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The guideline development process: an overview for stakeholders, the public and the NHS

Third edition

The guideline development process: an overview for stakeholders, the public and the NHS, 3rd edition

April 2007

This booklet summarises the process used for developing NICE clinical guidelines from April 2007 onwards, including:

- how organisations can register as stakeholders
- the stages when registered stakeholders can contribute to the development of a guideline.

The booklet is available from the NICE website (www.nice.org.uk) or from the NHS Response Line (telephone 0870 1555 455 and quote reference number N1233). This edition replaces the September 2006 edition of 'The guideline development process: an overview for stakeholders, the public and the NHS' (reference N1113).

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

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

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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: guidelines@nice.org.uk

NICE guidance

The National Institute for Health and Clinical Excellence (or 'NICE') is part of the NHS. It is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health for patients, healthcare professionals and the wider public.

There are three centres in NICE, which produce different types of guidance.

- The Centre for Clinical Practice produces:
  - clinical guidelines on the care and clinical management of people with specific conditions.
- The Centre for Health Technology Evaluation produces:
  - technology appraisals on the use of individual medicines, devices or other interventions
  - interventional procedures guidance on whether surgical techniques or other interventions are safe and effective enough for routine use.
- The Centre for Public Health Excellence produces:
  - public health programme guidance on types of activities to improve health (such as ways of helping people give up smoking)
  - public health intervention guidance on a specific activity (such as giving people advice to take more exercise).

Although the methods for developing the various types of guidance differ, they are all underpinned by our key principles of basing recommendations on the best available evidence and involving stakeholders (patients and carers, healthcare professionals, the NHS and companies) in a transparent and collaborative manner. There is more information on the development processes for each of our guidance programmes on the NICE website (www.nice.org.uk).

The clinical guidelines programme

What is a NICE clinical guideline?

NICE clinical guidelines are recommendations for the care of individuals by healthcare professionals, based on the best available evidence. They are also important for health service managers and commissioners. Guidelines can be used to develop standards to assess the practice of healthcare professionals, help in the education and training of healthcare professionals, help patients to make informed decisions, and improve communication between patients and healthcare professionals.

NICE clinical guidelines can cover any aspect of the topic, from prevention and self-care, through primary and secondary care to more specialised services. NICE clinical guidelines are expected to promote both effective and cost-effective care. Good clinical guidelines change the process of healthcare, ensure more efficient use of healthcare resources and improve outcomes for patients. The key principles underlying our clinical guidelines are given in box 1.

Box 1 Key principles underlying NICE clinical guidelines

NICE clinical guidelines:

- aim to improve the quality of clinical care
- assess the clinical and cost effectiveness of treatments or management approaches
- are advisory, but are expected to be taken into account by clinicians when planning care for individual patients
- are developed through a process that takes account of the views of those who might be affected by the guideline (usually including healthcare professionals, patients and their carers, service managers, NHS trusts, the wider public, government and the healthcare industries)
- are based on the best possible research evidence and expert consensus
- are developed using methods that are sound and transparent, and command the respect of the NHS and other stakeholders, including patients
- set out the clinical care that is suitable for most patients with the condition using the NHS in England and Wales.

However, guidelines are necessarily general and there will be instances when their recommendations are not appropriate for an individual patient. Healthcare professionals are expected to take our clinical guidelines fully into account when exercising their clinical judgement. The guidance does not, however, override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and/or guardian or carer. Healthcare professionals should document the reasons for not following a guideline.

NICE clinical guidelines are developed for the NHS but they may also be relevant to professionals working in non-NHS settings.

How NICE clinical guidelines are developed

Proposal of topics for guidelines

Anyone can suggest a topic to be considered; details of how to do this are on the NICE website (go to www.nice.org.uk and click on ‘Get involved’).

Selection of topics

Topics for guidelines are referred from the Department of Health. The Department of Health considers the following questions when deciding whether to refer a topic.

Would the guidance promote the best possible improvement in patient care and the reduction of inequalities in health, given available resources? In particular does the proposed guidance relate to:

- a topic that is a priority for the health service or the government
- interventions or practices that might have a significant impact on the financial or other resources of the NHS or society in general
- interventions that the NHS could stop using without impairing cost-effective patient care, thus freeing up resources for use elsewhere in the NHS
- a condition associated with significant morbidity or mortality
- interventions or practices that could:
  - significantly improve patients' or carers' quality of life
  - reduce avoidable morbidity
  - reduce avoidable premature mortality
  - reduce inequalities in health?

