

# **Contributing to NICE interventional procedure guidance – a guide for patients and carers**

This booklet is for:

- patient and carer organisations
- individual patients and carers

# Contributing to NICE interventional procedure guidance: a guide for patients and carers

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## Ordering information

This document is available from the NICE website ([www.nice.org.uk/xxx](http://www.nice.org.uk/xxx)).

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## Further information

NICE has produced a detailed programme manual that sets out the interventional procedures programme. It can be seen at: [www.nice.org.uk/ipprogrammmanual](http://www.nice.org.uk/ipprogrammmanual)

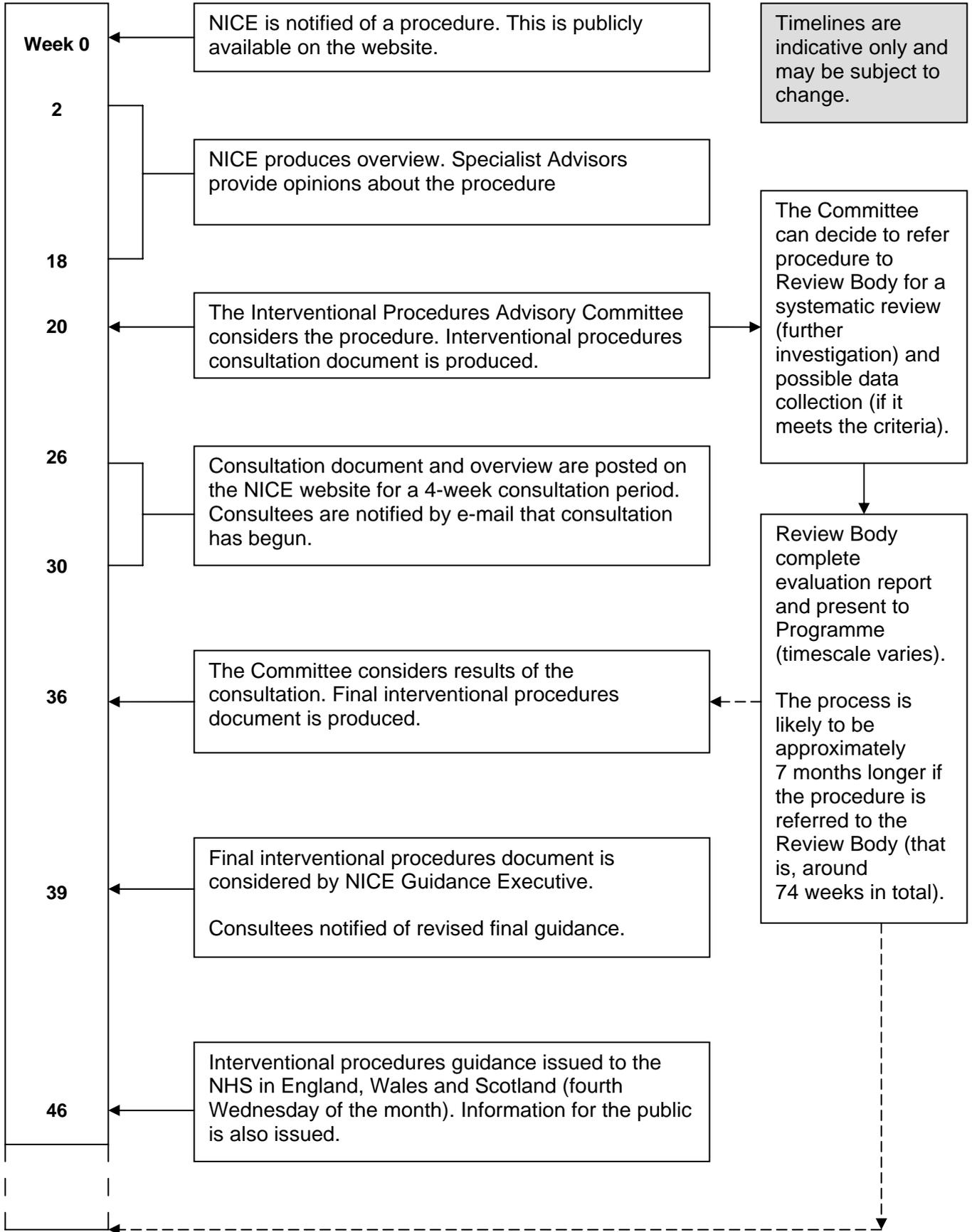
You can find out more about NICE on our website: [www.nice.org.uk](http://www.nice.org.uk)

## About NICE guidance

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. It produces different types of guidance including:

- **clinical guidelines** (recommendations about the treatment and care of patients with specific conditions in the NHS)
- **technology appraisal** and **interventional procedure** guidance (guidance on the use of new and existing medicines, treatments and procedures in the NHS)
- **public health** guidance (guidance on the promotion of good health and the prevention of ill health).

