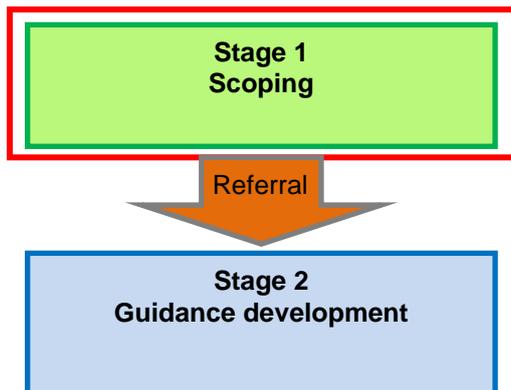


Scoping technology appraisals: a factsheet for patient and carer organisations

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 participating **in developing the scope of the appraisal**.



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
- Developing technology appraisal guidance: a factsheet for patient and carer organisations (after scoping)
- 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](#)
- [Guide to the process of technology appraisal](#)

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

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1 Introduction

1a What are 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 drug.

An 'appraisal' is a formal assessment of evidence using a defined process and methodology. The evidence is provided by the stakeholders in that particular appraisal topic and is appraised by the NICE technology appraisal committee, an independent advisory body who meet in public.

1b When does NICE appraise new technologies?

When NICE is informed that new technologies (or drugs) will soon receive a marketing authorisation (which means the technologies are safe and may be used in the UK) most come to NICE to be appraised.

1c Why does NICE appraise new technologies?

The purpose of the appraisal is to decide whether the new technology works well (is clinically effective) and good value for money (cost effective). If NICE decides it is then it will recommend that technology be used in the NHS.

Every time NICE recommends the use of such a technology 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 therapy would outweigh the potential cut of a service or treatment for patients with the same or other conditions.

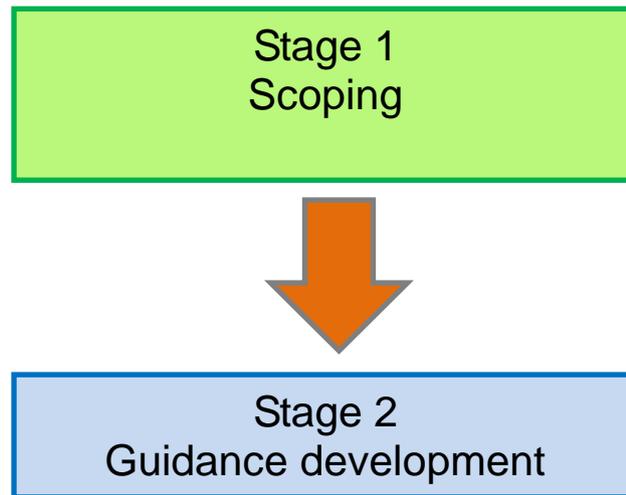
When NICE recommends a technology for use in England, [NHS England](#) must make sure it is available to those people it could help, normally within three months of the guidance being issued. Because NICE guidance is mandatory, it helps reduce variation in availability of a drug across the country.

1d What is the technology appraisal process?

The technology appraisals process is in two stages:

1. scoping
2. guidance development.

In the Public Involvement Programme, we think it is important for patient and carer organisations to be involved in both stages.



This document focuses on the scoping

If you would like more information on technology appraisals in general at NICE or about participating in the appraisals post-referral, please see [Developing technology appraisal guidance: a factsheet for patient and carer organisations](#).

2 Scoping

2a How does NICE choose the technologies for appraisal?

The majority of proposed topics are identified via the [National Institute for Health Research Horizon Scanning Centre](#). The topics will then go through the NICE topic selection process and must meet specific criteria to be considered for assessment under the technology appraisals programme.

2b When are scopes developed?

Scopes are usually developed before a technology has received a marketing authorisation and may be before or after an appraisal topic is referred to NICE for development by the Department of Health. There are some instances when the technology already has received a marketing authorisation.

Topics are scoped in batches 6 times a year; this is called 'block scoping'.

A technology appraisal topic cannot be appraised without a formal referral from the Department of Health.

NICE consults with stakeholders whilst developing the scope. A recommendation is sent to the Department of Health to make a final decision about whether a topic should be referred to NICE for appraisal.

2c Who are stakeholders for technology appraisals?

For technology appraisals at NICE, stakeholders are called consultees and commentators. Should the topic receive a referral, consultees would then be invited to provide a submission, respond to consultations, nominate clinical experts and patient experts, and can formally consider an appeal

against the final appraisal determination (FAD). Commentators may engage with the process in the same way as consultees, except commentators may not put in a submission.

