NHS

National Institute for Health and Clinical Excellence

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How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS

Fourth edition

How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS

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This booklet summarises the process used for developing NICE clinical guidelines from January 2009 onwards, including:

- how Guideline Development Group members are selected
- how organisations can register as stakeholders
- the stages when registered stakeholders can contribute to the development of a clinical guideline.

This booklet is available from the NICE website (www.nice.org.uk). For a printed copy, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk and quote reference number N1739. This edition replaces the April 2007 edition of 'The guideline development process: an overview for stakeholders, the public and the NHS' (reference N1233).

Other documents on the clinical guidelines process are available from the NICE website:

- 'The guidelines manual', which gives full details of the methods for developers of clinical guidelines (www.nice.org.uk/guidelinesmanual)
- 'A guide for patients and carers: contributing to a NICE clinical guideline', which explains how individual patients and carers, as well as patient organisations, can get involved (www.nice.org.uk/nicemedia/pdf/guidelinecontribute_how_to_CG.pdf).

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Abbreviations

GDG	Guideline Development Group
NCC	National Collaborating Centre
NICE	National Institute for Health and Clinical Excellence
PPIP	Patient and Public Involvement Programme

We welcome comments on this document. These should be emailed to: guidelinesmanual@nice.org.uk

About NICE guidance

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. We produce the following types of guidance:

- **Clinical guidelines** – recommendations about the treatment and care of people with specific diseases or conditions in the NHS in England and Wales[1].
- **Technology appraisal guidance** and **interventional procedures guidance** – guidance on the use of new and existing medicines, treatments and procedures in the NHS[2].
- **Public health guidance** – guidance on ways of helping people improve their health and reduce their risk of illness[3].

Key point

NICE is committed to promoting equality, eliminating unlawful discrimination and actively considering the implications of our guidance for human rights. We aim to comply fully with all legal obligations to:

- promote race and disability equality, and equality of opportunity between men and women, and
- eliminate unlawful discrimination on grounds of race, disability, age, sex and gender, sexual orientation, and religion or belief in the way we carry out our functions and in our employment policies and practices.

Our equality scheme and action plan* sets out how we are meeting these obligations on equality and discrimination and what we still need to do.

*Available at www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp

We encourage stakeholders to get involved in the development of our guidance at all stages. Stakeholders can include national organisations that represent patients and carers, local patient and carer organisations when there is no relevant national organisation, healthcare professionals, the NHS, organisations that fund or carry out research, and the healthcare industry.

[1] Clinical guidelines may also apply to Northern Ireland under special arrangements.

[2] Technology appraisal guidance applies to England and Wales; interventional procedures guidance applies to England, Wales, Scotland and Northern Ireland.

[3] Public health guidance applies to England only.

Key point

In this booklet we have used the terms 'patients' and 'carers' to cover all groups of lay people (people who are not healthcare professionals) who contribute to the development of our clinical guidelines. This includes:

- people who have the condition or disability
- people such as family and friends who provide unpaid care for them
- organisations representing patients and carers
- voluntary sector and non-governmental organisations.

We recognise that readers may use other terms such as 'consumer', 'service user', 'user representative' or 'patient representative'.

NICE clinical guidelines

What is a NICE clinical guideline?

NICE clinical guidelines give recommendations on how healthcare professionals should care for people with specific conditions. The recommendations are based on the best available evidence. Clinical guidelines are also important for health service managers and those who commission NHS services.

Our clinical guidelines can cover any aspect of a condition. This may include recommendations about:

- providing information, education and advice (for example, about self-care)
- prevention
- treatment in primary care (GPs and other community services)
- treatment in secondary care (provided by or in hospitals)
- treatment in specialised services.

The key principles underlying our clinical guidelines are given in box 1.

Box 1 Key principles underlying NICE clinical guidelines

Our clinical guidelines:

- aim to improve the quality of care for patients
- assess how well different treatments and ways of managing a specific condition work
- assess whether treatments and ways of managing a condition are good value for money for the NHS
- set out the clinical care that is suitable for most patients with a specific condition using the NHS in England and Wales
- take account of the views of those who might be affected by the guideline (including healthcare professionals, patients and carers, health service managers, NHS trusts, the public, government bodies and the healthcare industry)
- are based on the best available research evidence and expert consensus
- are developed using a standard process, and standard ways of analysing the evidence, which are respected by the NHS and other stakeholders, including patients
- make it clear how each recommendation was decided on
- are advisory rather than compulsory, but should be taken into account by healthcare professionals when planning care for individual patients.

A clinical guideline applies to all patients with a particular condition, but there will be times when the recommendations are not appropriate for a particular patient. Healthcare professionals are expected to take our clinical guidelines fully into account when exercising their clinical judgement. However, the guidance does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient. These decisions should be made in consultation with, and with the agreement of, the patient and/or their guardian or carer. Healthcare professionals should record their reasons for not following clinical guideline recommendations.

Our clinical guidelines are developed for the NHS, but they may also be relevant to professionals working outside the NHS, such as those working in social care.

What are short clinical guidelines?

Most published NICE clinical guidelines are standard clinical guidelines. A standard guideline covers broad aspects of clinical care and the management of specific conditions.

NICE short clinical guidelines, the first of which was published in 2007, address a smaller part of a care pathway. They are produced more quickly, and generally cover areas for which the NHS requires urgent advice.

The details of how standard and short clinical guidelines are developed differ in a number of ways. The development of a short clinical guideline is usually coordinated by the Short Clinical Guidelines Team at NICE, and not by one of the National Collaborating Centres.

The methods and processes described in 'The guidelines manual' and in this overview are those used for producing standard clinical guidelines. Any differences in the short clinical guideline development process are highlighted throughout this overview in boxes like this one. These differences are also described in more detail in the document 'Guide to the short clinical guideline process', which forms appendix N of 'The guidelines manual'.

Different versions of NICE clinical guidelines

Four versions of each standard clinical guideline are published (see box 2). We also produce tools to support implementation of the guideline in the NHS.