# Summary of interventional procedure process



## **About this guide**

This guide shows you how you can contribute to the development of interventional procedure guidance. It takes you through the process from start to finish, and shows how both individuals and organisations can take part.

A flowchart of the key events is shown on page 3. We suggest you refer to this when you are reading the guide.

The chart highlights the key ways in which organisations and individuals can participate.

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# 1 Getting started

## ***What is the purpose of this guide?***

This guide aims to:

- help patients and carers, and organisations representing them, to take part in producing interventional procedure guidance
- help people bringing a patient or carer perspective to the process to understand their role.

This introductory section gives a brief description of the process of producing interventional procedure guidance. In the subsequent sections you will be guided through each step of the process with a brief description of the step and the actions you can take, and the support you can get.

## ***Why has NICE invited you to take part?***

NICE believes it is very important to involve patients and carers in the process of making decisions about their healthcare and the development of its guidance. Patients and carers can help those responsible for developing **interventional procedure** guidance understand what it is like to have had a particular procedure, and the key issues from a patient's perspective. For instance, we want to know about:

- the practical, physical and emotional aspects of undergoing – or caring for someone who has undergone – a particular interventional procedure
- the views of patients and carers on:
  - what results or outcomes patients want from the procedure
  - how well the procedure works from a patient point of view – for instance, the tolerability and acceptability of the procedure, its side effects and benefits
  - the safety of the procedure and its risks – in the short and long term
  - the preferences of patients (for example, preferences for a procedure compared with a direct alternative, if available, or compared with choosing not to have a procedure at all)
  - the views or needs of different groups of patients (for example, in relation to age, ethnicity, gender or disability).

## ***What is an interventional procedure?***

An interventional procedure is used for diagnosing an illness or treating a patient, and involves one of the following.

- Making a cut or a hole to gain access to the inside of a patient's body – for example, when carrying out an operation or inserting a tube into a blood vessel. An example would be inserting electrodes (shaped like needles) into the kidney to deliver an electric current or heat to destroy cancer cells.
- Gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body – for example, examining or treating the inside of the stomach using an instrument inserted through the mouth, or a patient swallowing a small capsule containing a tiny camera to examine the inside surface of the small bowel as it passes through.
- Using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) – for example, using a laser to treat eye problems.

NICE does not look at procedures that are already used as standard practice in the NHS that have sufficiently well-known benefits and risks.

|   |
|---|
| Interventional procedures are used to diagnose or treat patients through an intervention (something entering) their body. |
|---|

## ***What does the NICE interventional procedures programme do?***

The NICE interventional procedures programme looks at whether particular procedures used for diagnosing an illness or treating a patient are safe enough and work well enough for wider use in the NHS. This is called safety and efficacy. Unlike in other NICE guidance, the cost of a treatment is not considered when making a decision about using the procedure.

## ***Who produces NICE interventional procedure guidance?***

Recommendations about the use of interventional procedures are made to NICE by the Interventional Procedures Advisory Committee. The Committee has 24 members who are independent of NICE. They have a range of expertise and include clinicians who carry out interventional procedures, experts working for high standards in healthcare and industry, and people who are familiar with the issues affecting patients and carers. The

Committee is supported by the NICE Interventional Procedures Programme team which includes analysts, a project manager and administrative staff.

The Committee meets once a month for 11 months of the year. It considers the best available evidence and takes advice from at least three clinical specialists (known as Specialist Advisors) who are usually doctors recommended by their professional organisations. It then makes recommendations to NICE on the use of interventional procedures in the NHS.

The Committee may recommend that:

- a procedure is safe enough and works well enough for routine use in the NHS
- there is not yet enough information about how safe a procedure is or how well it works and it should therefore only be offered to patients under certain conditions, where special arrangements are in place or as part of a research study
- a procedure is unsafe or cannot benefit patients and should not be offered to NHS patients.

## 2 The interventional procedures process and how you can contribute

### ***Notification***

Procedures accepted by the Interventional Procedures Programme are usually notified (suggested) to NICE by clinicians, and sometimes by patients. They are usually procedures that are new or relatively new to the NHS. They may have been used only in a few specialist centres or for a relatively small number of patients. Some procedures considered by NICE have been in use in the NHS, but concerns have been raised about their safety and/or how well they work.

