NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Accreditation assessment framework and advice for guidance development

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NICE National Institute for Health and Care Excellence

NICE accreditation support

Assessment framework and advice for guidance development

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Introduction

The aim of NICE accreditation is to help users identify trusted sources of guidance that have been developed using critically evaluated high quality processes. This will drive up the quality of information produced for health and social care decision makers and used in quality standards, and should result in improved outcomes for patients and service users.

For the purposes of the NICE accreditation process, guidance is defined as: **'systematically developed statements to guide decisions about appropriate health and social care to improve individual and population health and wellbeing'.** This definition covers any recommendations that are based on a systematic distillation of the evidence, including:

- clinical guidance
- social care guidance
- public health guidance
- referral guidance
- clinical decision support content
- healthcare technology guidance
- policy guidance
- clinical summaries
- commissioning guidance
- medicines information guidance
- safety guidance.

The potential benefits of guidance are only as good as the quality of the guidance itself. It is important for recommendations to be underpinned by systematic methodology and rigorous strategies, but the processes used to develop guidance vary widely.

The aim of this document is to help organisations improve their guidance development process. It is targeted at organisations who:

- have been accredited but have suggested improvements to make
- are applying for accreditation for the first time
- are reapplying for accreditation.

It is not intended to be an accreditation evaluation but instead provides a framework to:

- describe how NICE assesses the quality of guidance development processes in its accreditation programme
- provide a methodological strategy to develop guidance

- explain what information should be documented during guidance development and how it should be presented.

A key principle of accreditation is that the process used to develop guidance is fit for purpose. The scope of this document is purposely broad so that producers of different types of guidance can adapt the process to meet their purpose. It is structured around the 6 domains containing 25 accreditation criteria. These criteria are based on the AGREE[1] instrument and summarise the questions the analyst should discuss as part of their analysis. They are generic and can be applied to any health and social care setting. Not every criteria will be relevant but guidance producers will need to describe how their processes meet the criteria relevant to them.

A number of examples have been described in this document and suggestions provided for what should be included in guidance. These are not intended to be prescriptive, but should be included if they align with the overall objective and purpose of the guidance product. Similarly, analyst questions are provided that are appropriate for many, but not all, types of guidance.

[1] The AGREE Collaboration. Brouwers M, Kho ME, Browman GP et al. for the AGREE Next Steps Consortium (2010) AGREE II: Advancing guideline development, reporting and evaluation in healthcare. Canadian Medical Association Journal. doi:10.1503/cmaj.090449

Domain 1: Scope and purpose

Domain	Criteria
1. Scope and purpose is concerned with the overall aim of the guidance, the specific health questions and the target population.	These criteria consider whether the guidance producer has a policy in place and adhered to that requires them to explicitly detail: 1.1 The overall objective of the guidance 1.2 The clinical, healthcare or social questions covered by the guidance 1.3 The population and/or target audience to whom the guidance applies 1.4 That the producer ensures guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances

1.1 The overall objective of the guidance

NICE interpretation

The overall objective of the guidance should be described. The process should describe how this overall objective was reached. For example, if the aim of the guidance is decided in a scoping session this should be stated. The objective should be clearly identifiable from the guidance documents.

What should be included and where

The objective is often seen in the opening paragraphs or chapters of the scope and purpose of the guidance. For web-based guidelines it may be on an organisation's website. In some cases, the rationale or need for the guidance is described in a separate document from the guidance, for instance in the guidance proposal. Guidance sections or chapters where this information can be found include: introduction, scope, purpose, rationale, background, and objectives.

For concise guidance outputs, the overall aim may be explained in the heading of the guidance. There may be a single overall aim for all of the guidance produced through that process. Commissioning guidance may include quality outcomes, patient or service user experience and deliverables expected. For medicines information this may be specific to a particular drug or drug class, or be wider in the case of a formulary. Policy guidance may be specific to a training standard, population or a set of methods to follow.

Analyst questions

- Does the guidance specifically state its aims or are they implicit in the guidance?
- Is there a full description of how the objective was reached and by whom, for example by a topic selection panel?
- Does the process describe how the topic selection and scoping is done and explain how this will appear in the guidance?
- Is the aim of the guidance clear – for example, prevention, screening, diagnosis or treatment?
- Is it clear what the expected benefit or outcome is?
- Is there a template or style guide that requires the objectives to be stated?

1.2 The clinical, healthcare or social questions covered by the guidance

NICE interpretation

The guidance should include a detailed description of the questions considered during development, although they may not always be phrased as questions.

The process should describe how questions are formulated, at what stage this happens and by whom this is performed. In most cases these questions should be identifiable in the guidance products. These questions may be reached at the scoping phase.

What should be included and where

A detailed description of the key questions answered in the guidance is needed, particularly for the key recommendations. For example, it should be documented how topic selection and scoping takes into account equality issues (for example by identifying issues related to race, disability, sex, gender or age in defining the population and target audience, and by promoting equality in guidance). Guidance sections or chapters where this information can be found include: introduction, scope, purpose, rationale, background, section headings and objectives.

Commissioning guidance may include quality outcomes, patient or service user experience and deliverables. There may be a more general question about the efficacy of a medicine or group of medicines for medicines information guidance. In policy guidance the questions may be specific to a training standard or a set of methods to follow and safety guidance should describe the specific safety questions.

Analyst questions

- Does the process describe how these questions should be presented in the guidance examples?
- Are the questions evident in the guidance?
- Has a full description been included on how these questions or issues were reached?
- Has a tool been used to formulate the questions, for example, PICO (population, intervention, comparator and outcome) framework?
- Do the questions specify the user groups covered, the healthcare setting or context, interventions, outcomes and possible exclusion criteria?

