

Contributing to clinical guidelines – a guide for patients and carers

Factsheet 1: How NICE develops clinical guidelines and what documents we publish

This factsheet is one of a series that describes how patients, carers and the organisations that represent their interests can help NICE develop clinical guidelines.

- **Factsheet 1: How NICE develops clinical guidelines**
- Factsheet 2: How organisations representing patients and carers can get involved
- Factsheet 3: How individual patients and carers can get involved
- Factsheet 4: Support for patients and carers involved in developing a guideline
- Factsheet 5: Helping to put NICE recommendations into practice

The series aims to:

- help patients and carers take part in developing NICE clinical guidelines
- explain why NICE wants patients and carers to be involved
- explain what patients and carers can expect if they do get involved
- explain how NICE supports individuals and organisations throughout the development of a guideline.

What is NICE?

The National Institute for Health and Care Excellence (NICE) is an independent organisation that helps those working in the NHS, local authorities and the wider community deliver high-quality health and social care. We provide the following types of guidance or advice:

- Clinical guidelines – recommendations for the NHS about the treatment and care of people with specific conditions
- Health technology guidance – recommendations for the NHS on new and existing medicines, diagnostic techniques, treatments and procedures
- Public health guidance – recommendations for local authorities and others on promoting and maintaining good health and preventing disease
- Social care guidance – recommendations for local authorities and service providers about care for people using social care services

Different types of guidance apply to different parts of the UK. NICE also has other related responsibilities, such as developing quality standards for the NHS, local authorities and other providers of health and social care services in England. In all our work, we aim to ensure that our methods and guidance promote equality. For more information about our work see www.nice.org.uk

What do we mean by 'patients and carers'?

We use the terms 'patients' and 'carers' in this series to cover all groups of lay people (people who are not healthcare professionals) who contribute to NICE guidelines. This includes people who have a relevant condition or disability, and people such as family and friends who provide unpaid care for them. It also covers organisations representing patients and carers' interests, including voluntary sector or non-governmental organisations. We recognise that readers may use other terms such as 'consumer', 'service user', 'user representative' or 'patient representative'.

How NICE develops clinical guidelines

What is a clinical guideline?

A clinical guideline advises healthcare professionals about the most appropriate treatment and care for people with a particular condition. A NICE clinical guideline is developed by following a set method, and using the best available evidence. If there is not enough evidence from clinical research, the advice is based on the views of members of the group developing the clinical guideline (the guideline development group) and other experts. In some cases, the guideline development group may decide that there is not enough evidence to recommend whether a test or treatment is useful or not.

How topics are chosen for NICE clinical guidelines

NICE clinical guidelines cover many topics. Most are about a specific illness or condition, such as breast cancer, dementia, or eczema in children. Others are about broad types of care, such as maternity services, or cover more general topics or symptoms such as surgical site infection or feverish illness in children. You can look on the NICE website to see the list of clinical guidelines we have [published](#) and those currently [being developed](#) – click on 'Find guidance' on the home page.

The Department of Health decides which topics to give to NICE to develop a clinical guideline.

Why does NICE want patients and carers to take part?

NICE thinks that it is important to involve patients and carers in making decisions about their healthcare. You can see our ['patient and public involvement policy'](#) on our website. By working directly with patients and carers, NICE aims to produce guidance that addresses issues they are concerned about, reflects their views and meets their healthcare needs.

Patients and carers can help other members of a guideline development group to understand what it is like to live with a medical condition or disability,

and can give their views on different forms of treatment. For instance, patient and carer members add insights into:

- the practical, physical and emotional challenges associated with living with, or supporting someone with, a particular medical condition
- the many different things individual patients may want from their treatment and care
- how acceptable different options for care and treatment are to people
- what factors might affect patients' preferences for different types of treatment and care
- whether different groups of patients may have different views or needs, for instance, with regard to age, ethnicity, sex or disability
- what information and support patients and carers need to help them understand and deal with their condition.

How the guideline is developed

The developers

For each clinical guideline, NICE commissions one of four partner organisations (known as National Collaborating Centres) or the Internal Clinical Guidelines Programme to set up a guideline development group. The group includes healthcare professionals (and occasionally those from social care or education), researchers, and patients and carers. The professionals, patients and carers have specific knowledge of the guideline's topic. (Factsheet 3 describes in detail what patients and carers might expect as members of these groups.) The researchers offer specialist skills such as searching scientific journals for research studies (literature searching), deciding whether the evidence from the research studies is reliable (systematic reviewing and critical appraisal) and looking at how well treatments work in relation to their costs (health economics).