Box 2 Versions of the clinical guideline and support for implementation

The full guideline contains all the background details and evidence for the guideline, as well as the recommendations. This document is produced by the National Collaborating Centre that is responsible for the guideline (see pages O-11 to O-12).

The 'NICE guideline' contains only the recommendations from the full guideline, without the information on methods and evidence.

The quick reference guide summarises the recommendations in an easy-to-use format for healthcare professionals.

'Understanding NICE guidance' summarises the recommendations in everyday language. It is aimed at patients and their families and carers.

Implementation support tools (see page O-34) are produced by NICE to encourage and promote the uptake of guideline recommendations by the NHS. These may include:

- a costing report and costing template
- a slide set
- audit support
- other tools as required.

We publish all versions of the guideline, and the implementation tools, on our website (www.nice.org.uk). We also produce printed versions of the quick reference guide and 'Understanding NICE guidance', and anyone can get a copy.

Short clinical guidelines

There are usually three versions of short clinical guidelines: the full guideline, the quick reference guide and 'Understanding NICE guidance'.

How are NICE clinical guidelines developed?

Developing a standard NICE clinical guideline takes 18–24 months from the time we are asked to develop it by the Department of Health to its publication. Developing a short clinical guideline takes 11–13 months.

Proposing and selecting topics for clinical guidelines

Anyone can suggest a guideline topic for consideration. Details of how to do this are on our website (go to www.nice.org.uk/getinvolved and click on 'Suggest a topic').

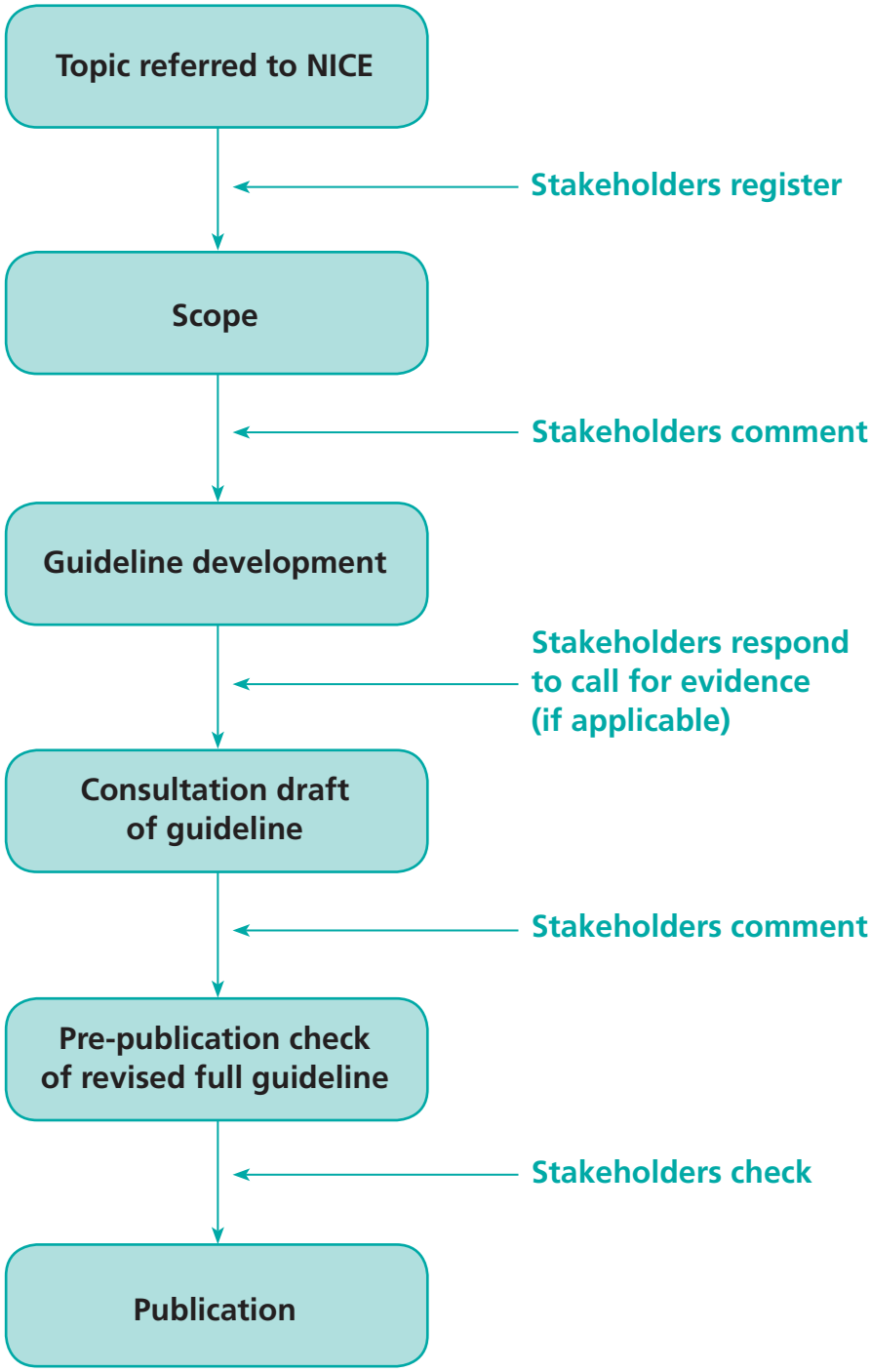
We look at each suggestion we receive to make sure that it is appropriate and that we aren't already producing a clinical guideline in that area. The suggestions are then filtered using a checklist based on selection criteria from the Department of Health. These criteria take into account:

- 'burden of disease' (this includes the number of people affected, the impact of the disease on them and the number of people dying because of it)
- resource impact of the proposed guideline (that is, the likely cost to the NHS, and to other public sector organisations if relevant)
- importance in relation to government policy (that is, whether the topic falls within a 'priority area')
- whether there is variation in clinical practice in different places
- any other reasons why the guideline is needed urgently.