1.3. The population and/or target audience to whom the guidance applies

NICE interpretation

The process should describe how the guidance will document who the guidance is aimed at (the target audience) and the population covered by the guidance. Both of these may be broad – for example all health and social care professionals or all people with diabetes – or more specific. The age range, gender, clinical or social care description, and comorbidity of the target population may be specified.

What should be included and where

The population and target audience should be documented as above. If there are any exclusions to the population (for example, children) they should be stated. It may be appropriate to detail the target audience and population in separate sections. Guidance sections or chapters where this information may be found include: patient or service user population, target population, relevant patients or service users, scope, and purpose.

For social care guidance, this criterion should show the range of populations covered by the guidance and the full range of audiences the guidance is written for, with reference to any social comorbidities.

Analyst questions

- Who is the target audience for the guidance?
- Are there sections in the guidance that target a specific audience?
- What population does the guidance cover?
- What population does each specific question cover and, if different, is this obvious from the guidance?
- Is the population information specific enough so that the correct people would receive the action recommended in the guidance?
- How are the specific target audience and patient or service user populations covered by the guidance defined?
- Does the guidance include, when relevant, information on target population gender and age, clinical condition, severity or stage of disease, comorbidities and excluded populations?

1.4 That the producer ensures guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances

NICE interpretation

The process should explain how it ensures that recommendations are specific to the right target population in the right circumstances so that they can be implemented. If an explicit link is needed between the recommendations and the evidence, this should be stated in the process. Users should be able to identify which components of the evidence are relevant to each recommendation.

What should be included and where

When a recommendation is targeted at a specific group of people for a particular procedure, is this clear in the recommendation? An example would be an intervention for a specific patient group defined by age, disease severity or comorbidities. An explicit link could be provided between the recommendations and the evidence base using a footnote, reference or hyperlink in the recommendation. The user can choose to follow this link to see which pieces of evidence led to each recommendation.

In adapted guidelines it is important to ensure that during translation of recommendations the meaning is not lost or changed. Specific recommendations should not be made more generic. Guidance sections or chapters where this information can be found include: recommendations and key evidence.

Analyst questions

- Does the process ensure that recommendations can be implemented for the right target population in the right circumstances?
- Do all recommendations clearly describe the specific circumstances in which they are to be used?
- Can recommendations be traced back to the evidence base specific to each recommendation?
- In adapted guidelines or clinical summaries, is it clear that the meaning of the original recommendation has not been amended or lost and there is a link to the primary guidance?

Domain 2: Stakeholder involvement

Domain	Criteria
2. Stakeholder involvement focuses on the extent to which the guidance represents the views of its intended users and those affected by the guidance (patients and service users).	These criteria consider whether the guidance producer has a policy in place and adhered to that means it includes: 2.1 Individuals from all relevant stakeholder groups including patients groups in developing guidance 2.2 Patient and service user representatives and seeks patients views and preferences in developing guidance 2.3 Representative intended users in developing guidance

2.1 Individuals from all relevant stakeholder groups including patients groups in developing guidance

NICE interpretation

Professionals, patient representatives and patient or service user groups should all be involved in guidance development. They should be included in the steering group, the research team that selects and reviews or rates the evidence and the group that formulates the recommendations. Where relevant, information about the background and expertise of the stakeholders should be provided.

What should be included and where

The composition of the guidance development group may be found in the opening paragraphs or chapters, the acknowledgement section or appendices. Guidance sections or chapters where this information can be found include: methods, guidance panel member list, acknowledgements, and appendices.

For example, the process might explain that the guidance development group should always contain a clinician and pharmacists. This can then be verified in the guidance examples. For social care guidance, charity stakeholders, community and local authority representatives may be part of the stakeholder group.

Commissioning guidance should be multidisciplinary, with clear input from a range of stakeholders.

Analyst questions

- Does the process have information about the composition of any groups involved with the development of the guidance?
- Does the process require relevant groups to be included in the guidance development process?
- Is there a clear process or policy describing how professionals and lay members are recruited?
- Is the process clear on how different groups are involved and how to ensure informed participation from each group?
- Are group members an appropriate match for the topic and scope? Potential candidates could include clinicians from relevant disciplines, social care or public health experts, researchers, policy makers, clinical administrators, and commissioners. A methodology expert may also be included (for example, a systematic review expert, epidemiologist, statistician or library scientist).

- Has it been considered how to involve representatives for children and young people, if appropriate?
- If guidance producers have been unable to include relevant stakeholders and patients, is there a clear rationale for why?
- Is there transparency in the guidance or supporting documentation of the members of the development group and their roles and affiliations?
- Is information given for each participant in the group, including:
  - name
  - expertise (for example, neurosurgeon, methodologist, patient representative)
  - institution or affiliation
  - description of their role in the guidance development group

2.2 Patient and service user representatives and seeks patient views and preferences in developing guidance

NICE interpretation

The process should state how patient and service users' views are considered in guidance development. Ideally this criterion would be met by including patients and service users in the scoping phase, in guidance development groups, during evidence review and consultation. If part of the evidence base is published guidance, the patient or service user involvement in the development of the primary guidance should be ascertained.

Guidance should be informed by both the experiences and expectations of healthcare of patients and service users. Alternatively, information could be obtained from interviews with these stakeholders or from literature reviews of patient and public values, preferences or experiences. There should be evidence that a process has been followed and that these stakeholder views have been considered.

The Guidelines International Network (G-I-N) Patient and Public Involvement Working Group has developed a toolkit (updated in 2015) to facilitate public involvement in guidance development. Topics covered by the toolkit include conducting public and targeted consultation, recruiting and supporting public members and developing lay versions of guidance.

What should be included and where

There are various methods for ensuring that patient and service user perspectives inform different stages of guidance development. These could include formal consultation with patients and the public to determine priority topics, participation in the guidance development group, or by external review of draft documents. Feedback from patients and service users on published guidance should be used to inform updates and amendments to that guidance wherever possible. A clear description of the patient or service user representatives' role should be included in the development process.

