NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Developing NICE guidelines: the manual

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2 The scope

The scope sets out what a NICE guideline or topic suite will and will not cover. Preparing the scope is the first step in developing a guideline. The scope is used to create a framework for the development work (see the chapters on developing review questions and planning the evidence review, identifying the evidence: literature searching and evidence submission, reviewing evidence, and incorporating economic evaluation).

2.1 Purpose of the scope

The scope of a guideline sets boundaries that ensure the work stays within the referral and the resulting guideline can support any relevant quality standard (see the section on choice of guideline topics in the introduction chapter). The scope for each guideline:

- defines the population(s) and setting(s) that will and will not be covered
- describes what the guideline will and will not consider
- identifies the key issues that will be considered and lists the draft questions
- describes the economic perspective(s) to be used
- identifies potential equality and health inequality issues among groups sharing protected characteristics and how these will be considered.

Occasionally, it may be necessary when preparing the scope to seek clarification on the referral (for example, to clarify how the NICE guideline will add value in relation to existing non-NICE guidance or to specify the boundaries and the extent of the

work) from the commissioning body (see the section on choice of guideline topics in the introduction chapter).

When a guideline is being partially updated or replaced, the existing guideline scope will be updated to include:

- the sections that will be updated
- any changes from the previous guideline scope.

A separate scope or hub page for a topic suite identifies:

- what is covered by the topic suite
- the guidelines included in the topic suite
- the areas being actively monitored
- the areas being updated.

2.2 Who is involved in developing the scope

The draft scope is prepared by the development team

. Topic-specific expertise may be provided by members of the committee. Independent quality assurance is done throughout the scoping process by staff with responsibility for quality assurance.

When several related guidelines or guidelines within a topic suite are being developed simultaneously, cross-representation of expertise on each scoping group may also be considered.

The draft scope is signed off by a senior member of staff with responsibility for quality assurance.

2.3 Scope development process

The scope is developed in stages. Stages 1 to 6 apply to new guidelines and stage 7 is for updates to the guideline:

- stage 1: the scoping search
- stage 2: identifying the population, settings and key issues
- stage 3: identifying and making decisions on overlaps with other NICE guidance

- stage 4: checking the population and selected key issues with stakeholders
- stage 5: consulting on the draft scope
- stage 6: finalising the scope
- stage 7: updates to the guideline

Stage 1: the scoping search

To support scope development a scoping search is done (see the chapter on identifying the evidence: literature searching and evidence submission). The search should not aim to be exhaustive. It should be based on the need to inform the development of the draft scope and the issues to be discussed at a scoping workshop (if held) [see stage 4: checking the population and selected key issues with stakeholders].

Stage 2: identifying the population, settings and key issues

Stage 2 includes identifying the population, settings and considering the key issues for inclusion in the scope. These may have emerged during preliminary work, or may be identified by the scoping search, by considering any health inequalities and impacts on equality, or by consulting experts.

Guidelines do not usually include key issues that are covered by other arms-length or government bodies such as the Department of Health and Social Care, NHS England or Public Health England. They do not usually cover training requirements, because these are the responsibility of the Royal Colleges and professional associations, but they may make recommendations on the need for specific knowledge and skills for a particular aspect of care.

Equality and equity issues at the scoping stage

During development of the scope, it is important to consider and assess any health inequalities and health inequities to establish:

- whether there is any risk of unlawful discrimination arising from the guideline
- whether the guideline offers any opportunities for advancing equality or reducing inequalities and health inequalities

- whether there might need to be reasonable adjustments to a recommendation to avoid putting any group of people covered by the scope at a substantial disadvantage
- whether, and to what extent, particular equality issues should be included in the scope.

Stage 3: identifying and making decisions on overlaps with other NICE guidance

Identifying related NICE guidance (both published and in development) is a key element of scoping. This helps to see where and how the guideline recommendations are likely to relate to existing recommendations in other guidance.

This process should aim to identify any gaps where new recommendations would be of value, and areas where recommendations already exist (see the chapter on linking to other guidance).

Stage 4: checking the population and selected key issues with stakeholders

NICE values the views of stakeholders on whether the population group(s) and key issues identified are relevant and appropriate. Stakeholders include organisations led by people using services, and organisations that represent the interests of people with the condition or people using services and their family members or carers, or the public.

For some guidelines, registered stakeholders (see the section on who is involved in the introduction chapter) may be invited to a scoping workshop to talk about the key issues in the scope, and discuss any other aspects as needed. A workshop may be held if the referral is in a new area, there is a new audience for NICE guidelines, or a guideline topic or an area of practice has unique complexities. Following discussions with the development team, staff with responsibility for quality assurance decide whether, and when, to hold a scoping workshop, and document the reasons for the decision.

If a scoping workshop has been held, the development team (with input from other teams) considers the issues raised and refines the scope after the workshop.