Will the proposed guidance help to reduce or avoid inappropriate:

- clinical practice
- variation in clinical practice
- variation in access to interventions or treatment?

Will the guidance still be relevant at the expected date of publication?

Are there any other reasons why guidance is urgently needed, for example is there significant public concern or is this a new disease?

This is a summary of the Department of Health's full selection criteria. For more details on the topic selection process go to www.nice.org.uk/getinvolved and click on 'Suggest a topic'.

The guideline development process does not begin until a formal referral is made by the Secretary of State for Health. A schedule for each guideline is available on the NICE website.

Production of the scope and guideline

Once a guideline topic is referred to the NICE programme, we commission one of seven national collaborating centres (NCCs) to develop the scope (see page 18) and guideline on our behalf. The NCC convenes a guideline development group (GDG) to produce the guideline. This GDG includes healthcare professionals and patients and carers, supported by technical staff employed by the NCC (see page 10).

A draft scope is published on the NICE website for public consultation.

Linking clinical guidelines with guidance from other NICE centres

When relevant, NICE guidelines incorporate guidance from other NICE centres. For example, a clinical guideline might include a technology appraisal. Topics that span across two or more centres are usually identified at the scoping stage.

Publication of the guideline

The GDG produces a draft guideline about 12–18 months after the scope is finalised. This is posted on the NICE website for an 8-week consultation, after which the GDG revises the recommendations. In rare exceptions NICE may hold a second consultation (more details are available in 'The guidelines manual', www.nice.org.uk/guidelinesmanual). Once the final draft is produced, the NCC and GDG work with NICE to finalise the guideline documents for publication (see box 2).

Box 2 Four versions of the guideline are published, with tools to support implementation

The full guideline contains all the background details and evidence for the guideline. This document is produced by the relevant NCC. Although styles may differ, all include:

- a summary chapter listing all the recommendations and an algorithm summarising them
- an introduction to the background of the guideline, and its aim and scope
- methods
- the recommendations and statements on the evidence they are based on
- full reference details of the evidence.

The NICE guideline contains all 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': information for patients and carers summarises the information in the NICE guideline for patients and carers. It can be freely reproduced for educational and not-for-profit purposes.

Implementation tools In addition to the four versions of the guideline, NICE also produces tools to support implementation of the guideline in the NHS. These include:

- **costing report** and **costing template** to estimate the savings and costs associated with implementation
- educational **slide sets**
- **implementation advice** on how to put the guidance into practice and national initiatives that support this locally
- **audit criteria** to monitor local practice.

All the versions of the guideline, and the implementation tools, are published on the NICE website (www.nice.org.uk). The quick reference guide and 'Understanding NICE guidance' are also available as printed copies.

Key groups and individuals

The development of NICE 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 groups. Box 3 lists the information about the guideline process that is available on the NICE website.

NICE

After the Department of Health asks NICE to produce a guideline on a particular topic, we commission the coordination of the guideline's development by one of the NCCs. The guidelines team in the Centre for Clinical Practice at NICE supports and advises the NCC during the process.

At the end of the process, NICE's Guidance Executive (the executive directors and centre directors) signs off the guideline. The Guidance Executive confirms that the NCC has developed the guideline in accordance with the terms of the remit from the Secretary of State for Health and the scope, and by following NICE's process and methods.

The NICE guideline is then issued to the NHS as NICE guidance.

Box 3 Information about clinical guidelines on the NICE website

The NICE website (www.nice.org.uk) has general information and resources, including:

- contact details for NICE
- lists of guidelines that are published and under development
- stakeholder registration form
- information on NICE staff involved in the guidelines programme
- information on the NCCs
- information on the guideline review panels
- general information about how guidelines are developed
- 'The guidelines manual', which gives more detailed information about the methods used for developing NICE clinical guidelines
- advertisements for positions of GDG Chair and GDG members.

The following information about each guideline will be made available on the website:

- the remit from the Department of Health
- list of registered stakeholders
- contact details of the NCC coordinating development of the guideline
- a schedule for the guideline
- the consultation draft of the scope
- the final scope
- a table of comments on the scope consultation
- project history, and information on the progress of the guideline
- the consultation draft of the guideline
- a table of comments on the consultation draft
- members of the GDG
- details of linked technology appraisals, interventional procedures 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.

