

# A guide for patient/carer groups

**Contributing to a technology appraisal**

# About the technology appraisal series

This document is one of a set that describes the process and methods that NICE uses to undertake technology appraisals and provide guidance for the organisations invited to contribute to these appraisals.

The documents in the set are:

- Guide to the technology appraisal process (reference N0514)
- Guide to the methods of technology appraisal (reference N0515)
- Contributing to a technology appraisal – a guide for patient/carer groups (reference N0516)
- Contributing to a technology appraisal – a guide for healthcare professional groups (reference N0517)
- Contributing to a technology appraisal – a guide for manufacturers and sponsors (reference N0518)
- Contributing to a technology appraisal – a guide for NHS organisations (reference N0519)
- Technology appraisal process – guidance for appellants (reference N0520)

These documents are available from the NICE website ([www.nice.org.uk](http://www.nice.org.uk)) or from the NHS Response Line (telephone 0870 1555 455 and quote the relevant reference number).

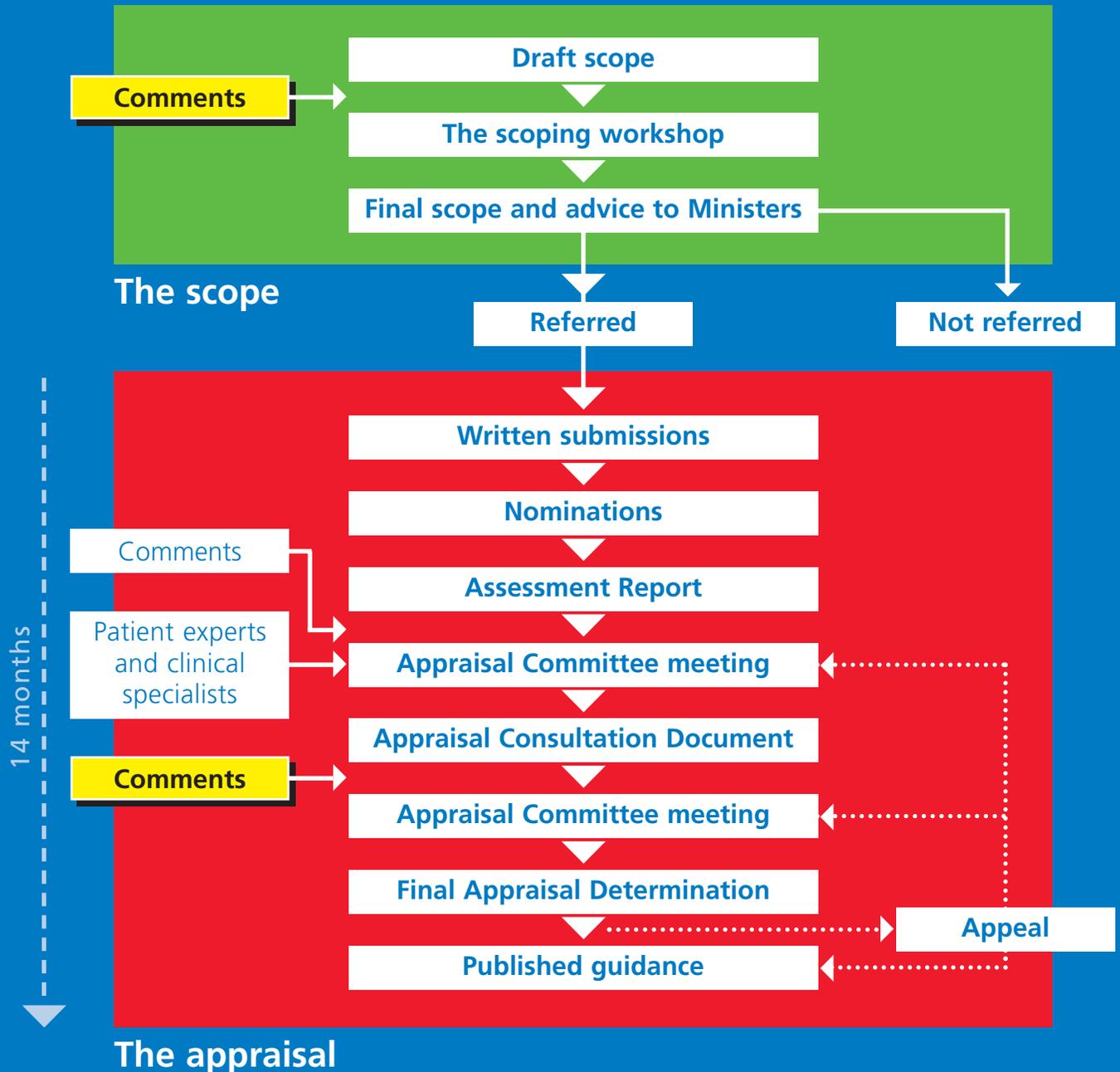
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ISBN: 1-84257-854-5  
Published by the National Institute for Clinical Excellence  
Designed by Westhill Communications  
Printed by Abba Litho (Sales) Ltd  
November 2004