By notifying a procedure, people are asking NICE to consider evidence collected on how safe a procedure is or how well it has been working for patients who have had the procedure. This enables NICE to recommend that procedures that have worked well so far and are sufficiently safe should continue to be offered to patients. It also allows NICE to identify problems with procedures that are not working as well as expected or where there are safety concerns. This results in a recommendation that use of a procedure should be in special circumstances only or discontinued altogether.

Anyone who wants to notify a procedure to the Interventional Procedures Programme should do the following.

- Look at the list of procedures on the NICE website to check whether it has already been notified or guidance has been issued, or ask the Interventional Procedures Project Manager for a list (details are below).
- Provide information about the procedure. This includes your contact details, the name and description of the interventional procedure, its indications (what it would be used to treat), and any other procedure the new procedure is likely to replace.
- Send the notification to the Interventional Procedures Team Project Manager by emailing [IP@nice.org.uk](mailto:IP@nice.org.uk), or ask for further advice (tel: 020 7067 5800 and ask for the Interventional Procedures Team Project Manager).

You can find details of interventional procedures on which guidance has been issued on the NICE website.

## ***Registering an interest in a procedure***

If you are interested in any of the notified procedures that NICE is going to consider, you can register an interest in that procedure on the NICE website. You will be sent updates of the procedure's progress through the Programme by email, up to the start of consultation. You will then have the opportunity to comment on the draft recommendations that NICE makes during the consultation period.

Anyone can register an interest in an interventional procedure that will be considered by NICE.

Let NICE know if you would like to contribute to the consultation on a notified procedure.

The NICE Patient and Public Involvement Programme contacts organisations that represent patients and carers to ask if they are interested in taking part in the consultation. Patient organisations are also encouraged to contact members who may be interested in responding individually.

Patient and carer organisations may wish to put an 'advert' on their website or an article in a newsletter about the consultation. This can alert individuals who may choose to respond to a consultation in their own right. This is especially important for procedures where very few people have had them to date. The Project Manager in the Patient and Public Involvement Programme may be able to help with wording of the text (see page 20).

More detailed advice on commenting on the consultation document can be found in section 3.

## ***Preparation of advice to the Committee***

After a procedure is accepted by the Programme, an analyst at NICE prepares an overview document that is used by the Interventional Procedures Advisory Committee to inform their decision-making.

The overview is a summary of the nature and purpose of the procedure and includes an analysis of the most useful published research studies about it.

New procedures often have potential benefits and, importantly, risks that are not yet fully described in the scientific literature. The Specialist Advisors complete questionnaires to

provide insight into these aspects of a procedure, drawing on their clinical experience and knowledge.

The overview document is available for public consultation at the same time as the consultation document (see page 12). Patients, carers and patient organisations are also welcome to comment on the overview document, but should not feel this is expected of them.

### ***The committee meeting***

When the overview document and the views of the Specialist Advisors are available, the Interventional Procedures Advisory Committee meets to consider them. The Committee considers the safety and efficacy of each interventional procedure and makes recommendations to NICE about its future use. It then either:

- produces a consultation document that sets out the Committee's draft recommendations on the future use of the procedure in the NHS, or
- refers the procedure to the Review Body (this is unusual but may happen for certain procedures, including those where the procedure is likely to cause serious adverse effects and/or substantial health benefits, or be used on large numbers of patients in the future).

The Review Body is a consortium of two British universities commissioned by NICE. It further investigates evidence on the procedure from all available sources, including published and unpublished research, and takes advice from specialists. This results in a detailed report (a 'systematic review') which informs the Committee's decision-making. If referral to the Review Body happens, the Committee will also invite written submissions from patient and carer organisations as part of an extended consultation process. Further advice on procedures referred to the Review Body is available in a separate leaflet available on request from the Patient and Public Involvement Programme (contact details on page 20).

## **Consultation**

Your comments should focus on the consultation document, although you can choose to read and comment on the overview.

The consultation document is produced after the Interventional Procedures Advisory Committee has met to consider the overview document. It sets out the Committee's draft recommendations. NICE publishes the consultation document and the overview document on its website for 4 weeks. Anyone who has registered an interest in the guidance on the NICE website, or said they would like to comment, is notified by email alert. Practical advice on how patient organisations, individual patients, carers and members of the public can comment on the consultation document is provided in section 3.

After the consultation period, the Committee meets again to discuss the responses and to modify the consultation document. This modified document is the final interventional procedures document that goes to NICE's Guidance Executive for approval.

