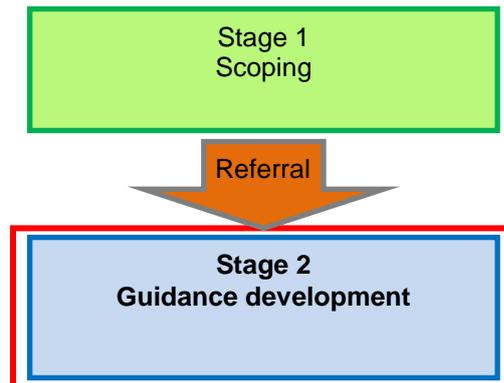


Developing technology appraisal guidance: a factsheet for patient and carer groups

The National Institute for Health and Care Excellence (NICE) has written this factsheet for national patient and carer organisations who participate, or are interested in participating, in NICE's technology appraisals.

This document is written as a guide to participation **after a topic has been referred to NICE.**



In this document, we will refer to you as 'you' and sometimes as 'patient and carer organisation', we will refer to the Public Involvement Programme as 'we', and the NICE technology appraisal programme as 'NICE'.

Other documents you might find useful are:

- An overview of NICE technology appraisals for patient and carer groups
- Scoping technology appraisals: a factsheet for patient and carer organisations
- Hints and tips on nominating patient experts

We have also written a document for individual patient experts on how they can participate in technology appraisals called:

- Hints and tips for patient experts

We also have guides on the methods and process of technology appraisals and these are available on the NICE website. These are not specifically written for patient and carer organisations. They are:

- [Guide to the methods of technology appraisal](#)
- [Technology appraisal process guides](#)

If you have any questions or would like further information, please contact the Public Involvement Advisers or for technology appraisals, Laura Norburn at laura.norburn@nice.org.uk or 0161 870 3023 or Chloe Kastoryano at chloe.kastoryano@nice.org.uk or 020 7045 2188.

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1 Introduction

1a What are NICE technology appraisals?

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

In the context of NICE a 'technology' frequently means a particular drug.

1b When does NICE appraise new technologies?

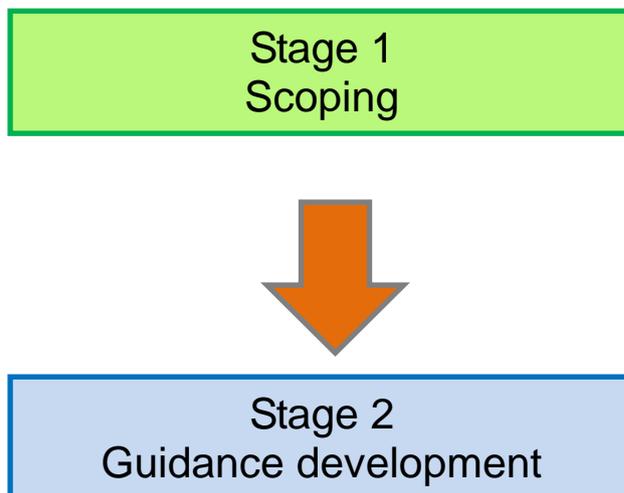
When NICE is informed that new technologies (or drugs) will soon receive their licence (are safe to be sold to the NHS) most come to NICE to be appraised. You will also hear the term Marketing Authorisation which means that a technology is both safe and may be sold in the UK.

1c What is the technology appraisal process?

Technology appraisals have two stages:

1. scoping
2. guidance development

At NICE, we think it is important for patient and carer groups to be involved in both stages to make sure their views can be included.



For more information on scoping (pre-referral – before a topic is referred to NICE for appraisal please see 'Scoping technology appraisals: a factsheet for patient and carer organisations'.