Commissioning guidance could provide recommendations on how to involve patients and the public to ensure that services will be suited to the local population.

Guidance sections or chapters where this information can be found include: scope, methods, guidance panel member list, external review, and target population perspectives. It is also often found in sections covering the guidance development process.

Analyst questions

- Are patients and service users, or organisations that represent these groups, involved throughout guidance development (including scoping, reviewing, developing recommendations and consultation), and is their role in ther process clearly defined?
- What support is provided for public representatives involved in guidance development to ensure they have equal participation?
- Has more than 1 patient representative been included to ensure equal patient representation at each stage of development?
- Which groups involved in guidance development contain public representation?
- Is the process of feedback and consideration of patient and service user views adequately described in the process? How is this feedback used to inform guidance development?
- Does the policy about gathering patient and service users' views specify including:
  - who is involved, for example members of the public with direct experience of the condition or aspects of care, patient or service user organisations, or other members of the public
  - why those particular groups or individuals are involved
  - what support is provided for them
  - at what stage(s) in the guidance development process are they involved
  - how their views are taken into account
- If part of the evidence base is published guidance, is there a stated process to ascertain patient or service user involvement in the development of the primary guidance?
- Are the strategies used to capture patient and service user views and preferences described clearly in the process and the guidance?
- Does the guidance reflect the views and preferences that were identified?
- Is there a description of how this information was used to inform guidance development or formation of the recommendations?

2.3 Representative intended users in developing guidance

NICE interpretation

The process should state how intended users of the guidance are involved in its development and provide evidence of this. If the guidance is defined as being for a diverse audience, the varied composition of the audience should be demonstrated.

What should be included and where

The opening paragraphs or chapters of the guidance may contain a description of the target users of the guidance and their role in guidance development. For example, the target users of guidance on low back pain may include GPs, neurologists, orthopaedic surgeons, rheumatologists, and physiotherapists. It should be documented why and how they were involved in developing the guidance, for example in scoping, reviewing or piloting guidance. Representatives of service providers and other agencies should be clearly visible in the development process for commissioning guidance.

Analyst questions

- Is there a clear description of the intended audience of the guidance and how they may use the guidance?
- Is there evidence for how and when the intended audience or specific users are involved in guidance development?
- Is there an explanation of how intended users are represented in guidance development (for example, specifying that a pharmacist should always be included at the peer review stage)?
- Is there a process for pretesting guidance among intended users?
- Does the guidance clearly state how users were involved in its development?
- Is there evidence of topic experts being involved in development if they are indicated as part of the process?
- If there is only limited user representation has the reasoning for this been explained (for example, it could be a specialised topic area)?

Domain 3: Rigour of development

Domain	Criteria
3. Rigour of development relates to the process used to gather and synthesise information and the methods used to formulate recommendations and update them.	These criteria consider whether the guidance producer has a clear policy in place and adhered to that: 3.1 Requires the guidance producer to use systematic methods to search for evidence and provide details of the search strategy 3.2 Requires the guidance producers to state the criteria and reasons for inclusion or exclusion of evidence identified by the evidence review 3.3 Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty 3.4 Describes the method used to arrive at recommendations (for example, a voting system or formal consensus techniques like Delphi consensus) 3.5 Requires the guidance producers to consider the health benefits, side effects and risks in formulating recommendation 3.6 Describes the processes of external peer review 3.7 Describes the process of updating guidance and maintaining and improving guidance quality

3.1 Requires the guidance producer to use systematic methods to search for evidence and provide details of the search strategy

NICE interpretation

The process should describe the methods used to search for evidence or information relevant to the guidance in development. If databases or hand searching are used, it should explain when in the development process this is done and why. The search strategy should be tied to the scope. The information on the search strategy and methods used may be noted in the process, the guidance or both.

What should be included and where

The type of evidence may vary but the key principle is to use a systematic approach. The process should state the general method, which might specify which databases (for example, MEDLINE, EMBASE, CINAHL) will be searched in every case. Sources of evidence can be wide and could include electronic databases, databases of systematic reviews (for example, the Cochrane Library, DARE), hand searching journals, reviewing conference proceedings, and others. It may also be appropriate to use best practice or consensus expert opinion.

In some cases the search strategies are described in separate documents or in an appendix to the guidance. Guidance sections or chapters where this information can be found include: methods, literature search strategy, and appendices.

Analyst questions

- Does the process describe a robust and systematic approach to identifying evidence?
- Is the search relevant and appropriate to answer the clinical, health or social care questions in the guidance?
- Does the process ensure that the search strategy is comprehensive, free from potential biases and sufficiently detailed to be replicated?
- Is there a process for identifying pre-produced systematic reviews, for example Cochrane reviews?
- Where searches are performed outside of routine systematic searches, is there a described process and is the reasoning explained in the search strategy (for example, some disciplines lack a rigorous controlled evidence base)?

- Is the search strategy transparent and publicly available? Is it described in the guidance, the appendices or on the guidance producer’s website?
- Does it include named electronic databases or evidence sources when a literature search was performed (for example, MEDLINE, EMBASE, PsychINFO, CINAHL)?
- Does the search strategy include the time periods searched and the date the search was performed?
- Is it clear which search terms have been used?
- Has an example search been included with the application?

3.2 Requires the guidance producers to state the criteria and reasons for inclusion or exclusion of evidence identified by the evidence review

NICE interpretation

The process should involve stating the criteria for including or excluding evidence identified by the search. Both the criteria and the reasons for it should be described. Some exclusion criteria may be defined as part of the evidence searches. For example, the guidance producer may decide only to include evidence from randomised clinical trials and to exclude articles not written in English.