The scope

When the Department of Health decides to refer a topic to NICE, it produces a brief description of the topic, called the remit. NICE and the guideline development team (a group that includes the chair of the guideline

development group and members of the National Collaborating Centre or Internal Clinical Guidelines Programme) produce a draft 'scope' based on this description. The scope sets out what the guideline will and will not cover. It identifies the most important parts of the topic, and defines an area for which it will be possible to produce a useful guideline within the available time and resources.

The draft scope is discussed with patient and carer organisations and other relevant 'stakeholders' at a 'scoping workshop' (see Factsheet 2). A revised draft is then put on the NICE website for a 4-week public consultation. Patient and carer organisations, NHS bodies, organisations representing healthcare professionals, and other relevant bodies are asked to comment on the draft scope. Following the 4-week consultation period, NICE and the guideline development team (a group that includes the guideline development group chair and members of the National Collaborating Centre) consider all the comments and produce a final scope, which is published on the NICE website.

The guideline development team responds formally to every comment received. A table of these comments and responses is published on the NICE website with the final scope. It is very unusual for changes to be made to the scope after the final scope is posted on the website.

Key clinical questions

The guideline development group uses the scope to decide a list of questions (called 'key clinical questions') that they hope to answer by looking at relevant research studies. It is important to make sure these questions include issues that are important to patients and carers.

Collecting evidence

Researchers employed by the National Collaborating Centre or the Internal Clinical Guidelines Programme use the key clinical questions to find relevant research papers. They assess the quality and relevance of these research papers (using a technique known as critical appraisal) and present summaries of their findings to the guideline development group.

Reviewing the evidence

The guideline development group reviews the research evidence on the guideline topic. If the group does not have enough evidence on patients' views and experiences, they may invite stakeholder organisations to submit information on any research they know about (see Factsheet 2) or gather extra information by other means, such as patient surveys (see Factsheet 3).

Draft guideline

After about 4 - 16 months, the guideline development group produces a draft guideline with recommendations for the NHS (and sometimes social care), based on the review of the evidence. The recommendations take into account clinical effectiveness (how well a treatment or procedure works) and cost effectiveness (how well it works in relation to how much it costs).

The draft guideline includes the recommendations, details of how they were developed and information about the evidence on which they were based. NICE usually also produces a short version (called the 'NICE guideline') that contains just the recommendations without details of the evidence on which they were based. These two documents are published on the NICE website. Organisations that have registered their interest in the topic (called stakeholders, see Factsheet 2), are invited to comment on them during a public consultation that lasts for 6 weeks.

Finalising the recommendations

After the consultation period, the guideline development group discusses the written comments it has received, responds to each comment, and amends the guideline (if appropriate) in the light of the comments. The final changes are agreed with NICE.

2 weeks before the publication date an advance copy of the final guideline and a copy of the responses to stakeholder comments are made available to registered stakeholders. This information is confidential ('embargoed') until the guideline is published. This allows stakeholders to prepare for publication, but it is not an opportunity to comment further on the guideline.

Final versions of the guideline are published (see ‘What guideline documents are published?’ below), with a number of other documents designed to help make sure the guideline’s recommendations are put into practice (see Factsheet 5).

'Short' clinical guidelines

NICE's 'short' clinical guidelines are based on the same principles and methods as those used for our standard guidelines, but they are developed in a shorter time. There are various reasons for deciding to produce a short rather than a standard guideline. For example the NHS may need guidance urgently on:

- care for a specific small group of people
- a small part of a care pathway or
- the role of specific types of treatments;
- or new evidence on a topic may mean that part of an existing guideline needs updating.

The process differs from the standard process in the following ways:

- Development takes approximately 11–13 months rather than 2 years.
- A short 'NICE guideline' version (see below) is not usually produced.

What guideline documents are published?

Usually four versions of a clinical guideline are published. They are available on the NICE website (www.nice.org.uk/Guidance/CG/Published).

The full guideline contains the recommendations and describes the evidence supporting the recommendations. It also explains how the recommendations were developed from the evidence. This is published online by the National Collaborating Centre and is often also available to buy as a printed version.

The NICE guideline lists all the guideline's recommendations in full, but does not contain details of the evidence or how the recommendations were developed from the evidence. This is available online only.

'Information for the Public' is a summary of the recommendations written in a clear and straightforward way for patients, carers and members of the public. The 'Information for the Public' version of a guideline does not give detailed information about a particular disease or condition, but tells readers what NICE has recommended to the NHS as the best treatment and care that should be offered to patients. The 'Information for the Public' version usually

includes the contact details of key patient or carer organisations relevant to the topic, and links to other sources of information, such as NHS Choices.