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# Summary of the technology appraisal process



# How you can contribute

This handbook guides you through the technology appraisal process from start to finish and shows when we would really like to hear from you.

On the fold-out page we have included a flowchart of the key events in the appraisal process. We suggest you keep the page open when you're reading so you can refer to the chart as you go along.

You do not need to contribute at every stage. If you have limited resources you can just concentrate on the sections

**highlighted on the fold-out page.**



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# Getting started

## What is the purpose of this handbook?

The National Institute for Clinical Excellence (NICE) provides guidance to the NHS in England and Wales on the use of selected new and existing **health technologies**. The process of producing this guidance is called a **technology appraisal**.

This handbook aims to:

- help organisations representing patients and carers take part in a **technology appraisal**
- help **patient experts** who have been nominated to attend a NICE **Appraisal Committee** meeting take part in a **technology appraisal**.

This introductory section gives a brief description of the **technology appraisal** process. 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.

In the back of the handbook, you will find a Glossary explaining the words and terms that are in **bold** typeface.

## Why has NICE asked you to take part?

NICE believes that it is very important to involve patients and carers in the process of making decisions about their healthcare. Patients and carers can help us understand what it is like to live with a disease or disability and what the impact of an existing or potential treatment would mean for them. We are particularly interested in hearing about:

- how the technology changes the lives of patients and carers. Does it improve quality of life? For example, does it change physical or mental health, reduce pain or disability, or help in carrying out daily activities?
- the side effects of the technology and how patients feel about them
- any practical implications of taking the treatment. For example, are there any adjustments needed to the patients' or carers' daily routine or lifestyle?
- whether the technology has a financial impact on the patients or carers (this could include the cost of travel, lost earnings or the cost of paying a carer).

As well as hearing your views we will also be asking for comments at each stage of the appraisal. NICE calls all the evidence and comments from patient/carer groups **patient evidence**. This evidence is very important as it ensures that the concerns of patients and carers are taken into account when the guidance is being developed.



The word 'technology' includes all types of medical intervention – for example, drugs, medical devices, types of operation and health education programmes

## What is a technology appraisal?

The **technology appraisal** process has two distinct phases – the **scope** and the appraisal. During both phases, NICE asks for evidence and comments from many different groups including NHS professionals, patient/carer groups, manufacturers and academics.

During the appraisal phase the evidence is reviewed by the **Appraisal Committee**, which makes its recommendations to NICE. NICE then publishes guidance for the NHS on how the technology should be used.

## Who makes the decision?

The **Appraisal Committee** makes recommendations to NICE on how the technology should be used in the NHS. This Committee is independent of NICE and has members from a variety of backgrounds, including doctors, nurses, pharmacists, health economists, statisticians and lay representatives. The Committee works with a wide range of technologies and many of its members may not be specialised in your specific disease area.

The Committee meets at least twice to consider all the evidence. The final recommendations on the use of the technology within the NHS are based on the technology's **clinical effectiveness** and **cost effectiveness**. NICE produces guidance for the NHS in England and Wales based on the Committee's recommendations.

## Topic suggestion

Anyone can suggest topics for the Department of Health and Welsh Assembly Government to consider referring to NICE. To suggest a topic please visit the NICE website ([www.nice.org.uk](http://www.nice.org.uk)) and go to the topic suggestion section and complete the online form.