The national collaborating centres (NCCs)

Seven NCCs have been established to support NICE's delivery of national clinical guidelines (see box 4). They have the capacity, skills and expertise to deliver products that are of a high quality. Each centre:

- is led by healthcare professionals, and has academic support
- works closely with members of the GDGs
- is complementary to the others, sharing skills and expertise
- employs governance arrangements that assure cooperation, wide participation, consultation and clear contractual accountability
- has areas of particular expertise but can work on any clinical topic.

Box 4 The NCCs that develop NICE clinical guidelines

- National Collaborating Centre for Acute Care
- National Collaborating Centre for Cancer
- National Collaborating Centre for Chronic Conditions
- National Collaborating Centre for Mental Health
- National Collaborating Centre for Nursing and Supportive Care
- National Collaborating Centre for Primary Care
- National Collaborating Centre for Women's and Children's Health

There is more information about the centres on the NICE website.

Each NCC has staff with, or access to:

- professional networks to support its activities
- expertise in engaging with patients and patient groups
- technical skills in:
  - project management
  - guideline development
  - health economics
  - reviewing evidence
  - using formal methods to reach consensus in the absence of other evidence
  - implementation of guidelines.

Role of the NCC

For each guideline, the NCC:

- prepares the draft scope before consultation
- prepares a workplan (which sets out proposed membership of the GDG, the work schedule, timescales and costings)
- establishes and works with the GDG to develop the guideline
- ensures that development processes are rigorous and documented
- prepares the consultation draft of the guideline
- makes changes in response to the consultation and NICE's review processes
- publishes the final full guideline
- advises NICE on issues concerning publication, dissemination, implementation and updating of the guideline.

Guideline development groups (GDGs)

The members of each GDG consider evidence from systematic reviews of the research evidence, examining clinical and cost effectiveness, integrating clinical understanding and considering the views of patients and carers. The group should be small enough to work together effectively: usually there are 13–15 members.

Membership

All members of a GDG need to have:

- an interest in and commitment to developing NICE guidelines
- time to attend all meetings (usually 10–15 in total, held at monthly intervals)
- time to do the background reading and comment on the draft recommendations
- good communication and team-working skills.

The groups are always multidisciplinary, comprising healthcare professionals, technical experts, and patients and/or carers. The membership reflects the range of stakeholders or groups whose professional activities or care will be covered by the guideline and includes at least two members with experience or knowledge of patient and carer issues. Individuals with relevant expertise may be co-opted to the group for specific discussions.

NICE is not represented on the GDG, but a Guidelines Commissioning Manager may attend meetings as an observer.

Manufacturers of pharmaceutical products or medical devices are not represented on the GDG because of potential conflicts of interest but have input into the guideline development process through the guideline review panels (see page 13) and as stakeholders.

During the development of the guideline, the GDG:

- defines the clinical questions that will guide the search for evidence, incorporating questions from stakeholders as appropriate
- identifies, assesses and synthesises evidence
- translates the evidence into broad findings
- uses expert consensus if evidence is poor or lacking
- formulates the recommendations
- reviews the drafts of the guideline.

There is more information on the role of the GDG in chapter 4 of 'The guidelines manual' (www.nice.org.uk/guidelinesmanual).

All members of the GDG are expected to abide by the NICE code of conduct, and to declare potential conflicts of interest. On appointment, all GDG members are asked to sign a confidentiality form.

GDG members do not comment on the stakeholder consultation of the draft guideline.

Members are reimbursed for travel and subsistence by the NCC. Patient and carer members are offered an attendance allowance as well.

The Patient and Public Involvement Programme (PPIP) at NICE

The PPIP is an integral part of NICE. The Programme's main role is to work with NICE and the NCCs to develop and support opportunities for patients, carers and the public to be involved in developing NICE guidance.

The PPIP also provides training and support for the individual patient and carer members of GDGs.

Advice and support to NICE

The PPIP:

- advises the guidelines team on patient and carer issues
- advises the guideline review panels on patient and carer issues
- identifies potential patient and carer stakeholders for individual guideline topics
- facilitates interaction between NICE and patient and carer organisations
- comments from patients' and carers' perspectives on NICE's guideline development process and drafts of the scope and recommendations
- advises and supports patient and carer organisations, and individual patients and carers, who are interested in contributing to the guideline development process.