### **Feedback on consultation comments**

Comments received from individuals and organisations, along with responses to them, will be published on the Institute's website when the guidance is published. There is more detailed information about the consultation process on the NICE website (see [www.nice.org.uk/ip](http://www.nice.org.uk/ip)).

### ***Producing the final guidance and information for patients and carers***

Once approved by the NICE Guidance Executive, NICE publishes guidance for the NHS about the use of the individual interventional procedure. NICE also publishes a separate document called 'Understanding NICE guidance', which explains what NICE has recommended in an easily understandable way for patients and their carers.

## **3 Practical advice for commenting on the consultation document**

### ***General***

NICE is interested in what patients, carers and patient organisations think about the draft recommendations made in the consultation document and particularly welcomes comments from:

- patient or carer organisations representing patients for whom the procedure would be appropriate
- people with direct experience of the procedure and/or experience of alternatives to the procedure
- individual patients or carers with personal experience of the condition for which the procedure is intended to be used.

## Tips for writing your response

- Do not feel your response has to be lengthy or that you have to comment on every part of the consultation document. A short, focused response giving a patient's perspective on an important area of a procedure is valued.
- Be as specific as you can about the particular procedure you are commenting on, rather than commenting generally on the management of the condition.
- It is always welcome when responses are as balanced as possible: positive as well as negative.
- The Committee does not consider the cost of the procedure, so there is no need to address this area.
- You do not need to give the Committee a detailed description of the procedure or the condition that it is being considered for, as that is already available in the overview document.
- Unfortunately NICE cannot deal with concerns about local treatment or arrangements, such as the setting, the way professionals treated you or the information they gave you to help you make a decision. This is because NICE works at a national level. If you have such concerns, you can discuss them with your clinician, or contact the Patient Advice and Liaison Service (PALS) who can offer support and information. Their details can be obtained from the hospital at which you received the treatment.

NICE is looking for a range of perspectives, and we are interested in both positive and negative experiences and views on the interventional procedure.

We provide some suggestions about the type of information that you might provide when commenting on the consultation document and its draft recommendations on page 16.

## ***Sending in your comments***

The easiest way to comment on the consultation document is to use the form on the website or send your comments by email. If you register your interest, you will be emailed links to the documents automatically (see page 10). Otherwise, you can click on 'current consultations' on the home page at [www.nice.org.uk](http://www.nice.org.uk) or contact the Interventional Procedures Programme Coordinator by phoning on 020 7067 5800. The Coordinator will also help if you need paper copies of documents.

### **If you decide to use the form on the website**

The form sets out the following boxes for responses (you do not have to fill in every box).

- Provisional recommendations.
- The procedure – indications (who and what it is for) and description.
- Efficacy (whether the procedure works).
- Safety.
- Other comments.

### **If you do not use the form on the website**

You can send an email or written comments (such as a Word document). It is helpful if you reference your comments to the consultation document, for example:

'The provisional recommendation in paragraph 1.2 of the consultation document is X, but patients have reported that this does not reflect their experience as follows...'

'We fully support the provisional recommendation in paragraph 1.3 of the consultation document as patients have told us that...'

## ***What issues should you include in your consultation response?***

NICE has identified some key areas on which we would like patient and carer views.

The Committee particularly welcomes the following information from people who comment on the draft consultation document (this guide also looks at this in more detail, section by section).

- Views on the provisional **recommendations** (are they clear; do you or your organisation agree with them or not; do they take into account patient and carer views on how safe a procedure is or how well it works?).
- Views on the **description of the procedure** and what condition or patient group it is being considered for.
- **Efficacy**: views on how well the procedure works (or doesn't work).
- **Safety**: views on how safe (or unsafe) the procedure is.
- Views on the **research evidence** used to inform the recommendations made and any missing research evidence.
- For patients who have **experience of the procedure**: in the light of your experience would you, with hindsight, have chosen to undergo the procedure and/or recommend it to other patients?

### **About you**

Please include a sentence or two, explaining who you are.

- If you work for a patient/carers organisation, please include the name and aim of the organisation, and who it represents.
- If you are an individual, please describe what experience you are drawing on, for example do you have the condition, have you had the procedure, or are you a carer?
- If you are responding on behalf of a group of individuals, please explain what experiences the group members have of the condition and/or procedure. Please also explain how the views of the group were gathered.
- Please name any advisors used in the preparation of your comments and their role or professional standing.