Next, the suggestions are reviewed by 'topic selection consideration panels' composed of experts in the topic, other healthcare professionals with a good knowledge of the NHS, public health and the public sector, and patient and carer members. The recommendations of the topic selection panels go to the Department of Health. The Secretary of State for Health makes the final decision on which topics are referred to NICE for the development of clinical guidelines.

More details about the topic selection process are available on our website.

Key stages of clinical guideline development



Who is involved in developing NICE clinical guidelines?

The development of NICE standard clinical guidelines involves:

- NICE
- National Collaborating Centres (NCCs)
- Guideline Development Groups (GDGs)
- the Patient and Public Involvement Programme (PPIP) at NICE
- Guideline Review Panels
- expert reviewers
- stakeholders.

The following sections explain the roles of these various groups.

NICE

When the Department of Health asks NICE to produce a clinical guideline on a particular topic, we commission one of the NCCs to coordinate the guideline's development. The guidelines team in the Centre for Clinical Practice at NICE supports and advises the NCC throughout the guideline's development.

NICE's 'Guidance Executive' is responsible for giving final approval of ('signing off') the guideline. The Guidance Executive confirms that the NCC has developed the guideline in accordance with the remit from the Department of Health (see page O-24), and by following the correct process and methods.

NICE publishes the 'NICE guideline', the quick reference guide and 'Understanding NICE guidance', as well as the implementation support tools (see box 2).

The National Collaborating Centres (NCCs)

The NCCs were established by NICE to develop clinical guidelines. The NCCs bring together the expertise of the medical and nursing royal colleges, NHS trusts, professional organisations, and patient and carer organisations. They have the capacity, skills and expertise to produce high-quality clinical guidelines, working closely with the GDGs.

Each NCC has staff with:

- technical skills in:
  - guideline development
  - project management
  - health economics
  - reviewing evidence
  - using formal methods to reach consensus in areas where there is a lack of good-quality evidence
- experience in engaging with patients and with patient and carer groups.

Each NCC also has access to professional networks to support its activities.

Role of the NCC

For each clinical guideline, the NCC:

- prepares the draft scope and refines it in response to comments received during consultation (see pages O-24 to O-28)
- establishes and works with the GDG to develop the clinical guideline
- undertakes systematic reviews of the literature and health economics analyses
- ensures that the processes described in 'The guidelines manual' are followed, and documents this
- together with the GDG, prepares the consultation draft of the guideline
- together with the GDG, makes changes to the guideline in response to comments received during consultation
- publishes the final full clinical guideline
- advises NICE on the publication, implementation and updating of the guideline.

There is more information about the NCCs on our website[4].

[4] www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/nationalcollaboratingcentres/national_collaborating_centres.jsp

Short clinical guidelines

The Short Clinical Guidelines Team at NICE is responsible for establishing and providing technical support to the GDG for a short clinical guideline. NCCs are not usually involved in the development of short clinical guidelines. NICE publishes all versions of short clinical guidelines.

Guideline Development Groups (GDGs)

One of the NCCs or the Short Clinical Guidelines Team sets up an independent GDG for each clinical guideline that is developed. GDG members include healthcare professionals, technical experts, and patients and carers who have relevant expertise and experience.

The role of the GDG in developing the clinical guideline is described in detail on pages O-16 to O-20 of this overview, and in chapter 3 of 'The guidelines manual'.

The Patient and Public Involvement Programme (PPIP) at NICE

The PPIP is an integral part of NICE. Its main role is to work with our guidance-producing teams and with the NCCs so that patients, carers and the public can be fully involved in developing our guidance.

The PPIP team also works with patient and carer organisations, and provides training and support for the individual patient and carer members of GDGs.

Advice and support to NICE

The PPIP team:

- advises the clinical guidelines team at NICE on patient and carer issues
- advises the Guideline Review Panels on patient and carer issues
- identifies potential patient and carer stakeholders for each clinical guideline topic
- helps in recruiting patient and carer GDG members by promoting vacancies and encouraging applications
- comments from a patient and carer perspective on the clinical guideline development process
- for each guideline, comments from a patient and carer perspective on the draft scope and the draft recommendations.

Advice and support to the NCCs

The PPIP team:

- advises on ways of involving patients and carers in the work of the NCCs and the GDGs
- encourages and supports applications from patients and carers who want to get involved in the NCCs' activities – such as membership of GDGs and NCC Partners' Boards
- provides dedicated training for patients and carers who are involved in the NCCs' activities.

Advice and support to patients and carers

The PPIP team:

- advises and supports patient and carer organisations, and individual patients and carers, who are interested in contributing to the development of NICE clinical guidelines
- advises and supports people who apply to become patient and carer GDG members during the application and selection process
- advises, supports and trains appointed patient and carer GDG members
- supports the lay members of Guideline Review Panels.

For information on involving patients and carers in clinical guideline development, see Kelson (2005)[5].

Factsheets accompanying this document explain in more detail how patients and carers, and the organisations that represent them, can get involved in developing our clinical guidelines[6].

[5] Kelson M (2005) The NICE Patient Involvement Unit. Evidence-based Healthcare and Public Health 9: 304–307.

[6] See www.nice.org.uk/getinvolved/patientandpublicinvolvement/patient_and_public_involvement.jsp

The Guideline Review Panels

There are four independent Guideline Review Panels. Each has four or five members. The healthcare professions, NHS commissioners and managers and the healthcare industry are represented, and there is also a lay member on every panel.

Each clinical guideline is allocated to one of the Guideline Review Panels. The panel:

- comments on the draft scope and the draft guideline
- ensures that stakeholder comments on the draft scope and draft guideline have been responded to appropriately
- makes sure that it will be feasible for the NHS to implement the final recommendations.

There is more information about Guideline Review Panels on our website[7].

Expert peer reviewers

We commission expert peer reviewers to carry out a statistical and health economics review of each clinical guideline. This takes place during the consultation period for the draft guideline (see pages O-30 to O-32).

Stakeholders

Stakeholders play an integral part in the development of our clinical guidelines. This is described in detail on pages O-24 to O-35.