### Suggesting a topic for appraisal

You could get involved by suggesting technologies:

- that would have a significant impact on patient outcomes
- for which there is uncertainty about which groups or subgroups of patients may benefit
- for which there may be a lack of fairness in the extent to which different patients or patient groups are able to access them.

## Support for patients and carers

NICE has a special team called the Patient Involvement Unit, which offers advice and support to all patient organisations that take part in NICE work. The Patient Involvement Unit can provide you with:

- advice
- extra leaflets at each stage of the appraisal process
- training sessions.

You can contact them by post, telephone or email:

PIU Appraisals Project Manager  
Patient Involvement Unit  
National Institute for Clinical Excellence  
MidCity Place  
71 High Holborn  
London WC1V 6NA

Tel: 020 7067 5847 (direct dial)  
020 7067 5800 (main line)  
Email: [patientinvolvementunit@nice.nhs.uk](mailto:patientinvolvementunit@nice.nhs.uk)



## The NICE project team

Each appraisal has a dedicated project team at NICE that includes a project manager, administrator, technical staff and an executive lead. Contact details will be given to you during the appraisal.

## Your contact details

Please keep us up-to-date with any changes in your contact details.

# The scope

A list of proposed appraisal topics is passed to NICE by the Department of Health and the Welsh Assembly Government. Not all of these topics will go forward for appraisal. The aim of the scoping phase is to gather views on the proposed topic to help us inform and influence the decision on which topics should go forward.

At this stage, NICE works to produce a draft **scope** based on the draft **remit** provided by the Department of Health and the Welsh Assembly Government. The aim of the **scope** is to decide the specific questions that would be answered by the appraisal.



Comments sent to NICE during the scoping phase will be published on our website if the appraisal goes ahead

## Comments on the draft scope

We will send you a copy of the draft **remit, scope** and **matrix** (list) of all the organisations that have been asked to take part.



### At this stage, please:

- tell us if you want to take part in the process
- let us know if there are any organisations that should be added or removed from the **matrix**, or if there are any mistakes
- send us your comments on the draft **remit, scope** and **matrix** by the deadline.

This is one of the most important stages of the appraisal process. Your comments on these documents can help determine whether or not the appraisal goes ahead

### What to look for in the draft scope

Are the right questions being asked?

Have the right comparators been identified?

Does the scope include measures of treatment effect or outcomes that are important to patients?

Does the scope define the right patient population or subgroups?

## The scoping workshop

After we have received comments on the draft **scope**, we will hold a scoping workshop. In this meeting, the main comments received will be discussed and we will explore in more detail some of the key issues raised. This will help to finalise the proposed **remit** and **scope**. NICE does not decide whether the appraisal will proceed, but your comments are an important component in helping Ministers decide whether the appraisal should proceed.

We encourage you to send up to two people from your organisation to the meeting. People from all participating organisations will be asked to attend, including patients/carers, healthcare professionals, manufacturers and academics, as well as representatives from the Department of Health and the Welsh Assembly Government.



### At this stage, please:

- contact the Patient Involvement Unit for advice on who are the best people to send to the meeting
- tell us if you would like to attend and give us the names of the people who will represent your organisation
- attend the meeting and be ready to share your opinions.

***Please remember that there is no guarantee at the scoping stage that a proposed topic will go forward for appraisal.*** If a topic is referred by Ministers to NICE for appraisal, you will hear from us again, where appropriate, with a formal invitation to take part in the appraisal. If a potential appraisal topic is not going to be referred to NICE, you will receive a letter from the Department of Health and the Welsh Assembly Government outlining the reasons why not. It may be some time before Ministers inform NICE of their decision. NICE will publish timelines on the website ([www.nice.org.uk](http://www.nice.org.uk)) as soon as possible.

### Preparing for the scoping workshop

It is a good idea to send two people to the workshop.

The people you send need to know about the comments your organisation made on the scope.

Workshops are interactive and participants will discuss the main issues identified from the comments on the scope.

The workshop will last about half a day.

# The appraisal

At the start of an appraisal you will receive a letter confirming that the appraisal is going ahead and asking you to be a formal **consultee** in the appraisal process.



