NICE National Institute for Health and Care Excellence

NICE Accreditation support:

Models and advice for guidance development

Contents

Introduction

The intent of NICE accreditation is to help users identify the most trusted sources of guidance developed using critically evaluated high quality processes. This will, in the longer term, drive up the quality of information produced for health and social care decision makers and used in quality standards. This should ultimately result in improved patient or service user outcomes.

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 for practitioners that are based on a systematic distillation of the most relevant evidence base, for example:

- clinical guidance
- referral guidance
- public health guidance
- policy guidance
- clinical summaries
- commissioning guidance
- medicines information guidance
- safety guidance
- social care guidance.

The potential benefits of guidance are only as good as the quality of the guidance itself. Appropriate methodologies and rigorous strategies in the guidance development process are important for the successful implementation of the resulting recommendations. The quality and rigour of guidance production processes can be extremely variable.

The models of practice are intended to assist organisations improve the quality of the processes used to develop guidance. This document summarises examples and experience accrued since the accreditation programme was implemented in April 2009. Further examples will be added as the NICE accreditation programme continues to evolve and develop. The document is structured around the six domains of the NICE accreditation criteria, which are based on the AGREE[1] instrument. It is aimed at organisations that have been accredited but have suggested improvements to make, organisations reapplying for accreditation, and those applying for the first time.

The purpose of this document is to provide a framework to:
1. describe how NICE assesses the quality of guidance development processes in its accreditation programme
2. provide a methodological strategy for the development of guidance

[1] The AGREE Collaboration. Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, Fervers B, Graham ID, Grimshaw J, Hanna S, Littlejohns P, Makarski J, Zitzelsberger L for the AGREE Next Steps Consortium. AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Can Med Assoc J. 2010*. doi:10.1503/cmaj.090449 (http://www.agreetrust.org)

3. inform what and how information ought to be documented in the guidance development process.

The content of this document is not intended to be an accreditation evaluation. The information contained within this document is purposely broad in scope to allow producers of different types of guidance to understand and implement a guidance production process which is fit for purpose. It is of most benefit if used in conjunction with the NICE Accreditation Gap analysis.

Types of guidance

NICE uses 25 criteria in six domains to assess the processes used by organisations to develop and update guidance.
The criteria are generic and can be applied to guidance development processes in any health and social care setting.

Types of guidance include public health, safety (such as drug and device safety), commissioning, social care, screening, diagnosis, treatment or other interventions.

A key principle of accreditation is that the process used to develop guidance should be fit for purpose. Guidance producers should describe how their processes meet the criteria. In some circumstances criteria may not be applicable.
A number of examples have been described within each criterion 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 questions and considerations are provided that are appropriate for many, but not all, types of guidance.

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

DOMAIN 1: SCOPE AND PURPOSE

1.1 The overall objective of the guidance

NICE interpretation

The overall objective(s) of the guidance should be described and the expected benefits from the guidance should be specific to the topic.
The process documents should explain where this information can be found in the guidance and describe how this overall objective was reached, for example, if the aim of the guidance is decided in a scoping session this should be described.

Examples

The objective of the guidance is often seen in the opening paragraphs/chapters for a description of the scope and purpose of the guidance. Commonly the overall objective of the organisation or suite of guidance products is described in response to this criterion. In some cases, the rationale or need for the guidance is described in a document separate from the guidance, for instance, in the guidance proposal. Examples of sections or chapters in guidance examples where this information can be found include: introduction, scope, purpose, rationale, background, and objectives.

Specific examples include:

- For concise guidance outputs, the overall aim may be indicated in the heading of the piece of guidance, with a high level overall aim indicated for all of the guidance produced via that process
- For commissioning guidance this 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
- For policy guidance it may be specific to a training standard, population or a set of methods to follow

Questions and considerations

Does the guidance specifically state its aims? A full description of how the objective was reached and by whom would be welcome, for example by a topic selection panel. The process documentation should describe how the topic selection and scoping is done and explain how this will appear in the guidance if fit for purpose.

Suggestions for guidance content include:
• intent(s) such as prevention, screening, diagnosis, treatment
• expected benefit or outcome
• target(s) (for example, patient or service user population, society)

DOMAIN 1: SCOPE AND PURPOSE

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

NICE interpretation

A detailed description of the questions covered by the guidance should be provided although they may not always be phrased as questions in the guidance.

The process should describe how the questions are formulated, at what stage in the guidance development 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.

Examples

The key question covered by guidance may be a more general health or wellbeing issue or a safety question. For medicines information this may be a more general question relating to the efficacy of a medicine or group of medicines. For policy guidance the questions may be specific to a training standard or a set of methods to follow.