[7] www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/guidelinereviewpanels

The Guideline Development Group (GDG)

The role of the GDG

The GDG is established by the NCC or the Short Clinical Guidelines Team, and is responsible for developing the clinical guideline.

During development of the clinical guideline, the GDG:

- agrees the questions about treatment and management of the condition that will guide the search for evidence
- considers the evidence and reaches conclusions based on the evidence
- uses expert consensus to make decisions if evidence is poor or lacking
- formulates the guideline recommendations
- considers comments made by stakeholders during consultation
- agrees the necessary changes to the guideline after consultation.

Key point

GDG members do not comment during the stakeholder consultation on the draft guideline (see page O-30) or during the pre-publication check of the revised full guideline (see page O-32).

There is more information on the role of the GDG in chapter 3 of 'The guidelines manual' (www.nice.org.uk/guidelinesmanual).

GDG membership

All members of a GDG need to have:

- an interest in and commitment to developing the clinical guideline
- time to attend all meetings (usually 10–15 in total, held monthly)
- time to do the background reading and help formulate the recommendations
- good communication and team-working skills.

Short clinical guidelines

There are usually three 2-day GDG meetings and one 1-day meeting; these are held at approximately 6-week intervals.

Each GDG is made up of healthcare professionals, technical experts and patients and/or carers. The membership reflects the range of stakeholders and groups whose professional activities or care will be covered by the guideline. Every GDG includes at least two members with direct personal experience or knowledge of patient and carer issues. As far as possible, the GDG will have an appropriate balance with regard to the principles of NICE's equality scheme[8]. Expert advisers may also be invited to attend GDG meetings for specific discussions.

NICE is not represented on the GDG, but the Guidelines Commissioning Manager who is responsible for overseeing the clinical guideline may attend meetings as an observer.

The healthcare industry is not represented on GDGs because of potential conflicts of interest. However, manufacturers have input into the clinical guideline development process through the Guideline Review Panels and as stakeholders.

All members of the GDG are expected to abide by the NICE code of conduct and the NICE equality scheme[8] and to declare potential conflicts of interest. On appointment, all GDG members are required to sign a confidentiality form.

GDG members are reimbursed for travel and subsistence. In addition, patient and carer members are offered an attendance allowance, and GPs are offered an allowance to enable them to provide locum cover at their surgeries.

Becoming a GDG member

Adverts for all GDG vacancies are posted on our website. A brief job description and person specification are provided, together with additional information and details of how to apply. All applicants must complete a declaration of interests form and an equality monitoring form. For details of vacancies and application forms, visit www.nice.org.uk and click on 'Get involved' and then 'Join a NICE committee or working group'.

When selecting GDG members, both of the following are taken into account:

- the suitability of individual applicants, and
- the requirement for the best combination of people to maximise the range of skills and experience of the GDG.

[8] See www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp

Short clinical guidelines

We may select the GDG Chair and technical members of the GDG (for example, epidemiologists, statisticians and health economists) from a pool of suitable members. This pool will be recruited through a formal advertisement and recruitment process to act as standing members for each guideline.

GDG Chair

The GDG Chair is appointed before work starts on the scope of the guideline (see page O-24). We inform registered stakeholder organisations about the vacancy. Applicants are required to submit a CV and a covering letter.

The GDG Chair is selected after interview. The selection panel includes the Director of the NCC, the Director of the Centre for Clinical Practice at NICE (or their representative) and a Non-Executive Director of NICE.

Short clinical guidelines

The selection panel for the GDG Chair includes the Director of the Centre for Clinical Practice (or their representative), as well as an Executive Director and a Non-Executive Director of NICE.

Clinical Adviser

Some GDGs have a Clinical Adviser who is an expert on the topic, and who provides extra support to the GDG. The Clinical Adviser is appointed in the same way as the GDG Chair, before work on the guideline scope begins.

Patient and carer members of the GDG

A key role of patient and carer members is to ensure that patient issues are considered in everything that the GDG does.

The Patient and Public Involvement Programme (PPIP) team at NICE contacts patient and carer organisations that have registered an interest in the guideline topic to notify them of vacancies. Vacancies are also advertised on our website, and individual patients and carers who are not associated with a particular organisation can also apply.

Patients and carers do not need any formal qualifications to become GDG members, and they are not required to act as a representative of a patient organisation. However, they should meet the following criteria:

- Be familiar with the condition being covered by the guideline and the issues that are important to people with it. For example, they might:
  - have (or have had) the condition themselves
  - be related to and/or care for someone with the condition
  - be a member of a patient organisation.
- Understand the range of experiences of people with the condition. They should be willing to reflect these different experiences, rather than basing their views only on their own experience.
- Have some familiarity with medical and research language. For example, it is helpful if they can understand an abstract from the 'British Medical Journal'. However, training and help will be available.

When considering whether to apply, anyone interested in becoming a patient and carer GDG member should bear the following in mind.

- The clinical guideline will usually cover the entire 'patient journey', from the first time a person contacts a healthcare professional to treatments and long-term care. An understanding of the different stages of the condition is therefore useful. We encourage applications from people with a broad knowledge of the condition. GDG members need the confidence to consider and to discuss all findings from research studies.
- The guideline will cover many aspects of treatment and care. Anyone who is only interested in a specific aspect of care should consider carefully whether they want to apply. The time spent discussing any one issue may be limited, and issues discussed will be restricted to those listed in the guideline's scope. Ideally, applicants should have an interest in, and a willingness to consider the evidence on, a wide range of possible treatments. It is useful for potential applicants to look at the scope (which will be available on our website) to get a clear idea of what the guideline will cover.

Selection of patient and carer members

Applicants should complete an application form describing how their skills and experience meet the specified requirements. The NCC and the GDG Chair shortlist applicants. Those on the shortlist are interviewed either in person or by telephone. The GDG Chair, with help from the NCC, makes the final decision on which patient and carer members to appoint, and is responsible for notifying both successful and unsuccessful applicants.