What should be included and where

Instructions on how to state the criteria may be in the section describing the guidance development process, in an appendix or in separate documents. Criteria may be based on characteristics of the target population (patients, service users or the public), study design, comparisons (if relevant), outcomes, language or context.

There may be more than 1 point for inclusion and exclusion. Exclusions may be specified during the evidence search – for example, only English language studies were used. If a piece of evidence is excluded after being identified by the evidence search the reason should be explained (for example, it might not be relevant).

Guidance sections or chapters where this information can be found include: methods, literature search, inclusion and exclusion criteria, and appendices.

Analyst questions

- Does the process ensure the guidance describes when and why specific exclusions and inclusions are used and where these criteria can be found?
- Is the reasoning behind the inclusions and exclusions clear?
- Are the inclusion and exclusion criteria relevant and appropriate to the guidance in development? Do they align with the health, clinical, social care or safety questions?
- If the guidance uses primary guidance, are the selection criteria appropriate and clearly stated?
- Does the process require the inclusion and exclusion criteria to be stated in the guidance or supporting documents?

3.3 Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty

NICE interpretation

The process should describe how to systematically assess the strengths and limitations of the evidence base. This may be through the use of a grading system or critical appraisal tool. The outcome should demonstrate which evidence is the strongest and this should follow through into the recommendations. Conversely where the evidence is limited this should also be made clear.

What should be included and where

Details should be included of how the methodological quality of the studies (for example, risk of bias) is critically appraised. Some guidance makes a clear distinction between description and interpretation of evidence, for instance by having separate results and discussion sections. Statements highlighting the strengths and limitations of the evidence can include explicit descriptions of the risk of bias for individual studies, specific outcomes or across all studies.

Assessment of the quality of evidence in social care guidance may use critical appraisal tools that are more appropriate for qualitative evidence.

Statements may be presented in different ways, for example using tables commenting on different quality domains; by applying a formal instrument or strategy (for example, Jadad scale, GRADE method, Drummond checklist for studies involving economic evaluations); or descriptions in the text.

Aspects on which to frame descriptions could include:

- study design
- study methodology limitations (sampling, blinding, allocation concealment, analytical methods)
- appropriateness or relevance of primary and secondary outcomes considered
- consistency of results across studies
- direction of results across studies
- magnitude of benefit versus magnitude of harm
- applicability to practice context.

Analyst questions

- Is the process for determining strengths and limitations of the evidence transparent to users?

- Does the process require the use of an assessment tool or other form of critical appraisal tool? If so, is this fit for purpose and the choice of method explained?
- Does the process give examples of appropriate tools to use and state how the assessment should be presented in the guidance or supplementary documents?
- Are the different grades showing the evidence strength described in full? Are the descriptions appropriate, objective and unbiased?
- All interpretations should be systematically applied. If a weaker evidence base has been used is it clear why this was chosen?
- Does the guidance describe the grading system used or give a narrative description of the evidence?
- Is there a description of how the evidence was evaluated for bias and how it was interpreted, either in the guidance or supporting information?
- Are the strengths and weaknesses of the evidence clear to users from the guidance?
- Is there an explanation of the grading system used or signposted to, for example in a table in the guidance?
- If primary guidance is used in development of recommendations, is there an appraisal system described in the process and guidance?
- If different authors assess the strengths and limitations of studies is there a clear process of the methods to be used to ensure consistency of assessment across all authors?

3.4 Describes the method used to arrive at recommendations (for example, a voting system or formal consensus techniques like Delphi consensus)

NICE interpretation

The process should describe the method by which recommendations are formulated based on the evidence. It should include how to reach a decision if there is deadlock or disagreement. It should also describe how the management of any conflicts of interest affects how recommendations are made.

What should be included and where

Common examples of processes used to arrive at final recommendations are voting systems and consensus techniques. Voting systems include open or secret ballots, with or without the option to abstain. Consensus techniques may be informal, such as an unstructured discussion, or formal such as a chaired meeting with a structured discussion, or the Delphi consensus method with a defined number of rounds and a threshold for accepting recommendations. The process should be clear about how information is presented in the guidance if agreement cannot be reached.

The process used to manage conflicts of interest may affect how recommendations are made, in terms of who can be involved and to what degree. For example, an expert with a declared research interest may be allowed to take part in a discussion but not vote, whereas someone with a financial interest may not take part in the discussion unless asked a direct question by the chair.

The method used to arrive at recommendations should be documented in the guidance. In some cases, methods are described in an appendix to the guidance or, more often, in the process. Guidance sections where this information may be found include the methods or a description of the guidance development process.

Analyst questions

- Is there a clear description in the process of what methods should be used to formulate recommendations and how final decisions are arrived at (for example, steps used in modified Delphi technique, voting procedures that were considered)? Is the method appropriate?
- How does the process used to manage conflicts of interest affect how recommendations are reached? Is the potential for undue influence accounted for?

- Is there a clear process for when disagreements occur and are the methods of resolving them described?
- If agreement cannot be reached how is this information presented?
- If the process describes a voting system what is the resolution process? Does the chair have the power of veto?
- Are any areas of disagreement highlighted in the guidance and supporting information?

3.5 Requires the guidance producers to consider the health benefits, side effects and risks in formulating recommendations

NICE interpretation

The guidance developer should consider health benefits, side effects and risks when formulating recommendations. These may include: survival, quality of life, adverse effects, harms and symptom management or comparisons of 1 treatment option with another. It should be documented that these issues have been addressed.

What should be included and where

The process should require the guidance producer to consider the risks and benefits of different courses of action (including of taking no action) in arriving at the final recommendations. This may only be noted in the recommendations – for example, by comparing treatments or describing the risks for each treatment or simply explaining why the guidance recommends a treatment even if the risks are significant. Guidance sections or chapters where this information can be found include: methods, interpretation, discussion, and recommendations.