## At this stage, please:

- let us know if you want to take part
- sign the confidentiality agreement and return it to us. If you have lost the agreement let us know and we will send you another copy
- make sure we have your up-to-date contact details.

Up-to-date  
timelines are  
available on  
our website:  
[www.nice.org.uk](http://www.nice.org.uk)

NICE  
will send you  
a letter telling you  
all the important  
dates for the  
appraisal

## Written submissions

You will be invited to prepare a written submission. This might include evidence on the impact of the condition on people's lives and the difference the technology makes. For details on the type of evidence to include, see 'All about written submissions' on page 29.

Your submission, along with others received, will form part of the **Evaluation Report** and will be shared with everyone at the first **Appraisal Committee** meeting, as well as being posted on the NICE website after the meeting.

Please feel free to team up with other **consultee** patient/carer groups or healthcare professional groups to work on a joint submission.



### At this stage, please:

- prepare your submission and send it to us by the deadline.

Send us your confidentiality agreement. There is very little information we can send you until we have received it

NICE is looking for a range of perspectives, and we like to have a balance of positive and negative experiences and views on the technology

## Nominations

You will also be asked to nominate **patient experts** to attend the first **Appraisal Committee** meeting. This is very important: it is your chance to ensure that the views of patients are heard at the Committee meeting.

**Patient experts** are there because of their personal knowledge and experience and are not considered to be representatives of the organisation that has nominated them.



### At this stage, please:

- nominate your **patient experts**. We need your nominations by the deadline
- provide information and support to your nominees to ensure they are willing and able to attend the first **Appraisal Committee** meeting if they are selected
- help your nominees get ready for the Committee meeting if they are selected to attend, and make sure they prepare their personal statement.

You can also nominate **clinical specialists** to attend the first **Appraisal Committee** meeting. Please see 'Contributing to a technology appraisal – a guide for healthcare professional groups' for more information.

## Choosing patient experts

Patient experts should be:

- happy to answer questions from the Committee
- willing to raise issues themselves
- able to talk about their own experience.

If you nominate more than one expert, try to choose people with a range of perspectives and experiences. For example, you might like to nominate a patient, a carer and/or someone working for a patient organisation.

You can contact the Patient Involvement Unit for more advice on who to nominate.

See  
page 23 for  
more details on  
the role of patient  
experts in the  
appraisal

## The Assessment Report

You will be sent a copy of the **Assessment Report** and given the chance to comment on its contents. The **Assessment Report** is a document written by an academic group (called the **Assessment Group**) that has reviewed published and unpublished evidence on the **clinical effectiveness** and **cost effectiveness** of the technology. It does not make recommendations about how the technology should be used in the NHS. The **Assessment Report** is simply part of the evidence received by the Committee.

Any comments you make on this report will feed into the first **Appraisal Committee** meeting and will later become part of the **Evaluation Report**, which will be sent to **consultees** and **commentators** and posted on the NICE website.



### At this stage, please:

- send us your comments on the **Assessment Report** by the deadline.

If you  
have not sent us  
your confidentiality  
agreement we won't  
be able to send you  
the Assessment  
Report

## Inside the Assessment Report

**Summary:** This highlights the key findings.

**Background:** This section describes the disease or condition that is being treated, current treatments and details of the technology.

**Methods:** This section describes how the literature was searched for relevant publications and how the quality of these publications was assessed.

**Clinical effectiveness:** Here, how well a technology works in routine clinical practice is described.

**Cost effectiveness:** This section shows how well the technology works in relation to how much it costs.

**Discussion:** Here, the results of the clinical and cost effectiveness are discussed.

*All of the documents you receive from NICE are confidential until made public on the NICE website*

## The Appraisal Consultation Document

Following the first **Appraisal Committee** meeting you will be sent a document containing the provisional recommendations made by the **Appraisal Committee**. This is called the **Appraisal Consultation Document** and you will be asked to comment on its contents. You will also be sent the **Evaluation Report** at this time. This should help you understand the **Appraisal Consultation Document**.

### At this stage, please:

- send us your comments by the deadline so that they can be considered at the next **Appraisal Committee** meeting.

Your comments on the Appraisal Consultation Document are very important. Please comment at this stage even if you are unable to take part at any other stage



### What to comment on

Do you agree with the provisional recommendations shown in Section 1? Let us know.