Advice and support to the NCCs

The PPIP:

- advises on methods for involving patients and carers in the work of the NCCs and their GDGs
- helps encourage applications from potential patient and carer participants in the NCCs' activities
- provides training for patients and carers actively engaged in the NCCs' activities
- advises and supports patient and carer members of GDGs.

For information on involving patients and carers in GDGs, see Kelson (2001) (details on page 26).

The guideline review panels

Four independent guideline review panels have been established. These provide external validation for the guidelines, mainly by ensuring that stakeholders' comments on the drafts of the scope and guideline are addressed and that the final recommendations can be implemented.

Peer reviewers

NICE commissions expert statistical and health economic review of the guideline via a third party. This process usually takes place during the consultation period.

Stakeholders

Stakeholders play an integral part in guideline development, and this is described on pages 14–25.

Stakeholder involvement in guideline development

This chapter describes the opportunities for professionals, patients, carers and companies to contribute to, and comment on, the guideline at different stages in the process. 'The guidelines manual' (www.nice.org.uk/guidelinesmanual) gives a summary of the guideline development process and shows the key points of stakeholder involvement.

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

Registering as a stakeholder

Stakeholder organisations are encouraged to register their interest in a particular guideline as soon as possible after a new topic is announced. However, potential stakeholder organisations may register at any time during the development process and contribute to the remaining stages in the development of the guideline.

How NICE alerts potential stakeholders

NICE publicises new topics for guideline development by:

- issuing a press release
- posting the topics on the NICE website, with details of how to register as a stakeholder
- contacting organisations that registered as stakeholders for previous guidelines to alert them to the new work programme
- writing to relevant consultees for a technology appraisal if the guideline will update the appraisal
- writing to other patient, carer and professional organisations that may have an interest in a topic on the new programme.

Stakeholders should register their interest in appropriate topics as early as possible in the development of a guideline.

Organisations that can register as stakeholders

In the NICE clinical guideline development process, stakeholders are:

- national patient and carer organisations that directly or indirectly represent the interests of people whose care is covered by the guideline ('patient and carer stakeholders')
- national organisations that represent the healthcare professionals who provide the services described in the guideline ('professional stakeholders')
- companies that manufacture the medicines or devices used in the clinical area 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 done nationally recognised research in the area.

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

Organisations that cannot register as stakeholders

For practical reasons, local patient, carer and professional groups cannot register as stakeholders, and nor can individuals. However, they are encouraged to participate via an appropriate registered stakeholder. The registered stakeholders for each guideline are shown on the NICE website.

How to register

To register an interest in a particular topic, potential stakeholders should complete the stakeholder registration form. This can be done on the NICE website (go to www.nice.org.uk/CG and click on 'Stakeholder registration'), or you can ask NICE 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 the organisation can make to the guideline
- provide contact details of a person who will be the principal contact for the organisation.

If an organisation fits the definition of a stakeholder (see above), NICE will confirm that the registration is accepted.

If a potential stakeholder has not received a confirmation within 28 days, they should contact the NICE guidelines team (guidelines@nice.org.uk).

NICE cannot guarantee to notify all organisations that may have an interest in any topic, so potential stakeholders are strongly encouraged 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

After registering as a stakeholder for a guideline, organisations are encouraged to check the summary pages about the guideline on the NICE website regularly. NICE also produces a monthly e-newsletter, which lists forthcoming guidance, consultations on guidance in progress, and future events. You can subscribe to the e-newsletter free of charge and it is also available on the NICE website.

Key point

To participate in the early stages of the guideline development process, potential stakeholders are advised to register within 6 weeks of the announcement of a new topic on the NICE website. However, potential stakeholders may register at any time during the development process and contribute to the remaining stages of the guideline's development.

Becoming a GDG member

Guidance for patients and carers interested in becoming GDG members

Advertisements for patient and carer members of the GDG are posted on the NICE website. The PPIP at NICE also publicises these vacancies to patient and carer organisations that have registered an interest in the guideline topic. The PPIP writes to the patient and carer stakeholder organisations, explaining how they can encourage applications from interested patients and carers. A brief job description, person specification and declaration of interests form are provided, together with details of how to apply. Individual patients and carers with no organisational affiliation can also apply via the NICE website; for vacancies and application forms visit www.nice.org.uk/getinvolved and click on 'Join a NICE committee or working group'.