Short clinical guidelines

The Short Clinical Guidelines Team usually carries out the tasks described in this section as being the responsibility of the NCC.

Healthcare professional members of the GDG

Between six and eight members of the GDG should be healthcare professionals ('healthcare professional members') who either treat people with the condition directly or manage services. The NCC and NICE agree a list of professions that will be represented on the GDG to ensure the widest possible range of viewpoints on the topic. If relevant, members from the social care professions will be included.

Healthcare professional GDG members should:

- have an interest in and experience of the guideline topic, but this need not be as an 'expert' – GDGs need to include clinicians who treat patients on a day-to-day basis in the NHS
- be chosen based on their individual skills and experience – they should not be asked to act as a representative of their profession or a professional organisation.

Selection of healthcare professional members

The NCC informs stakeholder organisations about vacancies for healthcare professional GDG members. Applicants are required to submit a CV and a covering letter.

Healthcare professional members of the GDG are selected by the Director of the NCC and the GDG Chair, subject to confirmation by the Director of the Centre for Clinical Practice at NICE. Applicants may be interviewed.

Key point

All GDG members are recruited as individuals and not as representatives of particular organisations or professional groups.

How to register as a stakeholder for a clinical guideline

Stakeholders play a vital role in the development of NICE clinical guidelines. Professional and government organisations, patient and carer groups and companies can all register as stakeholders for a clinical guideline.

Key point

We encourage stakeholder organisations to register their interest in a particular clinical guideline as soon as possible after the topic is announced. This will enable you to participate in the early stages of the guideline's development (including commenting on the scope). However, you may register your organisation as a stakeholder at any time during the development process. You can then be involved in the remaining stages of the guideline's development.

How NICE alerts potential stakeholders

We announce several new topics for clinical guidelines at the same time, after they are referred by the Department of Health. This usually happens three times a year. We publicise these new topics by:

- issuing a press release
- listing the topics on our website, with details of how to register as a stakeholder
- contacting organisations that registered as stakeholders for previous clinical guidelines to alert them to the new topics
- writing to other patient and carer and professional organisations that may have an interest in a new guideline topic
- writing to relevant consultees for a technology appraisal if the clinical guideline may update the appraisal (for further details, see section 8.1.2 of 'The guidelines manual').

Organisations that can register as stakeholders

The following can register as stakeholders for NICE clinical guidelines:

- national patient and carer organisations that represent the interests of people whose care will be covered by the guideline ('patient and carer stakeholders')
- local patient and carer organisations, but only if there is no relevant national organisation
- national organisations that represent the healthcare professionals who provide the services described in the guideline ('professional stakeholders')
- companies that manufacture drugs or devices used in treatment of the condition covered by the guideline and whose interests may be significantly affected by the guideline ('commercial stakeholders')
- providers and commissioners of health services in England and Wales
- statutory organisations, including the Department of Health, the Welsh Assembly Government, NHS Quality Improvement Scotland, the Healthcare Commission and the National Patient Safety Agency
- research organisations that have carried out nationally recognised research in the area.

NICE clinical guidelines are produced for the NHS in England and Wales, so a 'national' organisation is defined as one that represents England and/or Wales, or has a commercial interest in England and/or Wales.

Organisations that cannot register as stakeholders

For reasons of capacity, local patient and carer and professional groups cannot register as stakeholders unless there is no national organisation representing the group's specific interests.

Individuals cannot register as stakeholders. However, we encourage anyone with an interest in the topic to participate by contacting a registered stakeholder and expressing their views to them. The registered stakeholders for each guideline are listed on our website.

How to register

To register an interest in a particular clinical guideline, you should complete the stakeholder registration form. This can be done via our website[9],or you can ask us for a printed copy of the form.

The form asks potential stakeholders to:

- provide a brief description of their organisation
- indicate who the organisation represents
- describe the contribution that the organisation can make to the guideline
- provide contact details of the person who will be the stakeholder contact for the organisation.

If an organisation fits the definition of a stakeholder, we will confirm the registration. If you have not received a confirmation within 28 days of submitting the form, contact the NICE guidelines team (guidelines@nice.org.uk).

We cannot guarantee that all organisations that may have an interest in a particular clinical guideline topic will be notified about new topics. We strongly encourage potential stakeholders to visit our website regularly to check the list of guideline topics and register for appropriate guidelines.

Once an organisation has registered as a stakeholder

We encourage registered stakeholder organisations to check the summary pages about the guideline on our website regularly. You can also subscribe free of charge to our monthly e-newsletter 'NICE news', which lists forthcoming guidance, consultations on guidance that are in progress, and future events. The e-newsletter is also available on our website.

[9] www.nice.org.uk/ourguidance/niceguidancebytype/clinicalguidelines/shregistration/shregistration.jsp

How stakeholders can get involved

Stakeholder organisations can contribute to and comment on the clinical guideline at various stages during its development. A summary of the clinical guideline development process showing the key points of stakeholder involvement is on page O-10.

Stakeholder involvement is managed by the Centre for Clinical Practice working with the PPIP at NICE.

Short clinical guidelines

All tasks in this section described as being the responsibility of an NCC will usually be carried out by the Short Clinical Guidelines Team at NICE.

The scope

What is the scope?

The Department of Health gives NICE a short 'remit' for each clinical guideline. The next stage is to define exactly what the guideline will and will not cover. This process is called 'scoping', and the document containing this information is the scope.

The scope is drafted by the staff at the NCC, with input from the GDG Chair, the Clinical Adviser (if there is one), and the guidelines team and the PPIP team at NICE.

The scope gives an overview of what the clinical guideline will and will not include, and defines the aspects of care that it will cover. It may describe:

- groups of patients whose care is to be included or excluded – for example, particular age groups, or people with certain types of disease
- where treatment will be carried out – for example, by GPs (primary care), in hospital (secondary care) or in specialist units (tertiary care)
- treatments to be included and excluded – for example, diagnostic tests, surgical, medical and psychological treatments, rehabilitation.