If you don't agree, take a look at Section 4, the Consideration of the evidence, which explains how the Committee reached its decision. Let us know why you think the Committee has reached an inappropriate or incorrect decision.

If you think the Committee has failed to take account of evidence in the Evaluation Report, please let us know what that evidence is.

Your comments should focus on the Appraisal Consultation Document not the Evaluation Report

## The Final Appraisal Determination

At the next **Appraisal Committee** meeting, all comments on the **Appraisal Consultation Document** will be considered by the Committee. **Consultees** do not normally take part in this meeting.

After the meeting you will be sent a copy of the **Final Appraisal Determination**. This document contains the final recommendations made by the Committee to NICE.

If you do not agree with the **Final Appraisal Determination**, you may want to consider whether you have grounds to appeal against the guidance. But please note that only **consultees** for the appraisal have the right of appeal against the **Final Appraisal Determination**.

You will be sent a copy of the 'Technology appraisal process – guidance for appellants', which explains the appeal process. If no appeals have been received by the deadline then the **Final Appraisal Determination** will be published as NICE's guidance to the NHS in England and Wales.



### At this stage, please:

- let us know if you agree with the recommendations made in the **Final Appraisal Determination**

or

- if you do not agree with the **Final Appraisal Determination** decide if you have grounds to appeal. We must receive any appeal by the deadline

or

- let us know by letter or email, and by the deadline, if you are happy with the recommendations but want to correct any factual errors. The **Guidance Executive** at NICE will decide whether these changes should be made.

# A guide for patient experts

Each patient/carer organisation taking part in a NICE **technology appraisal** will be asked to nominate **patient experts** to attend the first **Appraisal Committee** meeting. The Chair of the Committee in collaboration with the NICE project team and the Patient Involvement Unit will then choose two or three **patient experts** from the list of nominations.

We will be looking for **patient experts** who have different perspectives on the technology, who will be confident in the Committee meeting and who have an understanding of why technologies are appraised.

## Help for patient experts

The Patient Involvement Unit is here to help all patient experts.

If you have been nominated they will contact you and may talk to you about why you feel you would be a good patient expert.

For more information on the Patient Involvement Unit, see page 9.

## Writing your personal statement

If you are selected to be a **patient expert** you will be sent a letter inviting you to attend the first **Appraisal Committee** meeting. This letter will be addressed directly to you, not the patient/carer organisation that nominated you. In this letter you will also be asked to write a short personal statement.



### At this stage, please:

- prepare your personal statement and send it to us by the deadline.

### What is a personal statement?

Your personal statement is a short report (at the most three sides of A4 paper) detailing your personal view of the technology.

Your statement will be used by the Appraisal Committee to help them understand the views of patients and carers.

If you are a patient or carer, the Committee will want to know about your experience of the condition and what kind of impact the technology has or would have on you.

If you work with patients, the Committee will be keen to hear what patients have told you about the technology and what kind of impact it has on them and their lives.

Both positive and negative views will be welcomed.

Your personal statement will be published as part of the Evaluation Report.

## Before the Appraisal Committee meeting

Before the first **Appraisal Committee** meeting you will be sent a copy of the **Evaluation Report**. This is made up of the **Assessment Report** as well as evidence from all of the other people and organisations taking part in the appraisal. For example, you will find evidence sent to us by the manufacturers of the technology as well as the evidence submitted by the patient/carer organisation that nominated you.

The **Evaluation Report** can be quite big and we don't expect you to read it all. If you have time to look at it, the overview document would be a good place to start. You will find it at the front of the **Evaluation Report**.



### At this stage, please:

- take a look at the **Evaluation Report**. The overview is a good place to start
- familiarise yourself with the submissions for the patient/carer groups.

## Attending the Appraisal Committee meeting

The first **Appraisal Committee** meeting will be split into two parts, and as a **patient expert** you will attend the first part. In the second part, the Committee members will discuss the details of the appraisal and work towards producing their provisional recommendations.

The meeting will start with a presentation given by members of the Committee. This presentation will summarise some of the important issues that are likely to be discussed in the meeting. This will be followed by a full discussion in which Committee members will ask you and the other experts questions.