Patients and carers do not need any formal qualifications, but they should generally:

- have an understanding of the condition and the issues that are important to people with it – for example, having direct personal experience of the condition or as a family member or carer, or a policy officer from a patient organisation
- have an understanding of (and a willingness to reflect) the experiences of a wider network of patients, rather than basing views only on their own experience

- be familiar with medical and research language – for example, it is helpful if they can understand an abstract from the 'British Medical Journal' (although training and assistance will be available).

When considering whether or not to apply, potential applicants should bear the following points in mind.

- The guideline will usually cover the entire patient journey, so an understanding of different stages of the condition is useful. NICE seeks applications from people with a broad knowledge of the condition and its prognosis, and with sufficient confidence to consider, and participate in discussions about, both positive and negative findings from research studies.
- The guideline will cover many aspects of treatment and care. People who are only interested in a specific aspect of care should consider carefully whether they want to apply, as the time spent discussing any one issue may be limited; if the issue is not listed in the guideline's scope it may not be discussed at all. Ideally, applicants should be people who have an interest in, and willingness to consider, the evidence on a wide range of possible treatments and interventions. It is useful for potential applicants to look at the scope to get a clear idea of what will be covered.

Selection of patient and carer members

Applicants are required to submit an application form, a declaration of interests form (see appendix A1 of 'The guidelines manual') and a covering letter. The NCC and the GDG Chair, in discussion with the PPIP when necessary, shortlists applicants by selecting the best combination of people to maximise the range of skills and experience of the GDG. Shortlisted applicants are interviewed either in person or by telephone. The final decision about recruiting patient and carer members rests with the NCC and the GDG Chair, as does the responsibility for notifying both successful and unsuccessful applicants.

As with all GDG members, patients and carers are not recruited to represent the views of a particular organisation, but as individuals. A key role of these members is to ensure that patient issues are considered in everything that the GDG does.

Guidance for healthcare professionals interested in becoming GDG members

Six to eight members of the GDG should be healthcare professionals ('professional members') who are either treating patients with the condition directly or managing services. As part of the workplan, the NCC and NICE agree a list of professions that will be represented on the GDG to ensure the widest range of contributions on the topic.

Professional members should:

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

Selection of GDG Chair and professional members

Advertisements for the GDG Chair and professional GDG members are posted on the NICE website. The NCC will inform stakeholder organisations about the adverts. Applicants are required to submit a CV, a declaration of interests form (see appendix A1 of 'The guidelines manual') and a covering letter.

As with patient and carer applications, the NCC identifies the best combination of people to maximise the range of skills in the GDG. The GDG Chair is selected after interview. The selection panel includes the NCC director, the director of the Centre for Clinical Practice (or delegate) at NICE and a non-executive director of NICE. Professional GDG members are selected by the NCC director and the GDG Chair, subject to confirmation by the director of the Centre for Clinical Practice at NICE. Applicants may be asked to attend an interview.

Commercial stakeholders

Commercial stakeholders are not asked to apply for membership of the GDG because of the possibility of conflicts of interest.

Scoping phase

The Department of Health gives NICE a short remit for each guideline. It is then necessary 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 clinical experts at the NCC. It sets the parameters of the guideline and provides a framework for the development work. It describes the epidemiology of the disease or condition and defines the aspects of care the guideline will cover, including:

- populations to be included or excluded – for example, age groups or people with certain types of disease
- the healthcare settings – for example, primary, secondary or tertiary care
- interventions and treatments to be included and excluded – for example, diagnostic tests, surgical, medical and psychological treatments and rehabilitation.

The draft scope is published on the NICE website, and commenting on this draft is the first point at which stakeholders can contribute to the guideline. NICE and the NCC consider comments from this consultation and redraft the scope.

The stakeholder meeting

NICE arranges a meeting for all registered stakeholder organisations during the scope consultation period. Key staff from NICE, the PPIP and the NCC attend. The purpose of the meeting is to:

- provide an overview of NICE
- provide an overview of the guideline development process
- describe the opportunities for stakeholders to contribute to guideline development during the various consultation phases and by nominating patient and carer members of the GDG
- discuss the scope of the guideline and hear stakeholders' views
- describe the role of the PPIP for NICE, the contributions of patient and carer stakeholders and the recruitment of patient and carer members of the GDG
- discuss how GDG members are recruited.