2 Guidance development

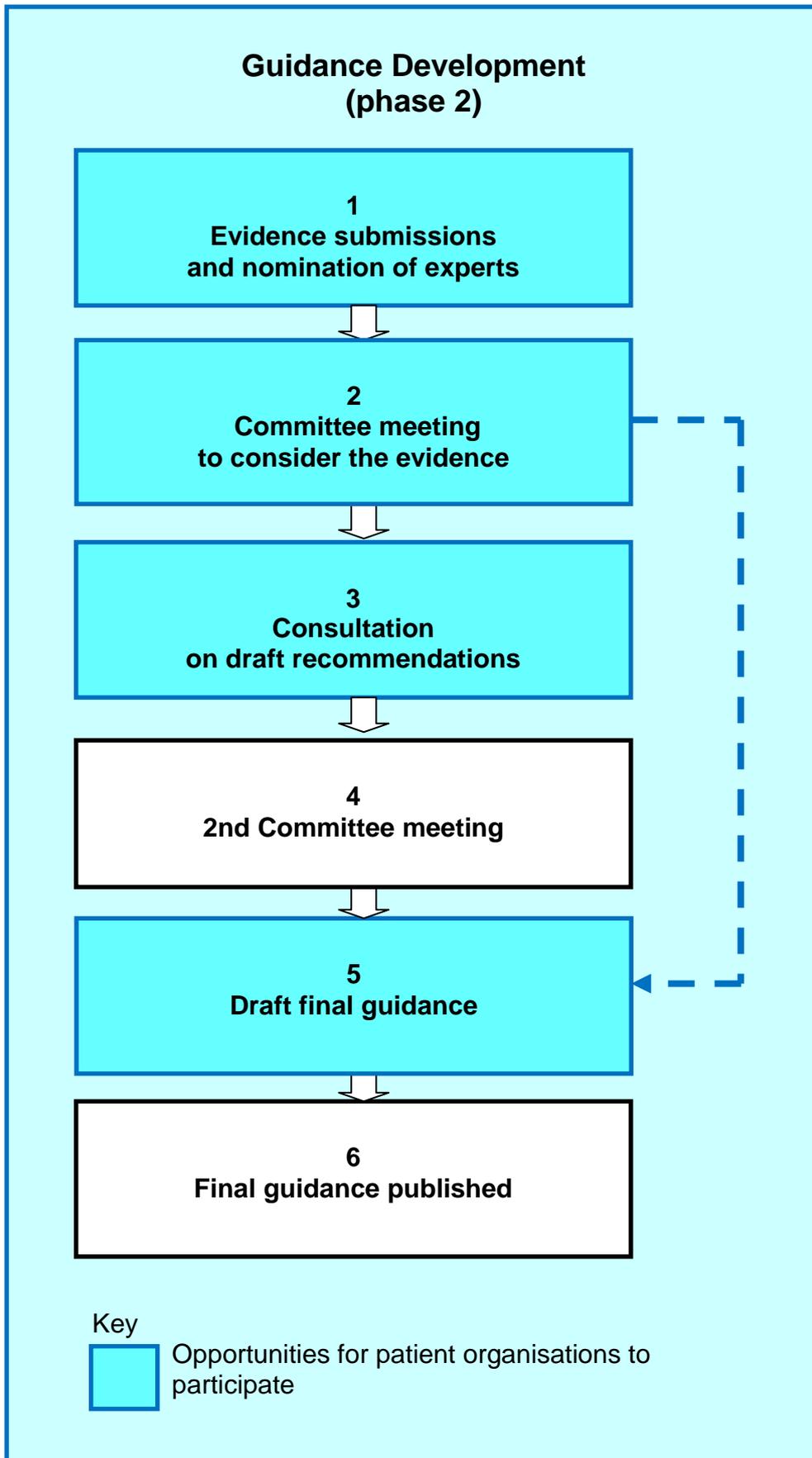
There are three ways that patient organisations can get involved:

1. Providing a written organisational submission
2. Nominating experts to attend the committee and provide a written statement:
 - a. patient experts
 - b. clinical experts.
3. Commenting on the appraisal consultation document (ACD) and the final appraisal determination (FAD).