Medicines guidance may include sections on the side effects of different medicines.

Analyst questions

- Is the discussion of benefits versus risks an integral part of the guidance development process in weighing up the alternatives and arriving at recommendations?
- Does the process describe how benefits and harms are weighed up and evaluated in making recommendations?
- Does the process require consideration of issues such as safety, risks to children, new techniques or surgeries?
- Are data that support benefits and harms clear in the guidance?
- Does the guidance include reporting of the trade-off between benefits and harms?
- Do recommendations reflect considerations of both benefits and harms?

3.6 Describes the processes of external peer review

NICE interpretation

Guidance should be reviewed externally before it is published. Reviewers should not have been involved in developing the guidance, and should include experts in the relevant area. Target population (patients, service users, public) representatives may also be included. The methodology used to conduct the external review should be described by the process and may be presented in the guidance comprising, for example, a list of the reviewers and their affiliations.

What should be included and where

The process should describe clearly the external review process, including the timeframe of consultation, and who is informed (and how) that guidance is available for comment.

This information is often found in sections describing the guidance development process, the acknowledgement section of guidance examples, or on the guidance producer's website. Guidance sections or chapters where this information can be found include: methods, results, interpretation, and acknowledgements.

Clinical Decision Support (CDS) systems may have internal peer review by people who have not been involved in the development process due to the commercial sensitivity of some of the information.

In small specialist groups some experts may need to be excluded from development so that they are able to be peer reviewers.

Analyst questions

- Is the methodology by which external peer review is performed documented?
- Are external reviewers independent from the specific guidance production process?
- Does the process describe how information from the external review is used by the guidance development group?
- If consultation is used as a form of peer review, is there a process to ensure active engagement with stakeholders and the public to encourage responses?
- Is there a process if no consultation responses are received?
- Are the methods of external review (for example, rating scale, open-ended questions) stated?
- Does the guidance state it was peer reviewed and by whom?

- If consultation is used, is it clearly explained how long consultation lasts and whether it is public?
- Is evidence kept that comments are received and explanation given about how they have been incorporated in the guidance, for example as comments tables or tracked changes in documents?
- Are the external reviewers (for example, the number and type of reviewers, and their affiliations) described in the guidance?
- Does the guidance describe how the information gathered was used to inform the guidance development process and formation of the recommendations?

3.7 Describes the process of updating guidance and maintaining and improving guidance quality

NICE interpretation

The aims of this criterion are to ensure that guidance is current, and to encourage the regular review of development processes to ensure that quality is maintained or improved. The process should specify a regular updating schedule and should address unscheduled updates – for example, updating guidance after feedback or important new evidence is published. The guidance examples should bear the date for the next update.

What should be included and where

A timescale may be given or a standing panel established that receives regular literature searches and makes changes to the guidance when needed. The process should describe the criteria for a scheduled or unscheduled update as well as how new evidence is identified and the process for performing this update. An introductory or closing paragraph to the guidance may contain this information, or it may be found elsewhere in the description of the guidance development process.

In terms of reviewing the guidance production process, a regular review date may be specified in the process, with instructions on how to conduct this review. Guidance sections where this information can be found include: methods, update, and date of guidance.

Analyst questions

- Is enough information provided to know what criteria would trigger an update for a piece of guidance?
- Is there an explicit time interval or criteria to guide decisions about when an update will occur?
- Is the updating schedule documented for the guidance development process and a timescale documented for reviews of the process?
- Is there an internal review group which aims to look at the quality of the guidance development process at defined intervals?
- Does the guidance explain that it will be updated, and describe what would prompt an update?
- For ad-hoc updates, are the triggers stated and are they appropriate for the organisation, for example in specialist areas would members be aware of relevant updates?
- Are regular evidence searches performed to identify new evidence since publication?

- Is it clear what the process is if new evidence is identified?
- How is the decision to produce an ad-hoc update made?

Domain 4: Clarity and presentation

Domain	Criteria
4. Clarity and presentation deals with the language and format of the guidance.	These criteria consider whether the guidance producer ensures that: 4.1 The recommendations are specific, unambiguous and clearly identifiable 4.2 The different options for management of the condition or options for intervention are clearly presented 4.3 The date of search, the date of publication or last update and the proposed date for review are clearly stated 4.4 The content and style of the guidance is suitable for the specified target audience. If the public, patients or service users are part of this audience, the language should be appropriate

4.1 The recommendations are specific, unambiguous and clearly identifiable

NICE interpretation

The process should state how the recommendations will be displayed to differentiate them from the rest of the information in the guidance. Recommendations are commonly summarised at the start or end of a section in the guidance document.

It should be easy for users to find the recommendations relevant to them. The recommendations should answer the main questions covered by the guidance.

What should be included and where

Many submissions provide a style guide to address this criterion. It should usually stipulate that recommendations use precise, unambiguous wording, and should be clearly identifiable – for example in a summary box, bold or underlined typeface, or through flowcharts or algorithms. Some guidance provides separate summaries with key recommendations, for example a quick reference guide. The recommendations should always make it clear what action is required and in what circumstances. Evidence of implementation may be found in the following sections of the guidance: executive summary, conclusions and recommendations.

For some guidance, recommendations may be in the form of implications for practice or care rather than prescriptive statements. For clinical summaries, care should be taken to preserve the intended meaning when translating from a primary guideline into a recommendation.

Analyst questions

- Does the process require the formulation of clear recommendations?
- Is there a style guide or template to ensure appropriate language is used?
- Are key recommendations appropriately selected and do they reflect the questions and issues addressed by the guidance?
- Are the recommendations precisely worded to avoid ambiguity?
- Is it clear from the recommendations what action is required and under what circumstances?
- Are recommendations displayed prominently or highlighted to ensure they are clearly identifiable?
- Is it easy to identify the intent or purpose of the recommended action and the population it is relevant for?