A detailed description of the questions covered by the guidance such as a description of how processes for topic selection and scoping take into account issues related to equality (for example by identifying issues related to race, disability, sex/gender or age in defining the population and/or target audience, and by promoting equality in guidance) should be documented.

Safety guidance should describe the specific safety questions, and commissioning guidance may include quality outcomes, patient or service user experience and deliverables.

Questions and considerations

Does the process describe how these questions will be found in the guidance examples? Is there enough information provided in the questions for anyone to initiate the development of guidance on this topic?
A full description should include how these questions or issues were reached and how the questions will look in the guidance examples.

Suggestions for guidance content include:
• target population
• intervention(s) or exposure(s)
• comparisons (if appropriate)
• outcome(s)
• health care setting or context

DOMAIN 1: SCOPE AND PURPOSE

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

NICE interpretation

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

Examples

The population and target audience should be documented as described in the process. Any exclusion to the population covered (for example children) should also be clearly stated. It may be appropriate to detail the target audience and population in separate sections. Examples of commonly labelled sections or chapters in guidance where this information may be found include: patient or service user population, target population, relevant patients or service users, scope, and purpose.

A specific clinical example may be: Guidance on the management of diabetes mellitus that only includes patients with non-insulin dependent diabetes mellitus and excludes patients with cardiovascular co-morbidity.
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.

Questions and considerations

Who is the guidance to inform? Are there sections within the guidance which targets any specific audience? If so is this described in the process documentation and implemented in the guidance? 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 and eligible individuals would receive the action recommended in the guidance?
The process documentation should describe how to define the specific target audience and patient or service user populations covered by the guidance and explain where the evidence of the implementation of this process will be found in each piece of guidance.

Suggestions for guidance content include:
• target population, gender and age
• clinical condition (if relevant)
• severity/stage of disease (if relevant)
• comorbidities (if relevant)
• excluded populations (if relevant)

DOMAIN 1: SCOPE AND PURPOSE

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

NICE interpretation

The guidance development process should explain how the guidance ensures that recommendations are specific for the right target population in the right circumstances so that they can be implemented appropriately. If an explicit link between the recommendations and the evidence on which they are based is required within the guidance, this should be stated in the process. The guidance user should be able to identify the components of the body of evidence relevant to each recommendation.

Examples

Where a recommendation is based on a specific group of people for a particular procedure, are the specifics clear within the recommendation? An example would be an intervention for a specific patient group defined by, for example, age, disease severity, co-morbidities. An explicit link between the recommendations and the evidence base could be provided by a footnote, reference or hyperlink within the recommendation. If they wish to, the user could follow this link to see which pieces of evidence led the guidance producer to provide this specific recommendation. Examples of commonly labelled sections or chapters in the guidance where this information can be found include: recommendations and key evidence.

Questions and considerations

Does the process ensure that recommendations are clear so that they can be implemented appropriately for the right target population in the right circumstances? Is it clear what audience/procedure/circumstances the recommendation covers? Can the recommendations be traced back to the evidence base specific to that recommendation? The process manual should request that the recommendations are formulated and described covering particular populations/circumstances and guidance should show considerations to ensure they are implemented appropriately. Within the guidance we would expect to see specific recommendations backed up by evidence.

Suggestions for guidance content include:
• describe how the development group link and use the evidence to inform recommendations
• ensure that all recommendations clearly describe the specific circumstances in which they are to be used
• ensure that the implementation of the recommendation is considered in the wording to ensure a clear meaning, linked to the scope/key questions where relevant

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

DOMAIN 2: STAKEHOLDER INVOLVEMENT

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

NICE interpretation

The aim of this criterion is to check that professionals and patient or service user groups relevant to the guidance are involved in its development. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence and individuals involved in formulating the final recommendations. Where relevant, information about the composition, discipline, and relevant expertise of the guidance development stakeholders should be provided.

Examples

Evidence of implementation of a process may be found in the opening paragraphs/chapters, acknowledgement section or appendices for the composition of the guidance development group. Examples of commonly labelled sections or chapters in the guidance where this information can be found include: methods, guidance panel member list, acknowledgements, and appendices.
A specific example may be that the process documentation explains 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.

Questions and considerations

Are the members an appropriate match for the topic and scope? Potential candidates could include clinicians from relevant disciplines, content experts, social care or public health experts, researchers, policy makers, clinical administrators, and funders. There may also be a methodology expert included in the development group (for example, systematic review expert, epidemiologist, statistician, library scientist).