The 'Information for the Public' version is available on the NICE website and chapters can be selected to print, save or share.

Pathways brings together the clinical guideline's recommendations with all related NICE guidance and associated products in an easy-to-navigate web format

Updating guidelines

Until 2013, all NICE clinical guidelines were regularly checked to see whether they needed updating. If we found new evidence, or if practice had changed and a guideline was therefore out of date, we may have updated all or part of the guideline through the standard process, or used the short guideline process to update only a small part.

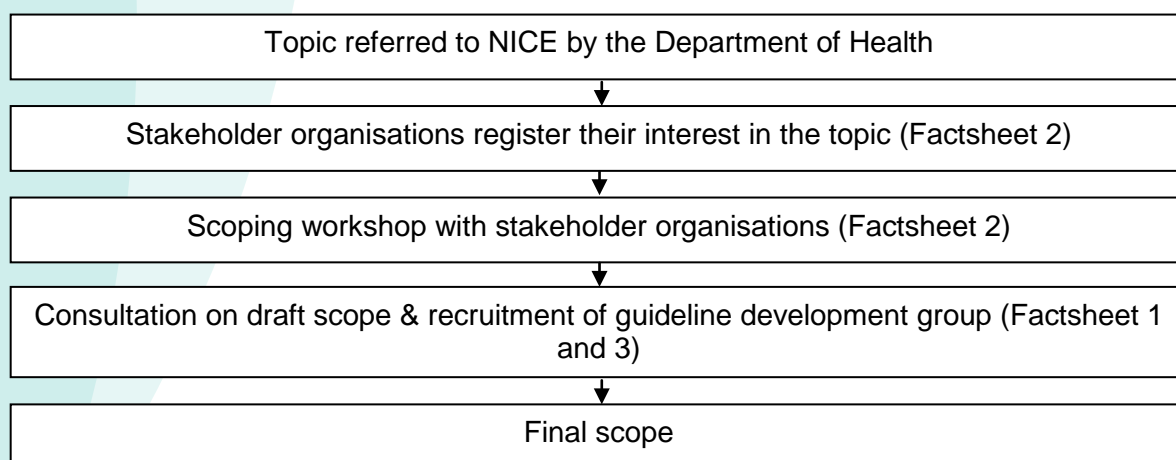
During 2013 and 2014, NICE is suspending its routine checking of clinical guidelines 3 years after publication to see whether they need updating. During this time we will be developing a new process for reviewing and updating clinical guidelines.

Further information

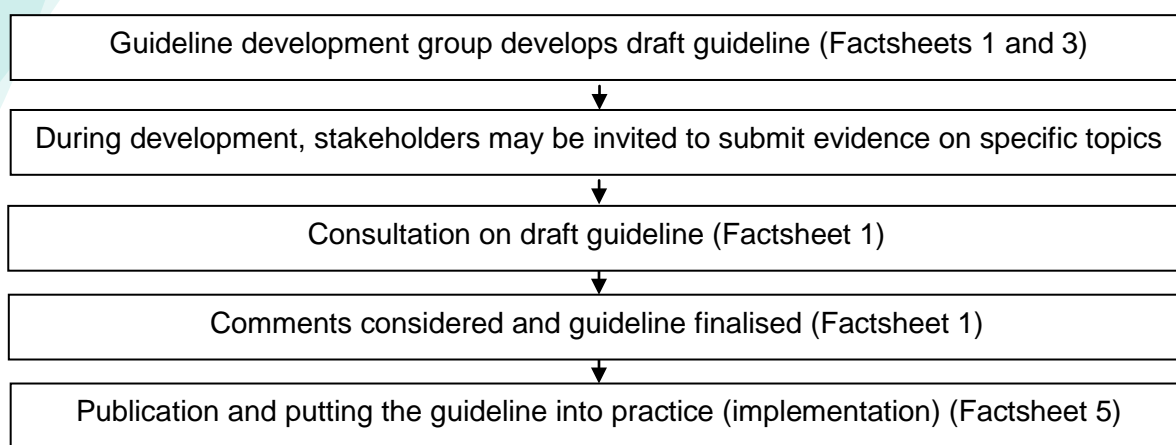
For more information on how NICE clinical guidelines are developed see 'The guidelines manual' available from www.nice.org.uk/guidelinesmanual

Summary of the guideline development process

Scoping the work and recruitment (over approximately 5 – 8 months)



Development and consultation (over approximately 10 – 24 months)



Many terms in this factsheet are described in the NICE website glossary

– www.nice.org.uk/website/glossary