The scope should also identify topics from other NICE guidance programmes (that is, technology appraisal, interventional procedures and public health guidance) that are relevant to the clinical guideline. For more information, see chapter 8 of 'The guidelines manual'.

The stakeholder scoping workshop

We arrange a workshop for all registered stakeholder organisations before public consultation on the scope. Key staff from the Centre for Clinical Practice at NICE, the PPIP and the NCC attend, as well as the GDG Chair and (if applicable) the Clinical Adviser. People attending the meeting are sent a first draft of the scope, which is intended as a starting point for discussion. At the workshop we:

- provide an overview of the NICE clinical guideline development process
- describe how stakeholders can contribute to the guideline by:
  - commenting during the consultations on the draft scope and draft guideline
  - informing their members and associates about GDG vacancies
- discuss the first draft of the scope and hear stakeholders' views on the key clinical issues that the guideline will cover.

What to do before the workshop

Each registered stakeholder can send one person to the workshop – please tell us who will be attending from your organisation. The person who attends should have a good understanding of the guideline topic. People attending from patient and carer organisations should have a good understanding of issues relating to the scope from a patient or carer perspective.

Note that each person is attending the workshop from their own perspective, and not to represent the views of their stakeholder organisation.

Key point

The stakeholder scoping workshop takes place before the public consultation on the scope. Note that expressing views at the workshop does not replace the formal scope consultation process. You should still send comments on the scope to NICE during the consultation.

Commenting on the draft scope

The NCC, GDG Chair, Clinical Adviser (if there is one) and NICE consider the issues raised at the scoping workshop and refine the draft scope for consultation. The draft scope is then posted on our website for a 4-week consultation period. We send a link to the document to registered stakeholders. Consultation dates are given on the website and in our monthly e-newsletter. Stakeholders should check the website regularly for any changes to timings.

We ask stakeholders to submit comments on the draft scope using the form provided. When commenting, it is important to take account of what NICE clinical guidelines can realistically be expected to cover (see box 3).

Some notes on how to comment during consultation are given in box 4 (these also apply to commenting on the draft guideline – see pages O-30 to O-31).

Box 3 Considerations when commenting on the draft scope

- NICE clinical guidelines apply to the NHS only, so they will not address the independent sector specifically. However, whenever an independent hospital, clinic or care home, social services or the voluntary sector is commissioned to provide NHS-funded care, it will be expected to adhere to NICE guidelines.
- Guidelines are generally published within 2 years of the development process starting (1 year for short clinical guidelines), so that information is up to date at publication. If the scope is very wide it will not be possible to complete the work in this time, so the scope must be restricted to what can realistically be covered.
- Guidelines will, if appropriate, address what drugs to use. However, it is assumed that prescribers will use the summaries of product characteristics* of medicines they are considering prescribing for individual patients. Therefore guidelines do not usually contain detailed information on contraindications and side effects.
- The scope may specify or exclude certain groups of patients. It is helpful if stakeholders can comment on whether such inclusions or exclusions may discriminate on the grounds of race, disability, sex and gender, age, socioeconomic status, sexual orientation and gender reassignment, or religion or belief.
- Clinical guidelines can cover any aspect of healthcare, but do not generally address how services are organised, or the skills or staff required. The scope sometimes includes aspects of service delivery, but only if the Department of Health has requested this.

*The summary of product characteristics for a drug includes information on uses for which the drug is licensed, dosages and contraindications. Summaries of product characteristics can be found at www.emc.medicines.org.uk

Box 4 A guide to commenting on drafts of the scope and the guideline

When the draft scope or guideline arrives, you should:

- circulate the draft within your organisation if appropriate, making it clear that it is for consultation and asking recipients to respond to you as the organisation's stakeholder contact (rather than responding directly to NICE)
- prepare your response and return it to NICE, remembering to:
  - collate the comments into one response from your organisation using the form provided (do not make changes to the draft document)
  - include the name of your organisation in the response
  - return the response by the closing date
- send comments electronically to the dedicated email address provided, adding your organisation's name in the subject box.

Please keep in mind the following:

- We will accept only one response from each registered stakeholder organisation. If several responses are received, it may be unclear which represents the view of the organisation. We do not have the resources to acknowledge or respond to comments from several individuals within a registered stakeholder organisation.
- All comments received from registered stakeholders will be made public on our website, so do not include confidential information (such as information about individual patients).
- Make sure that comments are constructive and clearly worded.
- We will not consider comments that are not prepared according to these instructions, or that arrive after the deadline.
- The Guidelines Coordinator (whose name is on the guideline page on our website) can answer questions on submitting comments.

Please see the document 'Protocol for managing guidance consultation comments'* for further details about how we deal with stakeholder comments received during consultation.

*www.nice.org.uk/media/307/97/Managingstakeholdercomments.pdf

Key point

Comments on the draft scope must be submitted by the end of the 4-week consultation period, using the form provided by NICE. We notify registered stakeholders of the deadline for submitting comments.

The final scope

We collect together the stakeholder comments on the scope into a 'scope consultation table'. The NCC then finalises the scope, taking into account the comments received. We 'sign off' the final version of the scope, with the approval of the Guideline Review Panel Chair. The final scope is then posted on our website, along with the scope consultation table, which contains the NCC's responses to stakeholder comments.

The clinical guideline

Evidence from stakeholders

The NCC and GDG draft 'review questions' for the guideline from the key clinical issues defined in the final scope. Each review question takes account of issues that are important to patients, such as acceptability of treatment and patients' preferences for treatment options. There is more information about review questions, including examples, in chapter 4 of 'The guidelines manual' (see www.nice.org.uk/guidelinesmanual). A search of the scientific literature is carried out to answer the review questions.

For some of the review questions, the GDG and NCC may believe that their literature search has not found all the relevant information. For example:

- the NCC may be aware that further research is being carried out
- a drug or medical device may be relatively new
- studies may have been published only as abstracts
- the NCC may be looking for data on side effects, economic models or studies of the experiences of patients, carers or healthcare professionals.

