

Process and methods guides

Developing NICE guidelines: a guide for stakeholders and the public

October 2014

1 Introduction

This guide gives an overview of the process and methods the National Institute for Health and Care Excellence (NICE) uses to develop guidelines on health and social care. It is for stakeholders and the public and explains how organisations and individuals can contribute to our guidelines.

1.1 *About NICE and NICE guidelines*

NICE is an independent public body that produces national guidance, standards and advice to improve the health, wellbeing and care of people in England. Decisions on how NICE guidance applies in other UK countries are made by ministers in the [Welsh Government](#), [Scottish Government](#), and [Northern Ireland Executive](#).

NICE guidelines make recommendations on a broad range of topics covering healthcare, public health and social care. (For information on other types of NICE guidance and advice, such as technology appraisal guidance, see [About NICE](#) on the NICE website.)

The topics covered by NICE guidelines include care and services for people with a particular condition or need, or in particular circumstances (for example, when leaving hospital). They may also cover ways to promote good health or prevent ill health, make recommendations on systems and processes (for example, managing medicines), make recommendations on safe staffing levels or how national and local organisations can improve the quality of care and services.

The recommendations in NICE guidelines are usually for people working in the NHS, local authorities, and local and national organisations in the private and voluntary sectors.

1.2 *How we develop our guidelines*

The processes and methods we use to develop our guidelines are based on methods that are recognised worldwide. They are set out in [Developing NICE guidelines: the manual](#) (published in 2014) and summarised in section 2. The 2014 edition of the manual is the first that covers all NICE guidelines. Previously, guidelines were developed using 4 sets of processes and methods, which covered

clinical guidelines, public health guidance, medicines practice guidelines, and social care guidelines.

Principles for developing NICE guidelines

NICE guidelines are based on the best available evidence. Experts from the NHS, social care, local authorities and others in the public, private and voluntary sectors work with people who use health and care services, and representatives of communities affected by the guideline, to develop recommendations for good practice. The box below lists the principles that we follow.

Principles for developing NICE guidelines

- Guidance is based on the best available evidence of what works, and what it costs.
- Guidance is developed by independent and unbiased Committees of experts.
- All our Committees include at least 2 lay members (people with personal experience of using health or care services, or from a community affected by the guideline).
- Consultation allows organisations and individuals to comment on our recommendations.
- Once published, all NICE guidance is regularly checked, and updated in light of new evidence if necessary.
- We are committed to advancing equality of opportunity and ensuring that the social value judgements we make reflect the values of society.
- We ensure that our processes, methods and policies remain up-to-date.

1.3 *Equality and social value judgements*

NICE guidelines, and the processes we use to develop them, take account of ethical and moral issues. [Social value judgements: principles for the development of NICE guidance](#) explains how Committees developing the guidelines take these issues into account when making judgements and writing recommendations.

NICE has an obligation to promote equality and consider how its guidelines might affect groups with characteristics protected by the Equality Act (2010). These protected characteristics are age, disability, gender reassignment, pregnancy and

maternity, race, religion or belief, sex and sexual orientation. When developing guidelines, we also consider other equality issues, for example socioeconomic status, for groups such as looked-after children, people who are homeless, people who misuse drugs and people in prison.