**Remember  
that the Evaluation  
Report is confidential  
until it has been  
published on the  
NICE website**

## Facts about the Appraisal Committee meeting

The Patient Involvement Unit can meet you before the meeting and provide support throughout the meeting if you want.

There will be about 35 people in the meeting.

The Committee comprises people of varied backgrounds, such as doctors, nurses, pharmacists, health economists, statisticians and lay representatives.

You will be asked to introduce yourself briefly.

You will be asked questions and have the chance to raise issues yourself.

You will not be expected to make a presentation.

You will not be involved in the decision making.

The meeting will last about half a day.

**This  
is your chance  
to ensure that  
the views of  
patients are  
heard**

## The Appraisal Consultation Document

Following the first **Appraisal Committee** meeting you will, as a **patient expert**, be sent a document containing the provisional recommendations made by the **Appraisal Committee**. This is called the **Appraisal Consultation Document** and you will be asked to comment on its contents (see page 20).



### At this stage, please:

- send your comments back to us by the deadline so that they can be considered at the next **Appraisal Committee** meeting.

## The Final Appraisal Determination

At the next **Appraisal Committee** meeting, all comments on the **Appraisal Consultation Document** will be considered by the Committee. **Patient experts** do not normally take part in this meeting.

After the meeting you will be sent a copy of the **Final Appraisal Determination**. This document contains the final recommendations made by the Committee to NICE. If no appeals are received this will be published as NICE's guidance to the NHS in England and Wales.

# All about written submissions

In this section, we aim to help patient/carer groups to prepare their written submission (page 16).

## Patient evidence

At NICE, **patient evidence** refers to any evidence originating from patients and/or carers that may guide the appraisal process. This includes the written submission prepared by the patient/carer organisation, comments on the **scope**, the **Assessment Report**, and the **Appraisal Consultation Document**, as well as the **patient experts'** personal statements and comments.

## Why do we need patient evidence?

There are two key ways in which **patient evidence** can help the appraisal process.

- Patients and carers are a unique source of evidence about the personal impact of a disease and the difference the technology can make. Their evidence can help set the context for the appraisal and enable the clinical and economic evidence to be interpreted realistically.
- **Patient evidence** can identify shortcomings in the published research. For example, sometimes measures of outcomes don't reflect what is important to patients.

## Patient evidence in the written submission

All patient/carer groups involved in the appraisal process will be invited to send us a written submission (page 16). This can include the views of individual patients and/or carers, or groups (such as groups of patients or carers, or voluntary organisations that represent patients).

NICE is most interested to hear about the technology that is being appraised. We are looking for a concise and balanced overview of the technology that reflects a range of patient and carer views, including both majority opinions and views that may be held by only a few patients. We are interested in hearing about experiences of living with the condition and the impact of the technology on a patient's symptoms and physical and psychological wellbeing, as well as what it might be like to live without the technology. **Patient evidence** is most useful when presented as a summary of information, balancing both positive and negative views, rather than as a series of individual testimonials.

## Points to consider

The following sections provide suggestions for what to include in your submission. These suggestions are not comprehensive and are designed to prompt you to submit important evidence. In some cases, patients may not have had much experience of the technology as it may be very new or it might only be available to a small number of patients. In this instance, patients may be able to tell us about the technologies that the technology is being compared to.

### **What is it like to have the condition?**

- What symptoms and problems do patients have as a result of the condition?
- How does the condition affect day-to-day life?
- Are there activities that patients are not able to do because of the condition?
- Does the condition have an impact on family, friends and employers?

## What are the outcomes that matter most to patients?

- Which aspects of the condition do patients most want the technology to help with?

## What difference does the technology make?

- How does the technology compare with other available treatments?
- What positive and negative impacts does the technology have on the condition?
- Which symptoms is the technology best or worst at treating?
- What difference does the technology make to patients' long-term health and wellbeing?
- Does the technology have an impact on others – for example, family, friends and employers?
- Does the technology have any side effects? If so, which ones are patients prepared to put up with and which ones do they find unacceptable?
- What would the impact be on the condition if the technology was not available?
- Are there any groups of patients who seem to benefit more (or less) from the technology?

