

## Contributing to clinical guidelines – a guide for patients and carers

### Factsheet 2: How organisations representing patients and carers can get involved

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](http://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 patient and carer organisations can contribute – registering as a stakeholder**

### ***What is a stakeholder organisation?***

A stakeholder is an organisation that has registered its interest in NICE guidance that is being developed. Stakeholders are sent the draft scope (see Factsheet 1) and the draft guideline and are asked for comments.

Stakeholder registration does not commit your organisation to anything. It does not affect your organisation's independence or mean that your organisation has to endorse the final guideline. Registering as a stakeholder simply ensures that you are kept informed about the guideline as it is developed (see Factsheet 1). As a stakeholder you will be asked to contribute at various stages but there is no obligation to do so.

NHS, voluntary and commercial organisations can register as stakeholders for a clinical guideline, as can organisations representing healthcare professionals and national organisations representing patients or carers. Occasionally, regional or local groups may be able to register if there is no national organisation to represent a particular group of patients.

### ***How to register as a stakeholder***

The Department of Health gives NICE a list of topics for new clinical guidelines. NICE then contacts all the organisations that have been stakeholders on previous clinical guidelines and invites them to register an interest in any new topics relevant to them. We also contact organisations that have not been involved with NICE before if we think they might have an interest in the topic. Previous and potential stakeholders are also notified if NICE is planning to update an existing clinical guideline.

Any organisation that fits into one of the groups listed in 'What is a stakeholder organisation?' can register as a stakeholder – you do not have to be approached by NICE first. You can register at any time, using the

registration form on the NICE website

[http://www.nice.org.uk/getinvolved/sh/shreg\\_form.jsp](http://www.nice.org.uk/getinvolved/sh/shreg_form.jsp)

It is important that organisations register their interest for each guideline or update.

### ***Recruiting guideline development group members***

Each clinical guideline is produced by a guideline development group that includes at least two patients, carers and/or people from relevant organisations. Vacancies for patient and carer members are advertised openly on the NICE website for 4 weeks, usually during the scope consultation period (see below).

The Public Involvement Programme asks patient and carer stakeholder organisations to let their members know about vacancies and to encourage people to apply. For more information about recruitment and the role of patient and carer members of guideline development groups see Factsheet 3.

### ***Developing the guideline***

#### **The stakeholder scoping workshop**

The topic areas to be covered by the guideline are set out in a document called the 'scope', and the guideline development group uses this scope to develop a list of questions that they hope to answer (see Factsheet 1). It is important to make sure these questions include issues that are important to patients and carers.

NICE invites all stakeholder organisations to attend a scoping workshop. You will be sent a first draft of the scope, which will be discussed at the meeting. We encourage you to send someone who knows about and can represent patients and carers' interests.

The meeting is an opportunity to:

- find out more about
  - what NICE does

- how NICE develops its clinical guidelines
- how stakeholders and others can contribute
- discuss the draft of the scope
- hear other stakeholders' views on the key issues that the guideline should cover.

After the meeting, the draft scope is revised and put on the NICE website for a 4-week public consultation (see Factsheet 1).

The scoping workshop does not replace the formal process of submitting comments on the draft scope during consultation; stakeholders who have attended the meeting are still asked to submit comments by email during the consultation.

### **Stakeholder comments on the scope during the consultation**

As a stakeholder you will be sent a website link to the draft scope with information about the deadline for comments. NICE greatly values the comments of patient and carer organisations about the draft scope alongside those of healthcare professionals, commercial organisations and others during the consultation period.

To make sure that all stakeholders are treated fairly, and that the process has been followed properly, NICE can consider only written comments submitted before the deadline, and on the form provided. If you have any questions about how the scope is developed, or about commenting on the draft scope, please contact the Public Involvement Programme.

There are four members of the Public Involvement Programme at NICE who support patients and carers involved in developing NICE clinical guidelines. They are:

- **Barbara Meredith:** Public Involvement Adviser  
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- **Emma Chambers:** Public Involvement Adviser  
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- **Laura Norburn:** Public Involvement Adviser

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### **Some ideas on what to look for in the draft scope**

- Does the scope take account of issues relating to treatment and care that are important for people who will be affected by the guideline?
- Does the scope mention medicines, procedures and other treatments or options for care that patients and carers think may be important? These may include advice and help with changes in a person's lifestyle that could improve symptoms and even avoid the need for medicine.
- Should the guideline include recommendations about treatments that are in current use but may not be considered by patients to be effective, acceptable or tolerable?
- Are there any groups of patients who might need particular consideration (for example; because of particular details of their condition, or because of factors such as their age, disability, ethnicity, culture, sex or sexuality)?
- Does the scope unfairly exclude any groups of patients (for instance by their age or their general health)?
- Does the scope take account of patients and carers' need for information and support specific to the condition?
- Is the wording of the scope sympathetic to and respectful of patients and carers?