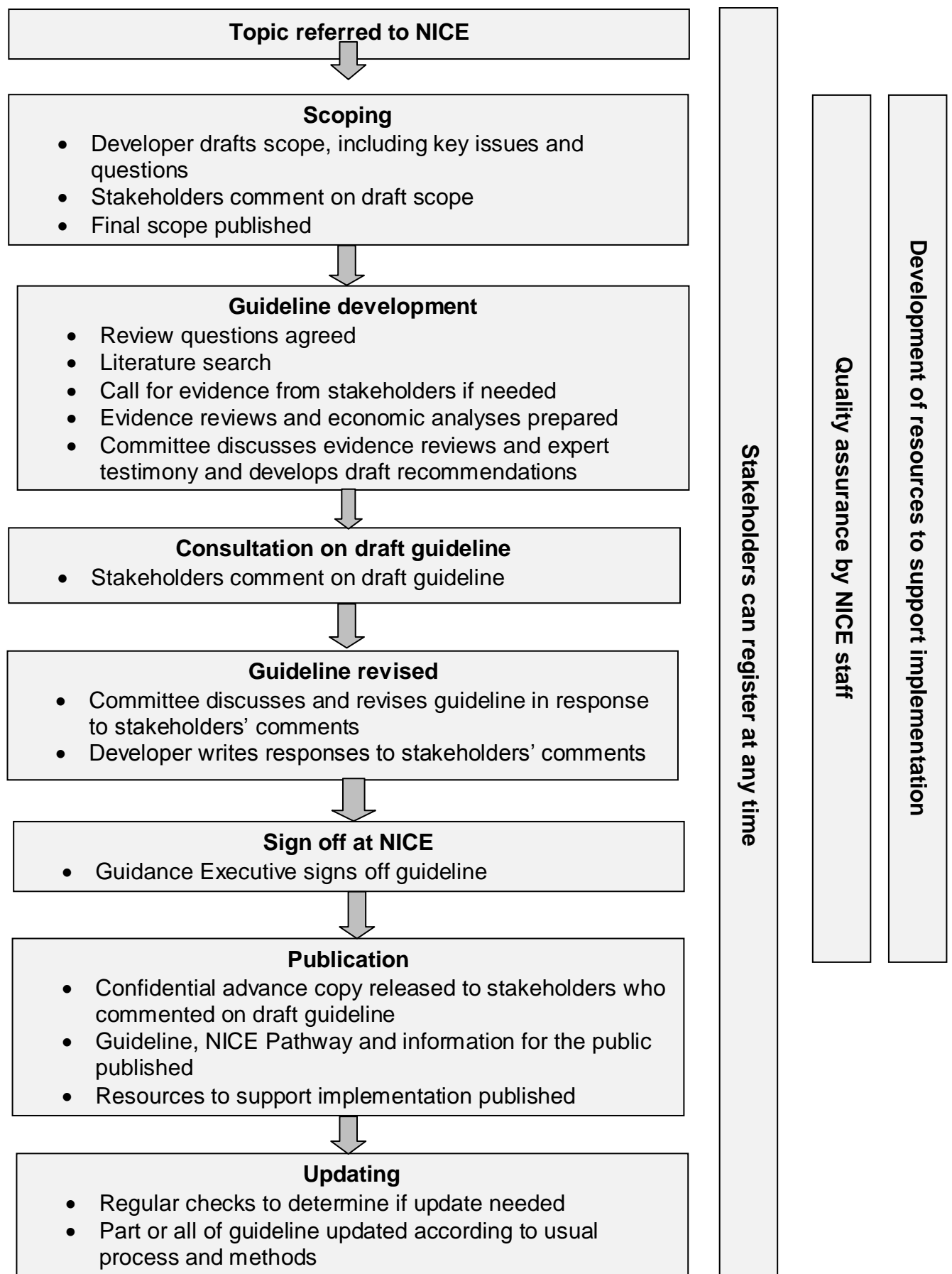
2 The guideline development process

NICE guidelines are developed by several groups working together:

- a Committee that makes the recommendations
- staff who undertake quality assurance (quality checking), based at NICE
- an evidence review team
- the Developer, a team that supports the Committee.

Some of these roles are carried out by contractors and some by NICE staff. Some Committees (topic-specific Committees) are formed to work on a single guideline. Others (standing Committees) work on more than one guideline. Exactly how the teams work depends on the topic and type of the guideline.

Figure 1.1 Stages of guideline development



3 How you can get involved

3.1 *How to register as a stakeholder*

To register an interest in a particular guideline, organisations should complete the [stakeholder registration form](#), on the NICE website.

If your 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, please contact NICE at nice@nice.org.uk.

There are different kinds of stakeholders:

- Public stakeholders: national patient, service user, carer and community organisations that represent the interests of people whose health or care is covered by the guideline, and local Healthwatch organisations.
- Professional stakeholders: national organisations that represent the people working in health and social care who provide the services described in the guideline.
- Commercial stakeholders: companies that manufacture medicines, devices, food or other products the use of which may be significantly affected by the guideline.
- Providers and commissioners of health and social care services in the UK.
- Government organisations including the Department of Health, NHS England, the Welsh Assembly Government, NHS Quality Improvement Scotland and the Care Quality Commission.