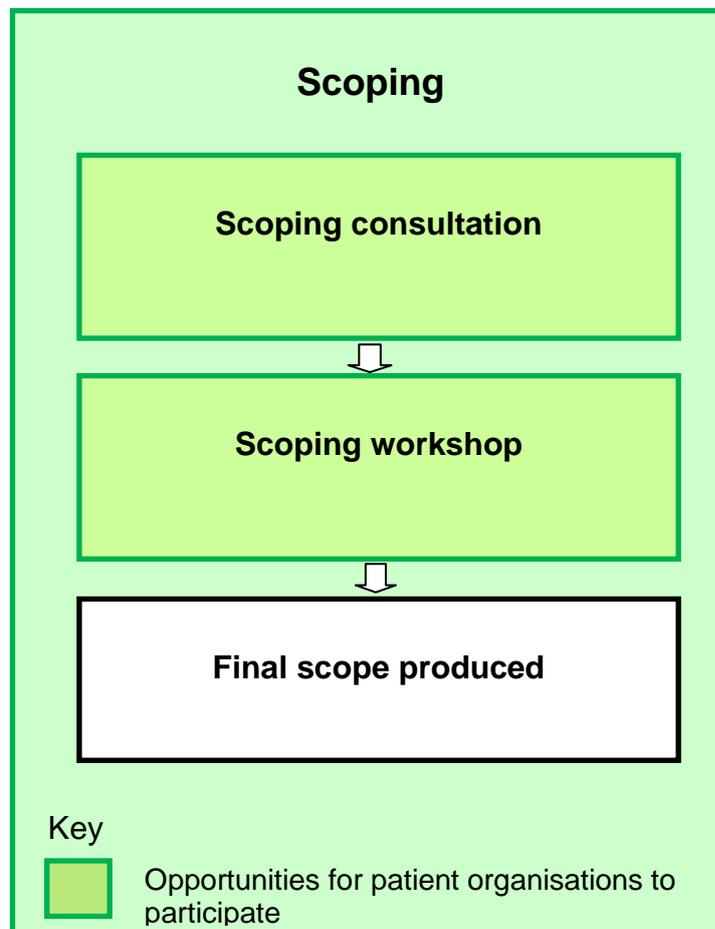
Patient and carer organisations are asked to be consultees.

3 How patient and carer organisations can get involved in scoping

There are two opportunities for you to get involved in scoping:

1. The **scoping consultation (written consultation)**. Consultees and commentators are invited to comment on the draft scope, draft remit and the provisional matrix of all stakeholders that should be involved in the appraisal. NICE provides a form which consultees have 20 working days to complete.
2. The **scoping workshop (oral consultation)**. These are held if the consultation responses received need further discussion. Consultees and commentators are invited to attend a workshop after the written comments have been received to discuss the draft scope, draft remit and all of the comments from the stakeholders.

Patient organisations can participate in either the written scoping consultation or the scoping workshop. **The Public Involvement Programme recommends you do both** if a scoping workshop is held.



4 The scoping consultation

4a What do patient and carer organisations receive for the scoping consultation?

When a proposed technology appraisal topic is scoped all consultees and commentators (stakeholders) are invited to comment in writing.

You receive an email with the following 6 documents available via a web facility called NICE docs:

For information

1. Procedure note– information about the consultation process, including a glossary.
2. Scoping workshop agenda if applicable

For consultation

3. Draft remit and draft scope for the proposed appraisal
4. Provisional matrix of consultees and commentators (stakeholder list) for the proposed appraisal

For completion and return

5. **Comment form** – for you to complete and return. The comment form contains 4 sections for you to comment on:

- (i) The draft remit
- (ii) The draft scope, including:
 - Background information
 - The technology/ intervention
 - Population
 - Comparator(s)
 - Outcomes
 - Subgroups
 - Equality
 - Innovation
- (iii) The provisional matrix (stakeholder list)

6. Scoping workshop reply form

4b How long is the consultation?

You have 20 working days to return your written comments on the consultation.

4c What is the remit?

The remit is the brief for the appraisal, given to NICE by the Department of Health. For example: “To evaluate the clinical and cost effectiveness of (technology x) within its licensed indication for treating (disease y)”.

4d What is a draft scope?

The draft scope contains the draft remit, a brief background to the condition and current treatment options, a short description of the technology and any relevant clinical trials.