- Are any qualifying statements or caveats to the recommendations clear (for example, patients to whom the recommendations would not apply)?
- When appropriate is there an explicit statement reflecting any uncertainty in the interpretation and discussion of the evidence, in the recommendations?

4.2 The different options for the management of the condition or options for intervention are clearly presented

NICE interpretation

Guidance that covers the management of a condition, a safety issue or intervention should consider all the different possible options. The benefits and harms of the alternatives should be clearly presented in the guidance. These may be further broken down into the specific circumstances as to when 1 option may be preferred over another, along with a link to the evidence base.

What should be included and where

A recommendation on the management of a condition may contain a statement or list of treatment alternatives (or other interventions, for example social care), or present them as options in a flowchart or pathway.

Guidance sections or chapters where this information can be found include: executive summary, recommendations, discussion, treatment options, and treatment alternatives.

Analyst questions

- Does the process require considering different options to manage a condition, and is it clearly stated how these should be presented in the guidance?
- At what point during guideline development are different options considered?
- Is the guidance about only 1 particular drug or device? If so, are different options applicable?
- Are the population and circumstance that each recommendation applies to clearly presented?
- Evidence is not always clear cut and there may be uncertainty about the best care options. In this case, is the uncertainty clearly stated in the guidance, with supporting evidence?
- Have algorithms, tables or pathways been used to clearly present different options?

4.3 The date of search, the date of publication or last update and the proposed date for review are clearly stated

NICE interpretation

Information should be documented to explain the process and intervals for updating the guidance and where the date of publication or last update and the date for review will be found. The date range of the evidence searches should also be evident in either the guidance or accompanying documents such as evidence tables or evidence reviews.

What should be included and where

The date of publication or last update may be found in the guidance or on the guidance producer's website. A 'master schedule' may be used internally by the guidance producer to monitor the updating schedules for guidance. Guidance sections or chapters where this information can be found include: front and back cover of the guidance, executive summary, publication information, style guide and search strategy.

Analyst questions

- Does the process provide a coherent structure for how the dates are presented?
- Is there a requirement that relevant dates are clearly stated in guidance? Is there a template or style guide that allows them to be presented in a consistent format?
- Are the following dates clear to the user from the guidance (or supplementary documentation):
  - publication
  - when the guidance was last updated
  - when the guidance is to be reviewed
  - the dates covered by the evidence search?
- Is it clear if the dates of all evidence searches are covered (for example if the guidance is an update there may be more than 1 set of dates of search indicated)?
- If a systematic review is used are the dates of any top-up searches clearly presented?
- If ad hoc or regular searches are performed are the dates of these clear?
- Is the review schedule clear from the guidance?

4.4 The content of the guidance is suitable for the specified target audience. If patients or service users are part of this audience, the language should be appropriate.

NICE interpretation

The process should describe the format and language the guidance is to follow (for example, using a style guide). Technical language in guidance is appropriate if the guidance explicitly states that the target audience is a professional one. The guidance producer should ensure that the language used can be understood by the target audience, for example patients or a non-specialist audience. Any specific needs should also be considered, for example different formats for people who are partially sighted.

What should be included and where

Specialist or technical terminology may be used in guidance aimed at health or social care professionals. But if the guidance includes information for the general public, jargon and technical language should be replaced by more easily understood terms.

Examples of different formats for diverse audiences may include: executive summary, patient information, large print and different languages, and apps. It may also be useful to include a glossary, or to create a separate format for online use..

Analyst questions

- Does the language in the guidance match the target audience (as defined in response to criterion 1.3)?
- Has the target audience been involved in the development of the guidance? If not, is the process explicit?
- Does patient information or summaries involve patients in their development – for example as members of the guidance development group, or a reviewing panel (involvement may be from individuals or patient organisations)?
- Does patient information have the Information Standard (gold standard but not an absolute requirement for this criteria)?
- Is the guidance in a form that is accessible to people with additional needs (for example, physical, cognitive or sensory disabilities) and is it culturally appropriate?
- Does the format relate to its use – for example, is it concise if it needs to be (for example bedside aids, formularies, safety notices)?

- Is there an implicit process for structure, format and language from the examples?
- Has a glossary of terminology been included that is suitable for the target audience?

Domain 5: Applicability

Domain	Criteria
5. Applicability deals with the likely organisational, behavioural and cost implications of applying the guidance.	These criteria consider whether the guidance producer routinely consider: 5.1 Publishing support tools to aid implementation of guidance 5.2 Discussion of potential organisational and financial barriers in applying its recommendations 5.3 Review criteria for monitoring and/or audit purposes within each product

5.1 Publishing support tools to aid implementation of guidance

NICE interpretation

For guidance to be effective it needs to be disseminated and implemented.

The process may describe how people will be helped to implement each piece of guidance. This may include providing resources and aids to implementation. The process may describe what form these support resources or aids may take and give a list of products that are produced with the guidance. The guidance producer should show evidence that support resources have been considered in their guidance.

What should be included and where

Many types of resources or aids may be appropriate. These include: a summary document, a quick reference guide, educational resources, results from a pilot test, patient leaflets, costing tools or apps.

For commissioning guidance, resources could include: benchmarking tools, data for comparison and modelling tools.

Resources and aids to support dissemination and implementation may be included in the guidance, for example in the resources or implementation sections, and in appendices. They may also be provided as separate documents or on the guidance producer's website.

Analyst questions

- Does the process require developers to consider what support resources may be needed?
- Is there information about the development of the implementation resources and validation procedures?
- Has the use of each piece of guidance been considered, rather than producing the same resources in all cases? For example, if the guidance is designed for use at a hospital bedside are the support resources appropriate for this?
- Is there an implementation section in the guidance or reference to where this can be found?
- Is there direction on how users can obtain tools and resources?
- Have examples of support resources or aids been provided?