In these situations, the NCC may call for evidence from stakeholders. They will specify the review question and the type of evidence they are looking for. These calls for evidence will be sent to all registered stakeholders, and may be made at any point during development of a clinical guideline. Stakeholders are usually given 4 weeks to respond.

As well as published studies, stakeholders may submit relevant unpublished data or studies. Any confidential information should be clearly marked (for example, by using a highlighter pen, or the highlighter function in an electronic version). The NCC also asks stakeholders to complete a checklist that lists and identifies the location of all of the confidential information contained in their submission.

Box 5 summarises what may, and may not, be considered confidential by NICE.

Box 5 A guide to submitting confidential information

- Data that may influence share price values ('commercial in confidence') or are 'intellectual property' (that is, awaiting publication) may be considered as confidential.
- Information marked as confidential should be kept to an absolute minimum, for example just the relevant part of a sentence or a particular result from a table.
- NICE will not agree to a whole study being designated as confidential. As a minimum, a structured abstract of the study or economic model will have to be made available for public disclosure during consultation on the clinical guideline.
- Results derived from calculations using confidential data will not be considered confidential unless releasing those results would enable back-calculation to the original confidential data.

It is important that the amount of confidential information in a submission is kept to a minimum. At the least, a summary should be publicly available by the time the draft guideline is consulted on. We need to be able to justify the recommendations in our clinical guidelines on the basis of the evidence considered by the GDG, so the guidelines team and the NCC will work with the data owners to find an agreed solution to the balance between confidentiality and transparency[10].

[10] For further details see the document 'Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the National Institute for Clinical Excellence (NICE) on guidelines for the release of company data into the public domain during a health technology appraisal' (www.nice.org.uk/page.aspx?o=229411).

The types of information listed in box 6 will not be considered by the GDG.

Box 6 Stakeholder material not eligible for consideration

- Studies with weak designs if better-designed studies are available.
- Promotional literature.
- Papers, commentaries and editorials that interpret the results of a published paper.
- Representations and experiences of individuals (unless assessed as part of a well-designed study or a survey).

Consultation on the draft clinical guideline

The GDG takes 12–18 months to develop a draft of the clinical guideline once the scope has been finalised. There is then an 8-week consultation period when registered stakeholders can comment on the draft guideline.

Short clinical guidelines

- Development of the draft guideline takes 4–6 months.
- The consultation period for the draft guideline is 4 weeks.

We notify registered stakeholders by email when the consultation draft of the guideline is posted on our website. Comments should be submitted using the form provided via the dedicated email address for the guideline. When commenting on the guideline, stakeholders should consult the final scope (on our website) to check what the guideline will and will not cover.

Stakeholders can comment on the full guideline (which includes the draft recommendations as well as explanations of how the GDG has interpreted the evidence to make the recommendations) and/or the 'NICE guideline' (which contains just the draft recommendations and only brief supporting information).

Issues that stakeholders may wish to comment on during consultation include:

- a general view (either positive or negative) of the quality and content of the draft guideline
- points or areas that appear to fall within the scope but are not covered in the draft guideline
- any gaps in the evidence that the recommendations are based on
- potential inconsistencies in the interpretation of the evidence
- disagreements with the interpretation of the evidence
- the practical value of the guideline
- wording (for example, could the recommendations be clearer, or the language more patient-centred; could the wording be perceived as excluding patients or groups of patients?)
- whether the recommendations discriminate against some groups on the grounds of race, disability, sex and gender, age, socioeconomic status, sexual orientation and gender reassignment, or religion or belief
- how easy the recommendations will be to implement
- the potential cost of implementing the recommendations.

Some notes on how to comment on the draft guideline are given in box 4 (see page O-27).

Key point

There is a single consultation period when registered stakeholders can comment on the draft clinical guideline (8 weeks for standard guidelines and 4 weeks for short guidelines). The GDG will not consider comments that are submitted late.

Finalising the clinical guideline

We collect together all the comments from registered stakeholders in a 'guideline consultation table', and pass them to the NCC to consider. The NCC adds its responses to the consultation table.

In very rare cases, we may decide to hold a second consultation on all or part of the guideline (see section 11.4 of 'The guidelines manual' for more details).

The NCC makes changes to the guideline in the light of comments made during the consultation by:

- registered stakeholders
- the Guideline Review Panel
- external reviewers (see section 11.2.2 of 'The guidelines manual')
- other teams at NICE (such as the PPIP, the editors and the implementation team).

Comments from the Guideline Review Panel and from NICE staff are entered into the guideline consultation table and are responded to in the same way as comments from registered stakeholders, but they are not posted on our website.

In response to advice from the Guideline Review Panel, and in consultation with the GDG, the guideline is revised.

The pre-publication check

The pre-publication check enables registered stakeholders to point out any factual errors and inaccuracies that exist in the revised full guideline after consultation. More details are given in section 12.2 of 'The guidelines manual'.

A pre-publication check is not a second consultation or an opportunity to reopen arguments and issues on which the GDG has made recommendations. Nor is it an opportunity for stakeholders to ask why the guideline has not been amended in response to their comments. New evidence will not be accepted.

Factual errors are instances where there is an error of fact in the proposed full final guideline that should be corrected before publication. Factual errors do not include disagreements surrounding scientific or clinical interpretation or judgement. Box 7 gives examples of what we may consider to be a factual error.

Box 7 Examples of what may be considered as a factual error

- Incorrect referencing of studies, for example wrong year or wrong journal.
- Errors in the transcription of data, for example '4.9 months' instead of '4.9 years', '£100' instead of '£1000'.
- Incorrect reference to the licensed indications of a drug.
- Errors of fact in appraising a study, such as describing it as randomised when it wasn't.

The pre-publication check happens after the NCC and the GDG have responded to stakeholder comments from consultation on the draft guideline, after the Guideline Review Panel has reviewed the stakeholder comments and responses, and before our Guidance Executive approves the final version of the guideline. However, final editing of recommendation wording may take place after the pre-publication check.