What to do before the meeting

Please tell NICE who will be attending the meeting. Organisations should send no more than two people; the most appropriate people are those with a good understanding of the issues relevant to the guideline topic.

Patient and carer stakeholders are advised to send at least one person who can specifically represent the interests of patients and carers – for example, a policy officer or someone with direct personal experience of the condition.

Key point

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

Commenting on the draft scope

Registered stakeholders will receive a copy of the draft scope for a 4-week consultation period. Consultation dates are posted on the NICE website and in our monthly e-update. Stakeholders should continue to check the website regularly for any updates to the timelines.

Stakeholders are asked to consider the draft scope and submit comments to NICE 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 5). Some notes on how to comment on consultation items are given in box 6.

Box 5 Considerations when commenting on the draft scope

- NICE guidelines apply to the NHS only, so NICE 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, those establishments or services will be expected to adhere to NICE guidelines and decisions.
- Guidelines are generally published within 2 years of the development process starting, so that information is up to date at publication. The scope must therefore be confined to what can be realistically covered in this time.
- Guidelines will, if appropriate, address what drugs to use, but it is assumed that prescribers will use the summaries of product characteristics* of medicines they are considering prescribing for individual patients. Therefore, guidelines will not necessarily contain detailed information on contraindications and side effects.
- Clinical guidelines can cover any aspect of healthcare, but do not generally address service configurations, skill mix or staffing requirements. The scope sometimes covers aspects of service delivery, but only if these are included in the remit.

* 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 6 A guide to commenting on drafts of the scope and guideline

When the draft scope or guideline arrives, stakeholders should:

- circulate the draft, if appropriate, making it clear that it is for consultation and asking recipients to respond to the organisation's stakeholder contact (rather than directly to NICE)
- prepare and return the organisation's response to NICE, remembering to:
  - collate the comments into one response from the organisation on the form NICE provided (do not edit the draft document)
  - include the name of the organisation in the response
  - return the response by the closing date for consultation
- send comments electronically to the dedicated email address given in the letter, adding the organisation's name in the subject box. If it is not possible to use email, comments can be submitted on a floppy disk or CD.

Please keep in mind that:

- NICE 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; NICE does not have the resources to acknowledge or respond to comments from individuals within registered stakeholder organisations
- all comments received will be made public on the website, so confidential information should not be included
- comments should be constructive and worded clearly
- if comments are not prepared according to these instructions, or arrive after the deadline, they will not be considered
- the Guidelines Coordinator can answer questions on submitting comments (his or her name is on the summary sheet on the NICE website).

Key point

Comments on the draft scope should be submitted within 4 weeks (this is the consultation period), using the form provided by NICE. Stakeholders are notified of the final date for submission of comments.

Suggesting clinical questions

Stakeholders may also suggest clinical questions relevant to the guideline (for example, is there evidence that a change in lifestyle, such as diet or exercise, improves outcomes for patients with diabetes?). These will be considered by the GDG, although it is not obliged to accept them.

Clinical questions should be submitted during the scope consultation period, at the same time as comments are submitted on the scope.

A good clinical question is clear and focused. It should be formatted in terms of a specific patient problem because this helps identify the clinically relevant evidence. Its exact structure will depend on the question being asked, but it is likely to fall into one of three main areas: intervention, prognosis and diagnosis. There is more information about writing clinical questions in chapter 5 of 'The guidelines manual' (www.nice.org.uk/guidelinesmanual).

After the scope consultation

NICE collates the stakeholders' comments into a 'scope consultation table'. The scope is then finalised and signed off by NICE. The final version of the scope is posted on the NICE website, together with the scope consultation table containing the NCC's responses to comments.

Development phase

Evidence from stakeholders

Once the workplan for the guideline is agreed, the NCC will start the development work by undertaking an initial search of the literature to answer the clinical questions.

For some clinical questions, the GDG and NCC may believe that there is relevant information that they have not found through their search. For example, the NCC may be aware of ongoing research, a technology may be relatively new, there may be studies that have been published only as abstracts, or the NCC may be looking for data on adverse effects, economic models, or studies of patients', carers' or healthcare professionals' experiences.