5.2 Discussion of potential organisational and financial barriers in applying its recommendations

NICE interpretation

Implementing the recommendations may affect resources or service delivery, including increasing or decreasing costs. The process should take this into account and there should be a discussion of the potential impact of the recommendations on resources and budgets.

Does the process describe how it considers the financial and organisational implications of implementing the guidance? For example if a recommendation has resource issues for an organisation, has the guidance producer addressed these? The guidance should give evidence of this discussion.

What should be included and where

The guidance should clearly highlight issues likely to impede or complicate its adoption. This criterion does not consider barriers to obtaining and implementing the guidance, but focuses on the barriers to implementing the recommendations. Organisational and financial barriers might include the need for more specialised staff, new equipment, or an expensive drug treatment. They might also include reluctance by staff to change working practices, or difficulties in applying the recommendations due to variations in contracts, conditions or legislation.

Facilitators and barriers may be detailed in separate documents setting out specific plans or strategies for implementing the guidance. Or in the guidance sections concerning dissemination and implementation; these may include sections on barriers, guidance utilisation, implementation and quality indicators. Minutes of meetings may document discussions of barriers.

Analyst questions

- Does the process require that both potential organisational and financial barriers are considered?
- Is there a process for including information on potential barriers in the guideline?
- Does the process describe the methods used to seek information about the facilitators and barriers to implementing recommendations (for example, feedback from key stakeholders, pilot testing of guidance before widespread implementation)?
- Is there a clear description of the methods used to seek cost information (for example, a health economist was part of the guidance development panel, the use of health technology assessments for specific drugs) and the types of cost information

that were considered (for example, economic evaluations, drug acquisition costs)?

- If the guidance presents different options for management, have potential barriers been considered for all recommended options?
- Does the guidance suggest specific strategies to overcome the barriers?

5.3 Review criteria for monitoring and/or audit purposes within each product.

NICE interpretation

Measuring how guidance recommendations are applied in practice can improve their use in future, and establish whether they are effective in meeting their objectives. This measurement requires clearly defined criteria derived from the recommendations. The criteria may include measures of processes, behaviour, or clinical, health or social care outcomes. The process should specify any methods for audit and monitoring of guidance uptake and implementation.

What should be included and where

Specific plans or strategies for monitoring the implementation and effectiveness of guidance may be set out in the process rather than the guidance products. Audit or monitoring tools may be part of the guidance, or produced as supporting documents; for example questionnaires to ascertain guidance uptake. There may also be monitoring criteria to measure specific outcomes (for example, blood values) if it is possible to link outcomes directly to the recommendations being followed.

Guidance sections or chapters where this information can be found include: recommendations, quality indicators and audit criteria.

Analyst questions

- Is there a process for auditing or monitoring guidance implementation?
- Does the process or the guidance explain how the implementation of each piece of guidance will be assessed. For example, by a physical audit, feedback or a data collection tool?
- Are there processes to enable monitoring of usage?
- Have criteria been identified to assess guidance implementation or adherence to recommendations?
- Are a range of criteria provided, including process measures, behavioural measures, and clinical, health or social care outcomes as appropriate?
- Are there criteria for assessing the impact of implementing the recommendations?
- Are there descriptions or operational definitions of how the criteria should be measured?
- Is there reference in the guidance to the criteria and monitoring processes?

Domain 6: Editorial independence

Domain	Criteria
6. Editorial Independence is concerned with the independence of the recommendations, acknowledgement of possible conflicts of interest, the credibility of the guidance in general and their recommendations in particular.	These criteria consider whether the guidance producer: 6.1 Ensures editorial independence from the funding body 6.2 Is transparent about the funding mechanisms for its guidance 6.3 Records and states any potential conflicts of interest of individuals involved in developing the recommendations 6.4 Takes account of any potential for bias in the conclusions or recommendations of the guidance

6.1 Ensures editorial independence from the funding body

NICE interpretation

The guidance producer should describe the ways in which it ensures that its processes are editorially independent. This may include; using multidisciplinary personnel, controlling the way in which recommendations are arrived at, and a transparent funding mechanism. If the process for editorial input is transparent, then it should be possible to see whether (or the extent to which) the editorial process changed the original decision.

What should be included and where

Guidance may contain a statement that the views and interests of the funding body have not influenced the recommendations. This can be corroborated by detailing the names and affiliations of those involved in developing the final recommendations. Multidisciplinary panels independent from the guidance producer may be used.

This information may be provided on the guidance producer's website or in the guidance, in the sections detailing the authoring process or funding information. Guidance sections or chapters where this information can be found include: methodology, authoring and funding source.

Analyst questions

- Does the process contain a clear description of the authoring processes used by the guidance producer?
- How did the guidance development group address potential influence from the funding body or people involved in developing the guidance?
- Is there an explicit statement that editorial independence has been achieved, and is it explained how the developer considers that this has been done?
- Is the membership of the guideline development group documented to explain its independence from the funding body?
- Is there potential for any funding body to influence the decision making?
- Is it clear that the chair or lead editor had no undue influence in developing recommendations?

6.2 Is transparent about the funding mechanisms for its guidance

NICE interpretation

Funding of the guidance should be clear. This may mean stating the main funding sources and governance of the guidance producer. Guidance is often developed with external funding (for example, from government, professional associations, charity organisations or pharmaceutical companies). Support may be in the form of financial contributions for the complete development of the guidance, or for parts of it (such as literature searches and review). All mechanisms by which funding is received and disbursed should be documented and transparent.

What should be included and where

The guidance producer should ensure that the mechanisms by which it receives and disburses funding are clear and transparent. This may include publishing their annual accounts or an explanation of how any sponsorship it receives is handled. This information could be provided on the guidance producer's or funding charity's website, in terms of reference or policies for the guidance development group or in the guidance. It may also be supplied separately as supporting information. Guidance sections or chapters where this information can be found include: disclaimer, acknowledgements, and funding source.