The full guideline is posted on our website for a period of 15 working days, along with the guideline consultation table that lists comments received during consultation from stakeholders and the responses from the NCC and GDG. Registered stakeholders are alerted by email. Stakeholders are invited to report factual errors using a standard form. Reports of errors received after the 15-working-day period, from non-registered stakeholders, or in a format other than using the standard form are not considered.

Short clinical guidelines

The full guideline is posted on our website for the pre-publication check for a period of 10 working days.

NICE, the NCC and the GDG Chair consider the reports of errors received from registered stakeholders and respond only to those related to factual errors as defined above. A decision is made on whether corrections to the guideline are needed.

If corrections are not needed, the guideline is considered and submitted to NICE's Guidance Executive for approval ('sign-off'). If corrections are needed, these are carried out and the full guideline is revised by the NCC and resubmitted to NICE, together with a table of comments about the factual errors and the NCC's responses. The revised guideline is submitted to Guidance Executive for approval.

After sign-off, the different versions of the guideline are published as described below.

Publication

Once Guidance Executive has given final approval of ('signed off') the clinical guideline, the different versions are published (see box 2). Registered stakeholders are notified when the guideline is published. If applicable, the comments and responses from the pre-publication check are published on our website along with the final guideline.

Any stakeholder comments on the published guideline (other than those about errors that require correction) are addressed when the guideline is updated (see page O-35).

After publication

Implementation support

Stakeholders are encouraged to use their networks and influence to encourage implementation of the clinical guideline at both national and local level.

We develop tools to help the NHS implement our clinical guidelines, and these are available on our website. These routinely include the following:

- costing tools:
  - a costing report that estimates the national savings and costs associated with implementation
  - a costing template that can be used to estimate the local costs and savings involved
- a slide set (in the form of a PowerPoint presentation) that highlights the key priorities and provides a framework for local discussion
- clinical audit support to help monitor and review local practice.

Depending on the topic, we may also produce other tools. These can include implementation advice to aid with action planning at an organisational level, referral letter templates, flow charts, fact sheets and checklists. Tools may be produced jointly with other organisations such as professional or patient groups.

Comments and correcting errors

Comments on published clinical guidelines should be sent to us at nice@nice.org.uk

Sometimes a comment after publication may highlight a potential error in a clinical guideline. This might be in either the interpretation or the presentation of the evidence considered by the GDG. In these cases the Director of the Centre for Clinical Practice and the NCC will consider whether the potential error:

- may result in harm to patients
- undermines the conclusions on which the recommendations were based
- indicates serious problems with our quality-assurance procedures.

If one of these criteria is met, the comment will be referred to our Guidance Executive, which decides what action to take. If the Guidance Executive does not accept that an error has been

made, the individual or organisation that made the comment will be notified. If the Guidance Executive accepts that an error has been made, a note will be put on our website, and the versions of the document on the website will be amended. Depending on the nature and significance of the error and the time since publication, registered stakeholders may also be notified in writing.

Reviewing and updating clinical guidelines

There is a formal process for reviewing and updating clinical guidelines, which is managed by NICE and the NCC. Chapter 14 of 'The guidelines manual' (www.nice.org.uk/guidelinesmanual) gives details of this process.

Usually a guideline is considered for updating 3 years after publication. In order to be brought up to date, a guideline may require:

- a full update (in exceptional circumstances)
- a partial update
- no update.

Other possible options are:

- transferring the guideline to a 'static list'
- withdrawing the guideline.

A partial update may also be carried out before the usual 3 years if significant new evidence emerges.

In cases where there is to be a full update, or a partial update where new key areas are to be included in the guideline, the usual process for producing and consulting on the scope is followed (see pages O-24 to O-28). The time needed to conduct a partial update is agreed between NICE and the NCC, but will be no more than 18 months. Stakeholders are informed.

A partial update of a guideline may also be carried out when some recommendations need updating but no new areas need to be included. In these cases the original scope is used and is not consulted on. NICE informs the stakeholders that it is conducting a partial update.

A guideline will be transferred to a 'static list' if the recommendations are unlikely to change in the foreseeable future, and so no further update is planned.

A guideline may be withdrawn if its recommendations no longer apply, but it is not a sufficient priority for updating. This decision will be consulted on with stakeholders.

General information about clinical guidelines on the NICE website (www.nice.org.uk)

Our website contains the following general information about NICE and clinical guidelines:

- contact details for NICE
- lists of clinical guidelines that are published and in development
- stakeholder registration form
- information on NICE staff involved in producing clinical guidelines
- information on the NCCs
- information on the Guideline Review Panels
- information on topic selection
- general information about how clinical guidelines are developed
- 'The guidelines manual', which gives more detailed information about the methods used for developing NICE clinical guidelines
- advertisements for the positions of GDG Chair and GDG members for each clinical guideline
- general information on the implementation of clinical guidelines:
  - implementation tools
  - examples of how organisations have successfully met the challenges of putting NICE guidance into practice (the shared learning database)
- details of NICE commissioning guides, which provide support for the local implementation of clinical guidelines through commissioning
- information on NICE's Patient and Public Involvement Programme (PPIP)
- information on other NICE guidance.

Information about individual clinical guidelines

The following details for each clinical guideline will be made available on our website (www.nice.org.uk), and updated regularly:

- the remit from the Department of Health
- a list of registered stakeholders
- contact details of the NCC coordinating development of the guideline
- a schedule for development of the guideline
- the consultation draft of the scope
- the final scope
- a table of stakeholder comments on the consultation draft of the scope and responses
- project history, and information on the progress of the guideline
- members of the GDG
- minutes of GDG meetings
- the consultation draft of the guideline
- a table of stakeholder comments on the consultation draft of the guideline and responses
- the 'pre-publication' version of the guideline
- a list of factual errors in the pre-publication version of the guideline reported by stakeholders (if applicable) and responses
- details of related NICE technology appraisal, interventional procedure and public health guidance
- all versions of the published guideline – full guideline, 'NICE guideline', quick reference guide and 'Understanding NICE guidance'
- tools to support implementation of the guideline.

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