Equality and health inequalities assessment

Before the draft scope is signed off for consultation, an equality and health inequalities assessment is completed by the development team and the committee chair to show which equality issues have been identified and considered during scoping, and to provide assurance that risks of adverse impacts on equality of any exclusions from the scope have been assessed and can be justified. The equality and health inequalities assessment is signed off by a member of staff with responsibly for quality assurance, and published on the NICE website with the draft scope. The assessment is updated by the development team and the committee chair after the scope consultation.

Stage 5: consulting on the draft scope

For new guidelines or for updates where consultation is required, the draft scope is signed off for consultation by a senior member of staff with responsibility for quality assurance. It is posted on the NICE website for a 2- to 4-week consultation, and registered stakeholders are notified. Information and prompts to support stakeholder input are posted with the draft scope. The purpose of these prompts is to seek their views on key issues (such as whether the identified outcome measures are in line with what matters to people with the condition or people using services) and to ask what should be included or excluded. We ask stakeholders to suggest areas where cost savings could be achieved.

Comments are invited from registered stakeholders. In particular circumstances, comments will also be requested from the relevant regulatory organisation; for example, the Medicines and Healthcare products Regulatory Agency (MHRA) when the off-label use of medicines is likely to be considered within the guideline or when advice is required on regulations related to medicines.

Registered stakeholders comment on the draft scope (and later on the draft guideline; see the section on what happens during consultation in the chapter on the validation process for draft guidelines, and dealing with stakeholder comments). Comments should be constructed as reasoned arguments and be submitted for the purpose of improving the draft scope. We reserve the right not to respond to comments that are hostile or inappropriate.

Tobacco companies and those who speak for them or are funded by them (collectively referred to as 'tobacco organisations') cannot register as stakeholders. Tobacco organisations are simply referred to as 'respondents'. Any comments received during consultation from respondents are reviewed for factual inaccuracy claims and are made public along with any responses.

The development team, staff responsible for quality assurance and public involvement programme (see the section on who is involved in the introduction chapter) routinely review the list of registered stakeholders to check whether any key organisations are missing. Registered stakeholders are also encouraged to identify potential stakeholders who are not registered. When the guideline covers social care, the team with responsibility for social care should be asked about appropriate stakeholders.

Stage 6: finalising the scope after consultation

Dealing with stakeholder comments

After consultation, the development team finalises the scope based on the comments received ensuring that the scope stays in line with the referral for the guideline.

Sometimes registered stakeholders ask for the scope of a guideline to be broadened. If the development team considers that a request to expand the scope would mean the guideline could not be completed on schedule, this should be discussed with staff with responsibility for quality assurance. Sometimes lower-priority areas are removed from the scope to keep the development work manageable. This is done in collaboration with the lead for any related quality standards. Suggestions that are clearly outside the original referral should not be included.

All comments from registered stakeholders, and the actions taken by the development team in response to each comment, are clearly documented by the development team in a 'scope consultation table'. The process for responding to comments from registered stakeholders should follow the principles described in the section on principles of responding to stakeholder comments in the chapter on the

validation process for draft guidelines, and dealing with stakeholder comments. Comments received from unregistered stakeholders and individuals are reviewed by the development team and staff with responsibly for quality assurance. We do not formally respond to these comments and do not publish them.

We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

Signing off the final scope

The final scope is signed off by a senior member of staff with responsibility for quality assurance. Once the final scope has been published no changes should be made to it unless the guideline is being updated or there are exceptional circumstances (see the section on amending the final scope after publication on the NICE website).

The final scope, the scope consultation table with comments from registered stakeholders and responses to these comments, and the equality and health inequalities assessment are published on the NICE website.

Stage 7: updates to the guideline

When we identify that recommendations need updating, the guideline scope is updated to reflect this. It lists:

- the sections that will be updated and
- any changes from the current guideline.

Small updates to the guideline scope are not usually subject to consultation with stakeholders. For larger updates, or where areas are added to the guideline, consultation with stakeholders may take place. The decision to consult with stakeholders is made by staff with responsibility for quality assurance. For all updates, the scope is published on the NICE website and stakeholders are informed.

2.4 Amending the final scope after publication on the NICE website

There can be exceptional circumstances when the final scope may need amending after it has been signed off and published on the NICE website. For example,

amendments may be needed in the light of policy changes, the withdrawal of a medicine, or inclusion of a NICE technology appraisal in development (see the section on related NICE technology appraisal guidance in the chapter on linking to other guidance). The decision on whether to amend the scope is made by a senior member of staff with responsibility for quality assurance, based on advice from the committee or development team as appropriate.

If a final scope is amended after publication, registered stakeholders are informed and the revised scope is published on the NICE website. No further consultation on the scope would usually be done.

2.5 References and further reading

Kelly MP, Stewart E, Morgan A et al. (2009) A conceptual framework for public health: NICE's emerging approach. Public Health 123: e14–20

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