Additionally for multiple technology appraisals, the patient groups and other consultees will be invited to comment in writing on the assessment report produced by the independent academic group. NICE will send you the report and invite you to comment before the first committee meeting.

Please see diagram of post-referral guidance stages overleaf.

The Public Involvement Programme recommends that patient organisations use all opportunities to participate.



3 How you will be notified that a topic has been referred for appraisal?

When a topic for technology appraisals has been referred to NICE, NICE will email you and let you know when to expect your invitation to participate in the appraisal.

3a Consultee and commentator information meeting (multiple technology appraisals only)

If the technology appraisal is a multiple technology appraisal your organisation may be invited to attend an information meeting for consultees and commentators. The purpose of the meeting is to:

- provide more information about NICE
- explain the appraisal process
- explore technical aspects of the appraisal.

Your organisation may send up to two people to the meeting. It would usually be people who volunteer or work for your organisation who have good knowledge of the condition, current technologies, the new technology and outcomes that are important to patients and who are comfortable with expressing their views. Often a policy officer might attend. We would not normally recommend you send a patient with personal experience of a condition and treatment to this unless they also have a good broad knowledge of the condition, treatments and important outcomes. However, an individual patient might be ideal to be nominated as a 'patient expert' (see section 4a(i)) to participate in a committee meeting.

At the meeting you will meet members of NICE staff, people from the independent academic group (the 'Assessment Group') and other stakeholders such as the company for the technology.

1
Invitation to Participate
(evidence submissions and
nominating experts)

4 What do you need to do when you receive your invitation to participate?

Your invitation to participate email explains how to get involved in the technology appraisal and includes a number of attachments - some for your information and some for completion and return.

Forms for information

Appendix A – Procedure note with key dates and contacts (including key dates for submissions, nominations and committee meetings)

Appendix B – Final scope

Appendix C – Final matrix (stakeholder list)

Appendix D – NICE's response to comments on the draft scope and provisional matrix

Forms for completion

Appendix E – Participation and confidentiality agreement

Appendix F – Expert nomination form

Appendix G – Patient/carer organisation statement template

You need to complete the **Participation and confidentiality agreement (Appendix E)** to participate in the technology appraisal.

You have 3 weeks to return this, but we recommend you do it as soon as you reasonably can because this document is key to the whole technology appraisal process:

- It means that you will receive all future mailings for this topic. You will be able to submit statements, comment on the appraisal consultation document (ACD) if NICE produces one and the final appraisal determination (FAD).

Please note that the contact details you give on this form will be used for all future correspondence.

We recommend you send the form back stating whether you wish to participate or not so that we know that you have received the mailing but have made a decision not to take part.

4a Nominating experts

4a(i) Nominating patient experts

We normally have places for two patient experts per technology appraisal topic.

We recommend that you nominate:

1. One patient expert with a broad knowledge of the condition, current treatments, new treatment and outcomes that are important to patients.
2. One patient expert with personal experience of the condition, and where possible the treatment in question.

Although there is a deadline for patient expert nominations, we understand that it is sometimes difficult to find the right person or that with some conditions it's necessary to wait until close to the committee meeting because the person may be so unwell. If this is the case, please let laura.norburn@nice.org.uk or chloe.kastoryano@nice.org.uk know as soon as you can so that they can keep the committee team updated. They will also be able to advise if we already have enough patient experts.

Nominations may come from **one organisation only, or you may jointly nominate** with one or more organisations.

Please note that the contact details patient experts give on the nomination form (Appendix F) will be used for all future correspondence including receiving the paper copy committee papers which need to be signed for.

Please note that nominations do not mean that the nominated person will automatically be approved by the committee chair as a patient expert. **There are only two places in total for patient experts**, so the chair will choose the two he or she thinks will be most helpful for the committee for that topic.

When a nomination has been approved by the chair, the committee project team will formally invite the individual to be a patient expert. The nominating organisation is copied into this invitation for information.

