responsible for securing this clinical advice. In preparing the systematic review it may also be necessary for the Review Body to seek input from appropriate individuals and organisations, including:

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

The Review Body contacts these individuals and organisations for advice in the course of developing the systematic review. They do not require formal submissions from manufacturers and patient groups.

<sup>&</sup>lt;sup>6</sup> NHS Centre for Reviews and Dissemination, University of York Report 4. Undertaking Systematic Reviews of Research on Effectiveness.

<sup>&</sup>lt;sup>7</sup> Cochrane Handbook for Systematic Reviews of Interventions and Open Learning Materials, www.cochrane.org/resources/revpro.htm

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