Analyst questions

- Does the organisation have transparent funding arrangements for guidance development?
- Have the processes used to gather and disburse funds been described in enough detail?
- Has the guidance producer ensured that a full description of how the organisation receives and disburses its funding is documented and auditable?
- If guidance is developed by volunteers, or only expenses are reimbursed, is this stated in the guidance or on the website?
- If the funding information is contained in the process manual, is the manual publicly available?
- If funding is from multiple organisations or sources, is the level of contribution from each clear?

6.3 Records and states any potential conflicts of interest of individuals involved in developing the recommendations

NICE interpretation

In some circumstances stakeholders involved in guidance development may have competing interests. Interests should be recorded and conflicts should be managed according to a defined policy. The aim is to minimise the potential for bias.

A declaration and management of interests policy should:

- be publicly accessible, or at least available on request
- be specific to the guidance development process
- apply to everyone involved in guidance development, including peer reviewers and lay members
- provide different categories covering both financial and non-financial interests (see examples below)
- be current
- be clear how conflicts are recorded and managed and how this affects how recommendations are developed
- manage conflicts appropriately to ensure that people with expertise or specialist knowledge can be involved in guidance development while minimising potential bias.

What should be included and where

People involved in developing the recommendations may be required to declare any competing interests before working on a piece of guidance. If the work is ongoing and involves frequent updates (for example developing and maintaining a medicines information resource) it may not be appropriate for everyone involved to declare interests for every small update. In these circumstances regular declarations, for example annually or quarterly, may suffice.

Examples of different categories of interest defined by the policy might include personal (pertaining to the person or their immediate family) or organisational interests, which can be split into financial and non-financial interests. An example of a personal financial interest might be a paid consultancy; a non-personal non-financial interest might be the employing organisation's membership of a campaign group, or that it undertakes a significant amount of research in a relevant area.

The NICE interpretation for this criterion details high-level requirements for a rigorous and robust conflicts of interest policy. However, it is important that a

policy is appropriate to the type of guidance and can be used in practice. It is detrimental to have a policy that prevents people from taking part who could make a valid contribution without compromising the integrity or safety of the recommendations.

One way to avoid this is to assess both the risk of bias and the potential harm of bias in the recommendations. Factors increasing the risk of bias might include significant commercial implications or an emotive issue with vocal pressure groups; the potential for harm might be increased if the recommendations are widely used or deal with serious risks or side effects. Taking these 2 factors into account, a guidance product with a high risk of bias and great potential for harm, would need a particularly robust conflicts of interest policy. This policy might prohibit the involvement of people with any conflicts of interest except under controlled circumstances, whereas a policy for guidance with a lower potential for harm might allow greater involvement. A submitting organisation should explain in the accreditation application why its policy is balanced and appropriate for the type of guidance it produces.

Guidance sections or chapters where this information can be found include: methods, conflicts of interest, guidance panel, acknowledgements and appendix.

Analyst questions

- Is there a process, appropriate to the type of guidance being produced, to identify and manage conflicts of interest?
- Is the method for identifying conflicts of interest clear and transparent? Is it publicly available or available on request?
- Is there an explicit process to cover all the required areas of conflict (financial and non-financial, personal and non-personal, commercial, specific or non-specific and family interests) pertinent to the potential scope of the guideline?
- Is the timeframe of conflicts reflected, to consider historical, current and planned conflicts?
- Is it clear when and how often declarations should be made?
- Is the process current. Has it been reviewed or updated within the last 3 years?
- Does the process apply to everyone involved in guideline development, including lay members and peer reviewers?
- Is there a requirement in the process for the chair of the guidance development group not to have any conflicts specific to the agenda?
- Does the process require that members with a conflict represent a minority of the group?

- Does the process outline how different categories of conflicts should be managed and what action should be taken?
- Is it clear and proportionate how conflicts are taken into account in the guidance process and development of recommendations (for example, is there a recusal policy)?
- Is it clear in the guideline where to find any conflicts that have been declared or is it stated where they are available?

6.4 Takes account of any potential for bias in the conclusions or recommendations of the guidance

NICE interpretation

This may be a summary of all the processes the guidance producer follows to ensure that no bias can influence its guidance. The checks and balances used to ensure the integrity of the recommendations should be described in the process.

What should be included and where

Using a systematic approach to gathering evidence and synthesising recommendations helps to eliminate bias at the search and development stages. This should be combined with recruiting specialists from a wide variety of disciplines or organisations. Transparent methods and validated tools for grading evidence help to ensure that all relevant evidence is considered appropriately, with results that are reproducible and free from systematic bias. A robust policy to identify and handle conflicts of interest is essential. External peer review provides additional scrutiny of the recommendations and further eliminates bias.

Transparency around the funding mechanisms for guidance development is important because it shows whether there is potential for financial considerations to influence the guidance. Transparency is needed to demonstrate editorial independence from the funding source and to eliminate possible bias from financial interests.

Information to address these points may be found on the guidance producer's website, in published accounts, or in the guidance sections that describe the development and funding of the product. Guidance sections or chapters where this information can be found include: methods, conflicts of interest, guidance panel or team, and appendix.

Analyst questions

- Are searches systematic, with clear inclusion and exclusion criteria?
- Is there a suitable range of stakeholder and lay involvement throughout the process?
- Is there a process for how agreement on recommendations is reached?
- Is there a process to ensure suitable external peer review?

- Is there a process to ensure measures are taken to minimise the influence of competing interests on guidance development or formulation of the recommendations?
- Are any conflicts of interest transparent to the user?
- Have all areas open to bias been considered and measures put in place to reduce or remove bias?