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

In addition to published studies, stakeholders may submit relevant unpublished data or studies. Any confidential information should be clearly marked. The amount of confidential information in a submission should be kept to a minimum, and at least a summary should be publicly available by the time of the consultation on the draft guideline. NICE needs to be able to justify the recommendations in guidelines on the basis of the evidence considered by the GDG, so NICE and the NCC will work with the data owners to find an agreed solution to the balance between confidentiality and transparency. For

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/TAprocess).

The types of information listed in box 7 will not be considered.

Box 7 Stakeholder material not eligible for consideration by the GDG

- 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).

Validation phase

The NCC takes 12–18 months to develop a draft guideline; this includes draft recommendations and explanations of how the GDG has interpreted the evidence to make the recommendations. The draft guideline then enters what is called the 'validation phase', during which there is a consultation period when stakeholders can comment on the guideline.

Key point

There is one 8-week consultation period when stakeholders comment on the draft guideline. The GDG will not normally respond to comments that are submitted late.

Registered stakeholders are notified by email when the consultation draft is posted on the NICE website. You should return your comments using the form provided via the dedicated email address for the guideline (given in the email notification and also available from the NICE website). When commenting on the guideline, bear the scope of the guideline in mind; the scope is on the NICE website.

Issues that stakeholders may wish to raise with the GDG include:

- a general view (either positive or negative) of the quality and content of the guideline
- points or areas that appear to fall within the scope but are not covered by the draft guideline
- gaps in the evidence base used to formulate the recommendations

- potential inconsistencies in the interpretation of evidence
- disagreement with the interpretation of evidence
- the practical value of the guideline
- wording (for example, could the clarity of the recommendations be improved, or the language be more patient-centred; could the wording be perceived as excluding patients or groups of patients?)
- observations on the resource implications of the guideline.

Some notes on how to respond are given in box 6 (see page 21).

After the consultation

NICE tabulates all the comments (the table is referred to as the 'consultation table'), and passes them to the NCC to consider. The NCC's responses are added to the consultation table.

A final draft of the guideline is then prepared, in the light of comments made during the consultation by:

- stakeholders and other reviewers
- the guideline review panel
- expert reviewers
- the PPIP at NICE.

In response to advice from the guideline review panel, and in consultation with the GDG, the different versions of the guideline (see box 2) are finalised and signed off within NICE.

There is no appeal stage in the guideline development process (unlike the technology appraisal process).

If a stakeholder has comments on the published guideline, these will be addressed at the time of review (see page 26).

Publication and dissemination phase

Once NICE has signed off the guideline, the different versions are published and disseminated. Stakeholders are notified when the guideline is published. At this stage, the consultation table, including the GDG's responses, is posted on the NICE website.

Implementation

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

The Healthcare Commission assesses the performance of NHS organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health' issued in July 2004. Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

NICE develops tools to help organisations implement clinical guidelines, and these are available from our website. Depending on the topic, they may include:

- slides highlighting key messages for local discussion
- costing tools:
  - costing report to estimate the national savings and costs associated with implementation
  - costing template to estimate the local costs and savings involved
- implementation advice on how to put the guidance into practice, and national initiatives that support this locally
- audit criteria to monitor local practice.

Comments after publication

Comments

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

Errors

If a comment after publication highlights an error in the guideline – in either the interpretation or the presentation of the evidence considered by the GDG – the director of the Centre for Clinical Practice and the GDG will consider whether it:

- undermines the conclusions on which the recommendations have been based
- may result in harm to patients
- opens NICE to criticism that its quality-assurance procedures are seriously compromised.

If one of these criteria is met, the comment will be referred to NICE's 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 the NICE 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, stakeholders may also be notified in writing.

Review and update

There is a formal process for reviewing and updating guidelines, which is managed by the NCC and one member of the original GDG (see chapter 15 of 'The guidelines manual', www.nice.org.uk/guidelinesmanual, for more details).

Further reading

Committee to Advise the Public Health Service on Clinical Practice Guidelines (1990) in: Field MJ, Lohr KN, editors Clinical practice guidelines: directions for a new Program. Washington, DC: National Academy Press.

Kelson M (2001) Patient involvement in clinical guideline development – where are we now? Journal of clinical governance 9:169–74.

Kelson M (2005) The NICE Patient Involvement Unit. Evidence-based healthcare and public health 9: 304–307.

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