We encourage stakeholder organisations to register their interest in a particular topic as soon as we start work on it. However, organisations can register as stakeholders at any point during guideline development. The list of stakeholders registered for each guideline is kept up to date on the NICE website. Registered stakeholders are encouraged to tell NICE if other relevant organisations are not registered.

3.2 *How to get involved*

How stakeholder organisations can contribute:

- Encouraging people with relevant skills and experience to apply to join the Committee working on a guideline.
- Attending a workshop to discuss the [scope](#) of the guideline, if one is held.
- Providing evidence if the guideline Developer makes a ‘call for evidence’.
- Commenting on the draft scope and the draft guideline, including on equality issues.
- Helping NICE to promote our guidelines and put them into practice (implementation).
- Telling us about reasons a guideline might need updating earlier than planned and contributing to consultations on whether to update a guideline.

How members of the public and practitioners can contribute:

- Contributing comments on the draft scope and draft guideline as part of a stakeholder organisation, or representing the organisation at a workshop.
- Becoming a committee member, either as a practitioner or a member of the public with experience in the topic of the guideline (lay member – see ‘What do Committees do?’).
- Encouraging others to apply for Committee membership.

For some topics, there may also be the opportunity to:

- Give evidence to the Committee as an expert witness.
- Participate in a group discussion, interview or survey to help the Committee answer specific questions or to give feedback on draft recommendations.

3.3 *Scoping workshop*

If we need advice from stakeholders to develop a draft scope, we may invite registered stakeholders to a workshop to talk about the key issues. If a workshop is held, this usually happens before the draft scope goes out for public consultation. We usually invite each stakeholder to nominate 1 person to attend the workshop. This means that we can hear views from a wide range of organisations. The person

attending should be an expert in the guideline area. If your organisation represents people using services, carers, or a community affected by the guideline, the person attending should have a good understanding from the point of view of a patient, carer or community. If there are so many stakeholders that it isn't possible for them all to attend a workshop, for practical reasons we may ask stakeholders to nominate representatives from specific groups or roles (for example, specific types of specialist doctor).

Sometimes, virtual workshops such as webinars may be held instead of face-to-face workshops, if this meets the needs of the stakeholder groups (for example, for reasons related to disability).

The workshop is run by a senior member of NICE's quality assurance staff.

At the workshop NICE may ask participants:

- For feedback on selected key issues, including any important considerations for putting the guideline into practice.
- To identify issues such as government policy or areas of care where people don't always receive the best possible service.
- What should or shouldn't be included (for example, which groups of people should be included and where they receive their care or participate in an activity, and which interventions or services should be looked at).
- To consider existing NICE guidance and how the planned guideline relates to them.
- Who should be on the Committee in addition to lay members (see 'What do Committees do?') (for example, GPs, specialist doctors, people working in social care and public health, or from local government).
- To encourage suitable members of their organisations or people in their network to apply to be on the Committee.

After the workshop, we finish drafting the scope, and put it on our website for consultation. A summary of the discussions and the key points raised at the scoping workshop is posted on the NICE website with the draft scope.

3.4 Scope consultation

We put the draft scope on the NICE website for a 4-week public consultation, and email registered stakeholders to invite them to comment. Information and questions for stakeholders are posted with the draft scope, to find out what stakeholders think about specific issues. Consultation dates are given in advance on the NICE website and in our monthly newsletter.

How to comment on the draft scope

- Choose a contact to coordinate comments in your organisation.
- Circulate the draft in your organisation if appropriate, making clear that it is for consultation and asking people to respond to the contact (rather than directly to NICE).
- Combine the comments into 1 response from your organisation using the form provided (do not make changes to the draft scope itself) and include the name of your organisation and contact in your response.
- Submit the comments by the closing date for the consultation, sending them to the dedicated email address for the topic.

After consultation, the scope is finalised, taking into account the comments received and the original 'referral' from the Department of Health and/or NHS England.