### **Finalising the scope**

Following the 4-week consultation period, NICE and the guideline development team consider all the stakeholder comments and produce a final scope (see Factsheet 1).

### ***Evidence from stakeholder organisations***

During development of the guideline, the National Collaborating Centre or the Internal Clinical Guidelines Programme may identify gaps in the evidence for specific areas defined in the scope. If this happens, stakeholder organisations will be asked if they know of any additional research evidence on these specific areas (stakeholders are usually given 4 weeks to respond).

Such evidence could include information on the impact of the condition on people's lives, the views of patients or carers about their care and treatment, or the difference a particular type of care or treatment might make. This information might come from, for example, any well designed studies that your organisation knows about or has carried out (such as surveys or questionnaires) that looked at patients' or carers' views and that might be

missed in a literature search of published work in clinical and scientific journals. If NICE calls for evidence, we will specify the type of evidence we are looking for, so that you can check that any research you have identified fits our criteria before submitting it.

### ***Commenting on the draft guideline***

The guideline development group produces a draft guideline. This is posted on the NICE website for a period of consultation and stakeholder organisations are invited to comment. This is your organisation's only opportunity to comment on the content and wording of the guideline. It is important that patients' and carers' views are included at this stage, especially if your organisation has concerns about any of the draft recommendations.

We tell stakeholder organisations well in advance about the consultation dates (which are also available on the NICE website – [www.nice.org.uk/Guidance/CG/InDevelopment](http://www.nice.org.uk/Guidance/CG/InDevelopment)). When the consultation starts your organisation will be sent an email with links to the draft guideline and information about the deadline for comments. The consultation period is normally 6 weeks. To make sure that all stakeholder organisations are treated fairly, and so it can be seen that the process has been followed properly, NICE can consider only written comments submitted before the deadline and on the form provided.

If you need paper copies of the consultation documents, contact the NICE Coordinator for the guideline (contact details are on the guideline's page on the NICE website). If you have any questions about consultations, or about commenting on the draft guidelines, contact the Public Involvement Programme (see above).

## The consultation

### Some ideas on what to comment on in the draft guideline

- Does the guideline make recommendations about all the issues from the scope that patients and carers consider important?
- Do the guideline recommendations reflect what the evidence says about treatment and care?
- Do you know about any important evidence that the guideline has not taken into account?
- Do you agree with the recommendations? If you don't, please explain why you don't.
- Does the guideline recommend treatments and care that patients and carers might consider unacceptable? Your comments could take into account, for example, what you know about the potential benefits and disadvantages (including side effects) of medicines and other treatments.
- Do the recommendations clearly show the need to take into account patients' preferences, for example if evidence suggests that two treatments may be equally effective?
- Do the recommendations take account of patients and carers' needs for information and support specific to the condition?
- If appropriate, do the recommendations consider the specific needs of different groups of patients (for example, children or young people, people from specific ethnic or cultural groups)?
- Do you agree that the right recommendations have been chosen as priorities for implementation?
- Are the recommendations clear and unambiguous?
- Is the wording respectful to patients and carers?
- Does the wording reflect the importance of partnership between healthcare professionals and patients?
- Do the research recommendations cover gaps in the evidence about important areas of patient and carer experience?

NICE usually puts two versions of the draft guideline on the website for the consultation:

- The full guideline, which contains the recommendations, details of how they were developed, and information about the evidence on which they were based.
- The shorter 'NICE' version of the guideline (see Factsheet 1), which lists the recommendations but does not describe the evidence on which they are based.



We prefer stakeholder organisations to comment on the full guideline because this document explains in detail how recommendations have been arrived at. However, you can comment on the NICE version if you do not have time to study the full guideline.

Please note that we are unable to accept:

- more than one response from a stakeholder organisation
- comments received after the consultation deadline
- comments that are not on the correct form
- confidential information, or other material that you would not wish to be made public
- personal medical information about yourself or another person that might reveal your or another person's identity.

### ***After the consultation***

The National Collaborating Centre or Internal Clinical Guidelines Programme responds to every comment made on the draft guideline, and the guideline is amended as necessary.

### ***Publication***

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.

All versions of the guideline are then published (see Factsheet 1), with other documents designed to help make sure the guideline's recommendations are put into practice (see Factsheet 5).

**Many of the terms in this factsheet are described in the NICE website glossary – [www.nice.org.uk/website/glossary](http://www.nice.org.uk/website/glossary)**