Have people relevant to the guidance under development been involved in the guidance development process?

Information about the composition of any groups involved with the development of the guidance should be indicated in the process manual with the evidence of implementation clearly demonstrated where relevant.

Suggestions for guidance content include:
Where relevant, for each guidance development stakeholder, the following information may be included:

- name
- discipline/content expertise (for example; neurosurgeon, methodologist)
- institution or affiliation (for example, NICE)
- description of the member’s role in the guidance development group

DOMAIN 2: STAKEHOLDER INVOLVEMENT

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

NICE interpretation

The process should state when and where in the guidance development process the views of patients or service users are considered. Ideally this criterion would be met by the inclusion such individuals in the scoping phase, guidance development groups and reviewers with consultation and feedback mechanisms which will inform the recommendations where applicable. Where part of the evidence base is published guidance, the patient or service user involvement in the development of the primary guidance should be ascertained.

Information about patient or service user experiences and expectations of health care should inform the development of guidance. Alternatively, information could be obtained from interviews with these stakeholders or from literature reviews of patient/public values, preferences or experiences. There should be evidence that process has been followed and that stakeholders' views have been considered.

The Guidelines International Network (G-I-N) Patient and Public Involvement Working Group has developed a toolkit to facilitate public involvement in guidance development. Some of the topics covered by the toolkit are how to conduct public and targeted consultation, how to recruit and support public members and how to develop lay versions of guidance.

Examples

There are various methods for ensuring that these perspectives inform the different stages of guidance development by stakeholders. For example, formal consultations with patients/public to determine priority topics, participation of these stakeholders on the guidance development group, or external review by these stakeholders on draft documents. Feedback from patient or service user stakeholders on published guidance should be used to inform updates and amendments to that guidance where possible.

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

Questions and considerations

Who is involved in guidance development that can provide the perspectives of patients or service users? Are patients, service users or organisations that represent these groups involved, and in what circumstances is the use of each justified? What support is provided for any public representatives involved in guidance development? Which groups involved in the guidance development process contain public representation? Is the process of feedback and consideration of patient or service user views adequately described in the documentation? How is this feedback treated and how does it inform the guidance development process?

The policy to gather patient or service users' views during guidance development should state:

- who is involved, for example members of the public with direct experience of the condition or aspect of care, patient or service user organisations, or 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

Suggestions for guidance content include:

• a description of type of strategy used to capture patient or service user views and preferences (for example, participation in the guidance development group, literature review of values and preferences)

• the methods by which preferences and views were sought (for example, evidence from literature, surveys, focus groups)

• what views and preferences were identified

• a description of how the information gathered was used to inform guidance development or formation of the recommendations.

DOMAIN 2: STAKEHOLDER INVOLVEMENT

2.3 Representative intended users in developing guidance

NICE interpretation

The process should state when and where in the guidance development process the intended users are involved. If the guidance is defined as being for a diverse audience, the composition of that audience should be demonstrated and evidence provided of where and when these users are involved in the guidance development.

Examples

The opening paragraphs/chapters may contain a description of the target users of the guidance and how they have been involved in the development of the guidance. For example, the target users for guidance on low back pain may include general practitioners, neurologists, orthopaedic surgeons, rheumatologists, and physiotherapists. How and why the target users are involved in the guidance development process should be documented. Users may be involved in scoping, reviewing or piloting guidance, and the processes should be described.
For example representative service providers and other agencies should be clearly visible in the development process for commissioning guidance. It may describe how primary, secondary and community services working together across a whole health economy will deliver greater benefits than individual providers.

Questions and considerations

Are specific professions described as intended users for a piece of guidance? If so is there evidence as to how and when the specific intended user is involved in the development of the guidance? Does the guidance include information to demonstrate how users have been involved in development? Evidence that the target audience are involved in guidance development should be demonstrated.

Suggestions for guidance content include:
• a clear description of the intended guidance audience and how the guidance may be used will define the types of professions to evidence
• explanation of when and how any intended users should be included in the guidance development process (for example, always include a pharmacist at the peer review stage of guidance development)

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

DOMAIN 3: RIGOUR OF DEVELOPMENT

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 systematically search for the evidence relevant to the guidance in development. The process should state the routine approach to the evidence search including the methods used. If databases and/or hand searching is done systematically, when and why this is done in the development of the guidance should be explained. The process documents should tie the search strategy to the scope. The information on the search strategy and methods used may be noted in any process documents, the guidance or a combination of both.