All comments, the changes made as a result, and the responses from NICE to each comment, are recorded in a table. This is sent to stakeholders 5 working days before the final scope is published.

The final scope, the comments and responses, and the equality impact assessment (see below) are posted on the NICE website.

Raising equality issues during the draft scope consultation

NICE considers how to promote equality, and how its guidelines might affect groups with characteristics protected by the Equality Act, throughout the process of guideline development.

During development of the scope, NICE and the Developer consider any equality issues to decide whether:

- the planned guideline is likely to promote equality and prevent discrimination
- there are any concerns about equality that should be included in the scope.

The draft scope lists any groups or issues that need specific consideration – or states that no groups or issues need specific consideration. Stakeholders can raise equality issues during consultation on the scope.

3.5 *Calls for evidence*

The Developer may invite stakeholders to submit evidence if stakeholders may have useful evidence that will not be found by electronic searches. This might include information on how a condition affects people's lives, or how people or their carers feel about their care. The Developer may also invite other relevant organisations or individuals with an interest in the guideline topic to submit evidence. A call for evidence is sent directly to all registered stakeholders and posted on our website. We normally request a response in 2–4 weeks. Further detail on calls for evidence can be found in [‘Developing NICE guidelines: the manual’](#).

Confidential information

Confidential information should be used as little as possible when developing a guideline. Confidential information includes information that may affect share prices (this information is known as 'commercial in confidence') and information that is someone's intellectual property (this information is known as 'academic in confidence', because it has not been published yet). Organisations or individuals who submit evidence are asked to complete a checklist about any confidential information. Further detail on confidential information can be found in 'Developing NICE guidelines: the manual'.

3.6 *Joining a guideline Committee*

What do Committees do?

The Committee is the group that looks at the evidence and develops the recommendations, taking into account the views of stakeholders. It is made up of specialists in the topic, people working in health and social care more generally (such as GPs), commissioners, and at least 2 lay members. Lay members are people using health and care services and/or carers or advocates, and people from

communities affected by the guideline (for example, if a guideline is aimed at a particular ethnic or social group). The Committee can invite expert witnesses to attend a meeting if needed, or bring in new Committee members who are specialists in areas covered by some of the recommendations.

There are 2 types of Committee:

- Standing Committees develop more than 1 guideline with the same Chair and core members. They also recruit topic experts to join the Committee for the development of a particular guideline.
- Topic-specific Committees are recruited to develop a single guideline. The Committee includes people able to consider all the different viewpoints of the topic they are working on (for example, the viewpoints of people using services and the viewpoints of specialists working in this area).

Committee members use their expertise to develop recommendations in the areas covered by the scope.

Manufacturers of pharmaceutical products or medical devices are not represented on the Committee if their drug or device is of direct relevance to the topic, because they could have a conflict of interest. However, they are able to register as stakeholders. If a guideline is likely to cover general areas relevant to the pharmaceutical or medical device industries the Committee may include members of industry bodies to make sure that these industries are represented.

Applying to join a Committee

Committee members and Chairs are usually recruited according to the procedure in NICE's policy on [Committee recruitment](#). NICE works to make sure that the recruitment process is open, with positions advertised on the NICE website and other appropriate places, and relevant stakeholders notified. Stakeholders are also invited to send the advert to their members and networks, and encourage suitable candidates to apply.

When selecting committee members, the following is taken into account:

- The Committee needs to include people with the greatest possible range of skills and experience.
- Committee members are recruited for their individual experience and do not represent their organisations or professional groups.

Details of the different roles in each Committee can be found in the manual.

The Developer provides an induction, training and support to all members of the Committee.

Training and support for members of the public to work with NICE

The Public Involvement Programme (PIP) is a team at NICE that supports public involvement in NICE's work. The PIP:

- finds ways for the public to be involved in NICE's work
- provides support on getting the public involved to NICE's internal teams, and the Developer
- works with organisations representing service user, carer and community interests to help them get involved in the development of NICE guidelines
- provides information, training and support to people who are interested in or contribute to NICE's work
- contributes to the information for the public about NICE guidelines
- advises the Developer on service user and public issues relevant to the development of the guideline
- assesses the level and impact of the involvement of people using services, carers and the public in NICE's work.