## Using the technology

- How well or badly does use of the technology fit into patients' lives? For example, do patients have to go to hospital to receive the technology, or does the technology need to be administered by someone else?
- Is there anything about the technology that makes it hard or easy to use?
- Are there any groups of patients that have difficulty using the technology?
- Are there any costs to patients or their families in using the technology, including time, transport costs and carer costs?

The information in this section has been adapted from the 'Guide to the methods of technology appraisal'.

## Your organisation's submission

This can be as long as you like, but if it is over ten pages please include a one-page 'summary' sheet.

We prefer to receive your submission by email, but this is not essential.

Take care not to include any personal details such as names that could identify an individual.

# Glossary

## **Appraisal Committee**

An independent advisory committee to NICE. It has members from a variety of backgrounds, including doctors, nurses, pharmacists, health economists, statisticians and lay representatives.

## **Appraisal Consultation Document**

Sets out the **Appraisal Committee's** provisional recommendations to NICE.

## **Assessment Group**

An independent academic group commissioned to compile the **Assessment Report**.

## **Assessment Report**

A critical review of the **clinical effectiveness** and **cost effectiveness** of a technology/technologies. It is prepared by the **Assessment Group**. To prepare the report, the **Assessment Group** carries out a review of the published literature and the submissions from manufacturers.

## **Clinical effectiveness**

How well a technology works in routine clinical practice.

## **Clinical specialists**

Act as expert witnesses to the **Appraisal Committee**. They have specialist expertise and personal knowledge of the use of the technology and other treatments for the condition.

### Commentator

**Commentators** are invited by NICE to take part in the appraisal process and comment on the various documents produced during the process. **Commentators** (with the exception of manufacturers) can nominate **patient experts** or **clinical specialists**, but are not asked to produce a written submission. In addition, **commentators** can not appeal against the **Final Appraisal Determination**.

### Consultee

**Consultees** are invited by NICE to take part in the appraisal process. This involves both commenting on the various documents produced and writing a submission. In addition, **consultee** organisations (with the exception of manufacturers) are asked to nominate **patient experts** or **clinical specialists**. Only **consultees** can appeal against the **Final Appraisal Determination**.

### Cost effectiveness

How well a technology works in relation to how much it costs.

### Evaluation Report

Made up of the **Assessment Report**, written submissions and **patient expert** personal statements, and **clinical specialist** personal statements, as well as comments received on the **Assessment Report**. The **Evaluation Report** is all of the evidence seen by the **Appraisal Committee**.

### Final Appraisal Determination

Sets out the **Appraisal Committee's** final recommendations to NICE on how the technology should be used in the NHS in England and Wales.

### Guidance Executive

A team comprising the Executive Directors and Programme Directors at NICE who are responsible for approving the **Final Appraisal Determination** before publication.

### Health technology

**Health technologies** include any medical intervention such as drugs, medical devices (for example, hearing aids or inhalers), diagnostic techniques (tests used to identify diseases), surgical procedures (for example, repairing hernias), health promotion activities (for example, ways of helping people with diabetes understand and manage their condition).

### Matrix

A list of all organisations asked to take part in a **technology appraisal**. At the **scoping** stage NICE issues a draft **matrix** and asks for comments on it.

### Patient evidence

Any form of patient-based evidence, which can include the views, assessments and evaluations of individual patients, individual carers or groups. **Patient evidence** encompasses any written submissions, personal statements and comments made by patient/carer groups or **patient experts**.

### Patient experts

Act as expert witnesses to the **Appraisal Committee**. They have experience of the use of the technology either personally or as part of a representative group. They provide an individual view on the risks and benefits of the technology from personal experience as a patient or carer, and an understanding of the wider range of patient/carer views.

**Remit**

The brief given to NICE by the Department of Health and Welsh Assembly Government when a technology is referred to NICE for appraisal.

**Scope**

Provides a framework for the appraisal process and defines the disease, the patients and the technologies that will be assessed.

**Technology appraisal**

The process of developing recommendations on the use of new and existing **health technologies** within the NHS in England and Wales.

NICE would like to thank the Patient Evidence Working Party  
who laid the foundations for this guide.



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Clinical Excellence***

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[www.nice.org.uk](http://www.nice.org.uk)

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