It also sets out what the technology appraisal will cover and the questions that need to be addressed. It will steer and focus the appraisal if and when the technology is formally referred to NICE for appraisal.

The scope contains the:

- **Population** – the group of patients that NICE’s recommendation will apply to. This will be set out in the marketing authorisation (see 1b). NICE cannot make recommendations to a wider group than is in the marketing authorisation.
- **Intervention** – name of technology and whether it is given alone or in combination with other treatments
- **Comparators** – alternative treatment options currently used to treat the condition in established clinical practice
- **Outcomes** – important outcomes to show the effects of treatment. Clinical trials may show how the treatment is measured clinically, however patients may measure outcomes in different ways and often identify different outcomes that are important to them.
- **Subgroups** – any subgroups of the population in which the technology is likely to work better or provide more value for money. Again this can only include subgroups within the population covered by the anticipated marketing authorisation.
- **Equality issues** – consideration of whether the appraisal could lead to recommendations that have a different impact on people protected by equality legislation than on the wider population.
- **Innovation** – does the technology give a significant improvement either in: the way it works on the body, the health improvement it brings, or the way it is taken, compared with existing treatments? This is sometimes referred to as a ‘step change’.

Dosage and costs are not included in the draft scope.

4e What is the purpose of a scope?

The scope provides a framework for the appraisal. The scope defines the issues of interest (for example, population and comparators) as clearly as possible. It also sets the boundaries for the work undertaken by those producing reports for the appraisal committee, including the independent academic group and the manufacturer or sponsor of the technology.

4f What is a matrix (stakeholder list)?

A matrix (called the matrix of consultees and commentators - see 2c above) is a list of the key national organisations for a particular technology appraisal that will be invited to participate in the appraisal if it is referred. At the scoping stage, the matrix is called a provisional matrix as it is a draft version.

5 The scoping workshop (if appropriate)

5a When will you receive the scoping workshop invitation?

When you receive the scoping consultation documents you will receive your invitation to attend the scoping workshop if one is appropriate for the appraisal.. We usually provide at least 6 weeks notice of the scoping workshop date.

5b When is the scoping workshop held?

The scoping workshop is held after the written scoping consultation has closed so that the comments received can be discussed at the workshop.

5c Who should come to the scoping workshop?

People who come to the scoping workshop will usually be people who volunteer or work for your organisation who have good knowledge of the condition, current treatments, the new treatment and outcomes that are important to patients, and who are comfortable with expressing their views.

You can send two people to the scoping workshop from your organisation. Often a policy officer might attend. We would not normally recommend you send a patient with personal experience of a condition and treatment to the workshop 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' to be involved later in the process if the topic gets formally referred to NICE for appraisal.

5d What happens at a scoping workshop?

The scoping workshop may last for up to 2.5 hours. It is usually chaired by a chair or vice chair of a technology appraisal committee. Members of NICE staff who work in the technology appraisal programme and the NICE scoping team will attend the workshop and all organisations on the matrix (stakeholder list) are invited.

There are two presentations at the workshop:

- A presentation on the topic selection and scoping process.
- A presentation of the key comments and issues raised from the written consultation.

These are followed by a discussion.

5e What is the aim of the workshop?

The aim of the workshop is to:

- Ensure that the scope and remit have been appropriately defined.
- Discuss the main issues raised by stakeholders in their written comments on the draft remit and draft scope.
- Ensure that relevant issues are highlighted to:
 - the company for the technology who will be making the evidence submission if the topic is formally referred for appraisal
 - The NICE technology appraisal technical team, who will be overseeing the appraisal.

5f What happens after the scoping workshop?

After the scoping workshop the scope is finalised by the NICE technical team. The team will also submit NICE's recommendation on whether the topic should be referred, based on the comments received during consultation and at the workshop, to the Department of Health for consideration. These are included in the 'block scoping report'.

5g What happens after scoping?

- The block scoping report containing scoping topics will be published here: <http://www.nice.org.uk/ourguidance/niceguidancebytype/technologyappraisals/proposedappraisals/blockscopingreports.jsp>. The block scoping report summarises the results of the consultation and scoping workshop discussions for a batch of topics.
- If a topic is referred to NICE, NICE will let all organisations on the matrix for that topic know, including an indication of when we expect the full appraisal to start. When the appraisal process begins, your organisation will receive a formal invitation to participate in the appraisal.

If you have any questions or for more information about participating in the appraisal process for technology appraisals after scoping, please contact:

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