If you are a member of the public or work for a voluntary or community organisation and would like to be involved in guideline development, contact the PIP at pip@nice.org.uk.

If you work in healthcare, public health or social care, or are a potential stakeholder organisation, email our general enquiry address at nice@nice.org.uk.

3.7 *Draft guideline consultation*

Consultation with registered stakeholders is a crucial part of developing a guideline. Comments from stakeholders help us make sure the guideline is accurate, relevant to people who will be using it, and of a high standard.

What happens during consultation?

The draft version of the guideline is put on our website for consultation with registered stakeholders. We tell registered stakeholders that the draft is available for commenting, outlining consultation dates and how to submit comments. Questions for stakeholders are posted with the draft guideline. The purpose of these questions is to get stakeholders' views on important issues, such as how easy it will be for people to follow the recommendations. Consultation usually lasts for 6 weeks. A 4-week consultation may be used for small guidelines or guideline updates.

All comments from your organisation should be combined into 1 response. If your organisation and another registered stakeholder have similar views on the guideline, we encourage you to send a joint response.

The Developer will acknowledge each comment and answer it as completely as possible. The Committee considers whether changes to the guideline are needed because of consultation comments. If changes are made, this is made clear in the response to the comment. If no changes are made, the response to the comment explains why not.

The Committee considers comments from organisations that are not registered stakeholders and individuals when revising the guideline but does not respond to them or publish them on the website.

Fieldwork with people working in health or social care

When a draft guideline on a new, complicated or sensitive topic is issued for consultation the Developer may decide to field test the guideline with people providing services, people working in health or social care, or organisations that commission services.

The Developer asks how easy it will be to follow the draft recommendations, and how the recommendations might work. Fieldwork with people working in health and social care usually takes place during consultation. For details see [Developing NICE guidelines: the manual](#) appendix H.

Additional work with people using services

The Developer may arrange additional work with people affected by the guideline to find out how relevant and acceptable the guideline is to them. Additional work with people using services can also be done earlier in the process. For example, people using services may be invited to participate in a group discussion, interview or survey to help the Committee answer specific questions, or to give feedback on selected early draft recommendations. For details, see '[Developing NICE guidelines: the manual](#)' appendix B.

How stakeholders can get involved in the equality impact assessment during the guideline consultation

When finalising a guideline, NICE and the Developer consider any concerns about equality raised during the development of the guideline and record how these have been addressed.

Stakeholders are able to raise additional concerns about equality during guideline consultation, and these may be included in the final equality impact assessment after consultation. The final assessment is published on the NICE website with the final guideline.

3.8 *Publication and putting guidelines into practice*

When a guideline is published, we email all registered stakeholders to let them know. Either when the guideline is published or soon afterwards we publish tools that help stakeholder and other organisations put the guideline into practice. The Developer and Committee members work with NICE's communications and implementation teams to promote the guideline when it is published and afterwards.

NICE may work with registered stakeholders and others to promote the guideline and support implementation.

3.9 *Checking the need to update guidelines*

Guidelines are checked regularly to see if they need updating. If checks at 4 or 8 years after publication (or at any 4-year check after that) indicate that the guideline should not be updated, we hold a 2-week consultation with stakeholders about this.

We also consult stakeholders when we propose:

- withdrawing a guideline
- placing it on the static list – guidelines are placed on the static list if the evidence they are based on is unlikely to change, and are then checked every 5 years.

(See section 13.3 of '[Developing NICE guidelines: the manual](#)' for more details about checking for updates).

Stakeholders and members of the public should let NICE know at any time, if they:

- are aware of new evidence that would change the recommendations in the guideline
- are aware of a relevant new technology (for example, new medicines or medical devices) or if certain medicines or medical procedures are no longer used
- have concerns about the safety of some of the recommendations
- notice errors (such as misunderstood evidence or incorrect calculations) after the guideline is published.

About this guide

This guide gives an overview for stake holders and the public of the process and methods used to develop NICE guidelines on health and social care. Full details of the process and methods are set out in [Developing NICE guidelines: the manual](#).

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