Once a patient expert has been invited, they cannot be replaced unless it is for personal or health reasons. If they need to drop out for these reasons, then we ask the nominating organisation to let us know and submit a nomination for a suggested replacement patient expert to go to the committee chair for approval.

Please note that patient experts are nominated and chosen as **individuals**, to give their individual opinion of the condition and treatment. They are not there as 'representatives' of an organisation.

For further information, please see our separate 'Hints and tips on nominating patient experts' document.

4a(ii) Nominating clinical experts

Patient organisations may nominate clinical experts **in addition** to patient experts. If you wish to do so, please use the Expert Nomination form (Appendix F).

Please note that clinical expert nominations **must** be in by the deadline to be accepted (unlike patient experts). It is normal for there to be more clinical experts nominated than we have places available and so nominations do not mean that the nominated person will automatically be approved by the committee chair as a clinical expert. **There are only two places in total for clinical experts**, so the chair will choose the two nominees he or she thinks will be most helpful for the committee for that topic.

When a nomination has been approved by the chair, the committee project team will send the individual an invitation to invite them to be a clinical expert. The nominating organisation is copied into this invitation for information.

4b Organisational statements and patient expert statements

4b(i) Organisational statements

Please use the **Patient/carer organisational statement template (Appendix G)**.

You have 8 weeks to return this for a single technology appraisal and 14 weeks for a multiple technology appraisal and it must be submitted by the deadline. The deadline date is in Appendix A sent with your invitation to participate.

If you wish to include case studies, we suggest that you summarise them and include key quotes as part of your statement. Case studies are not shared with the Committee

Statements may come from your organisation only, or you may choose to collaborate with one or more organisations to produce a joint statement.

4b(ii) Patient expert statements

Patient experts must either:

1. Agree with the organisational statement (if one has been submitted) of their nominating organisation

or

2. Submit their own written patient expert statement.

We recommend that, where possible, the patient expert writes his or her own statement in addition to the organisational statement. However, this may not always be practical, for instance, if they wrote the organisational statement themselves.

Please note that wherever possible we need to receive the patient expert statements at **least two months before the committee meeting**. This is to give the lead team sufficient time to read all the statements and prepare the presentations for the committee.

The patient experts will have the committee paperwork posted out to them before the committee meeting. Please note the patient experts receive the paperwork and not the organisation.

For more information on patient expert statements, preparing to be a patient expert and the committee meeting, please see our separate 'Hints and tips for patient experts' document.

4c Commenting on the assessment report (multiple technology appraisals only)

You will be sent the assessment report prepared by the independent academic group for that particular topic. You will have 20 working days to send in your comments on the technical content of the report if you wish to. All comments will be incorporated into an evaluation report which will be considered by the committee with the rest of the evidence at the committee meeting.

2
Committee meeting
(to consider the evidence)

5 What happens at the first committee meeting?

The committee meets to discuss the evidence from all the stakeholders. The patient and clinical experts are invited to answer questions and take part in the discussions.

Based on all the evidence, the committee considers two main things:

- i) *Clinical effectiveness* – how well the treatment or therapy works, compared with current treatment in the NHS
- ii) *Cost effectiveness* – is the new treatment or therapy good value for public money, compared with current treatment in the NHS?

Every time NICE recommends the use of such a technology (drug or medical device) to the NHS, savings from existing budgets have to be made to pay for the new treatment. In practice, this often means that something else can no longer be paid for. The committee need to be as certain as possible that the effectiveness and benefits of the new treatment would outweigh the potential cut of a service or treatment for patients with the same or other conditions. The committee may refer to this as ‘opportunity costs’.

Technology Appraisals Advisory Committee meetings are open to the public as part of NICE’s commitment to openness and transparency. There is potential for up to 20 people to observe the meeting. We anticipate that many of these places will be taken by interested members of the public and may also include members of the press and people from stakeholder organisations including drugs companies.

Patient organisation members are welcome to register to observe the committee from the public gallery using the facility on the NICE website.