The following sections list areas that you may wish to focus on when commenting on the consultation document for a given interventional procedure. Some items in the list may be more relevant to some procedures than others.

The list is intended as an aid (if needed) and is not intended to be prescriptive. You are free to comment on whatever issues you choose, and there is no obligation to comment at all if you do not wish to do so.

### **Recommendations**

- Is it clear in the consultation document what NICE is recommending about this procedure?
- Do you agree with each recommendation? If not, please state which recommendation(s) you do not agree with and explain why. Please refer to the specifically numbered part of the document, if you can.
- Do the recommendations take into account patient or carer views on how well the procedure does, or does not, work? (See section on efficacy below.)
- Do the recommendations take into account patient or carer views on how safe the procedure is? (See section on safety below.)
- Are there any patient or carer issues that have **not** been taken into account by the Committee that might alter the recommendations?

### **The procedure: indications and outline of the procedure**

- Do you consider the outline of the procedure to be accurate and adequate? If not, please explain why.
- Do you agree with the description of which patients the procedure is suitable for ('patient selection')? If you disagree, please say who you think it would be suitable for.
- Do you agree with the description of the clinical circumstances under which the procedure should be used? If you disagree, please explain what you think should be different about the situations described.

### **Efficacy (how well the procedure works)**

- Do you think that the **benefits** (if any) that patients can experience as a result of the procedure are fully considered and accurately represented in the consultation document? Please list any benefits to patients that have not been adequately considered. Perceived benefits of the procedure may include improvement in the condition, improvement in symptoms experienced (for example, pain, level of disability), improvement in quality of life or well-being, impact on others (for example, family or carers).

## **Safety**

- Do you agree with the Committee's assessment of how safe the procedure is? If you disagree, please explain why.
- Have the recommendations taken into account safety issues that patients consider to be important?
- Please let us know of any short- or long-term safety issues that you think have not been addressed and that may alter the recommendations.
- Do you think that short- or long-term **disadvantages or side effects** of the procedure are considered fully and represented accurately? Please list drawbacks or side effects that have not been considered. Drawbacks and side effects may include views on the acceptability of the procedure (for example, how invasive or painful it is); worsening of the condition or symptoms experienced; level of disability or quality of life; complications of surgery; areas of uncertainty or other unwanted results of the procedure; and impact on family or carers.

## **Other comments**

Please add any other comments that you wish to make. You may wish to comment on one or more of the following (but there is no obligation to do so).

### ***Information and consent***

- If appropriate, have the relevant issues relating to patient information needs or consent been considered in the recommendations? (Please let us know if there are any information or consent issues missing.)
- Are there any other important considerations for patients about what happens before, during or after the procedure that you think should be considered by NICE?

### ***Research***

The Committee does not expect patients or patient organisations to be research experts (although some are!). There are analysts working with the Committee who are experts in summarising the research evidence in the consultation document. So do not feel you have to read or comment on the detail of the research, unless you would like to.

If you would like to comment on the research evidence that underpins the Committee's recommendations, you may wish to comment on the following.

- Areas where you do not agree with the Committee's interpretation of the research evidence that has been considered.
- The relevance of any of the following that have been used in the research considered by the Committee (especially any measures that have been missed from the research that you think are important).
  - Outcome measures (that is, ways of measuring the result/s of the procedure, for example reducing pain).
  - Quality of life measures (that is, ways of measuring the effect(s) of the procedure on the patient's quality of life, for example are they now able to enjoy hobbies that they had been forced to give up, due to ill health).
  - Safety or other issues.
  - Any research that has been missed by the Committee (you don't need to describe this in detail but please provide a reference to the research or survey, and a brief description of what it shows).

## 4 Support for patients and carers

The Patient and Public Involvement Programme offers advice and support to all patients and carers, and the organisations representing them, that take part in NICE's work.

There is a Project Manager within the team who supports people taking part in the interventional procedures process. The Patient and Public Involvement Programme can provide:

- advice on the interventional procedures process, and opportunities for involvement
- information and support at each stage of the process.

You can contact the team by post, telephone or email.

Patient and Public Involvement Programme  
National Institute for Health and Clinical Excellence  
MidCity Place  
71 High Holborn  
London WC1V 6NA  
020 7067 5800 (ask for the PPIP Project Manager for Interventional Procedures)

Email: [ppip@nice.org.uk](mailto:ppip@nice.org.uk) or [patientandpublicinvolvement@nice.org.uk](mailto:patientandpublicinvolvement@nice.org.uk)

If you need support to comment or respond, please contact the Patient and Public Involvement Programme