For detailed information on the committee meeting please see our separate ‘Hints and tips for patient experts’ document.

3
Consultation
on the draft recommendations

6 How to participate in the consultation

After the committee meeting NICE will send you an email saying what type of document will be produced after the committee meeting and when you should expect the document:

1. If the guidance is broadly in line with the licence for the technology, there is no formal consultation. NICE produces a final appraisal determination (FAD) document directly from this first meeting, and it contains the final recommendations made by the committee to NICE.
2. If the guidance is restrictive however, NICE produces an appraisal consultation document (ACD). This is draft NICE guidance and is completed 3 weeks (15 working days) after the committee meeting. It is sent out to all consultees, commentators and experts for comments, and posted on the NICE website for open public consultation 1 week later (5 working days).

6a Appraisal consultation documents

There are three ways patients, carers and the public can comment on an appraisal consultation document:

1. as a patient organisation
2. as a patient expert
3. as a member of the public.

6a(i) Patient organisations

Participating patient organisations have 4 weeks (20 working days) to email their comments on the appraisal consultation document.

Please note that patient organisations have suggested strongly to the public involvement team that even if you agree with every aspect of an appraisal consultation document, that you comment to say so, otherwise NICE will only hear from those who do disagree and might assume everyone disagrees as they have no comments to the contrary.

Please do not use the NICE website to send your comments. If many members of your organisation wish to comment, we recommend that you contact either laura.norburn@nice.org.uk or chloe.kastoryano@nice.org.uk or your committee project team for the best way to do this.

6a (ii) Patient experts

Patient experts may comment on an appraisal consultation document by email, either as an individual or with their nominating organisation, or organisations. Experts also have 4 weeks (20 working days) to email their comments.

Please do not use the website to send your comments, as this is only for the general public.

6a (iii) Members of the public

We encourage people to use the website to comment if they cannot give their opinion through a participating patient group but wish to give their opinion and their own examples. As the ACD goes on the website 1 week after the consultees, commentators and experts receive it, members of the public have 3 weeks to comment.

4 2nd Committee meeting

7 What happens at the second committee meeting?

The second committee meeting is held to consider the consultation response.

During the second committee meeting the Chair summarises the issues discussed at the first meeting and the responses received on the consultation (the Appraisal Consultation Document) produced after the first meeting.

It is unusual for patient and clinical experts to attend the second committee meeting. However, if experts are invited to the second committee meeting it will be to answer questions that have arisen from the consultation, or occasionally because new evidence has been identified during the consultation. If they, or their nominating organisations, have responded to the consultation there may be questions about their response if the committee needs more information.

Patient organisation members and patient experts are welcome to register to observe the committee from the public gallery.

Occasionally, if the draft guidance for a single technology appraisal topic is broadly in line with the marketing authorisation of the treatment, NICE will not produce an appraisal consultation document and there will be no second committee meeting.

5
Draft final guidance

8 What is a Final Appraisal Determination?

A final appraisal determination (FAD) is produced after the final committee meeting and is the pre-publication version of the final guidance.

The FAD is sent out to participating organisations and the experts:

1. to check for factual inaccuracies
2. for certain stakeholders (only the consultees) to lodge an appeal if they think they have ground. (How to lodge an appeal is explained in the email that accompanies the final appraisal determination).

The final appraisal determination is also put on the website a week later, only for public information and not for comment.

6

Final guidance published

9 When is final guidance published?

As a stakeholder for the topic (consultee) you will receive advance notice of when the guidance will be published. You will also receive a final version of the guidance 48 hours before it is published.

Guidance is usually published on the fourth Wednesday of every month, except for December when it is published earlier. The month NICE anticipates publishing an appraisal can be found on the topic's page of the NICE website.

We produce a plain English version of the guidance for patients and carers, called '**Information for the Public**'. We include the contact details of the relevant key patient organisations so patients and carers know where to go for more support and information.

If you have any questions, please contact:

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