Examples

The type of evidence may differ between different types of guidance. The key principle is that a systematic approach is used to find relevant evidence. The process documentation should state the general method, and this may specify which databases (for example, MEDLINE, EMBASE, CINAHL) will be searched in every case. Evidence such as best practice or consensus expert opinion. Sources of evidence will vary according to the type of guidance and may include electronic databases, databases of systematic reviews (for example, the Cochrane Library, DARE), hand searching journals, reviewing conference proceedings, and others. In some cases the search strategies are described in separate documents or in an appendix to the guidance.
Examples of commonly labelled sections or chapters in the guidance where this information can be found include: methods, literature search strategy, and appendices.

Questions and considerations

Does the process describe a routine and systematic approach to identifying evidence relevant to the guidance?
Is the search relevant and appropriate to answer the clinical, health or social care question?
Does the process ensure that the search strategy is as comprehensive as possible and executed in a manner free from potential biases and sufficiently detailed to be replicated?

Suggestions for guidance content include:

- named electronic database(s) or evidence source(s) where the search was performed (for example, MEDLINE, EMBASE, PsychINFO, CINAHL)
- time periods searched (for example, January 1, 2004 to March 31, 2008)
- the date the search was performed
- search terms used (for example, text words, indexing terms)
- where searches for evidence are performed outside the routine systematic searches, this should be described and the reasoning explained (for example, some disciplines lack a rigorous controlled evidence base)

DOMAIN 3: RIGOUR OF DEVELOPMENT

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 explain that criteria for including/excluding evidence identified by the search should be provided. These criteria should be explicitly described and reasons for including and excluding evidence should be clearly stated. Not all evidence returned from the evidence searched may be relevant to the guidance being produced. Some exclusion criteria may be defined as part of the evidence searches. For example, guidance authors may decide to only include evidence from randomised clinical trials and to exclude articles not written in English.

Examples

The process should describe how the inclusion or exclusion criteria for selecting the evidence may be detailed in the section describing the guidance development process, an appendix to the guidance, or in separate documents. Examples of commonly labelled sections or chapters in the guidance where this information can be found include: methods, literature search, inclusion/exclusion criteria, and appendices.

Questions and considerations

Does the process ensure that there is a rationale given for the stated inclusion/exclusion criteria?
Do inclusion/exclusion criteria align with the health/ clinical/ social care /safety question(s)?
The process should ensure that guidance describes when and why specific exclusions and inclusions are used and where this can be found. The reasoning behind the inclusions/exclusions should be clear. There may be more than one point for inclusion and exclusion. First there may be exclusions specified during the evidence searching, for example, only English language studies used. Secondly evidence should be provided as to why a piece of evidence is excluded after being identified by the evidence search, for example excluded on grounds of relevancy. This should be documented and provided as evidence of implementation of the process.

Suggestions for guidance content include:
explanation of what criteria have been used for inclusion/exclusion of evidence or reference to where these criteria can be found. Specific inclusion/exclusion criteria may be based on:

- target population (patients service users, public) characteristics
- study design
- comparisons (if relevant)
- outcomes
- language (if relevant)
- context (if relevant).

DOMAIN 3: RIGOUR OF DEVELOPMENT

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 by use of a grading system or critical appraisal tool. The outcomes of these assessments 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 clear.

Examples

Information may be included that details how the methodological quality of the studies (for example, risk of bias) is critically appraised. Evidence tables are often used to summarise quality features. Some guidance makes a clear distinction between description and interpretation of evidence, for instance, in a results section and a discussion section, respectively.
Statements highlighting the strengths and limitations of the evidence should be provided. This ought to include explicit descriptions - using informal or formal tools/methods - to assess and describe the risk of bias for individual studies and/or for specific outcomes and/or explicit commentary of the body of evidence aggregated across all studies.
This may be presented in different ways, for example: using tables commenting on different quality domains; the application of a formal instrument or strategy (for example, Jadad scale, GRADE method); or descriptions in the text.

Questions and considerations

Has an assessment tool or other form of critical appraisal tool been used and if so is this fit for purpose and the choice of appraisal explained? 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?

Suggestions for guidance content include:

- type of evidence used and why
- descriptions of how the body of evidence was evaluated for bias and how it was interpreted.

Aspects upon which to frame descriptions include the:

- study design(s) included in body of evidence
- study methodology limitations (sampling, blinding, allocation concealment, analytical methods)
- appropriateness/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.

DOMAIN 3: RIGOUR OF DEVELOPMENT

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 how the recommendations are formulated based on the assessed evidence base and which method is used to arrive at the final recommendations. The process should describe how to reach a decision if there is deadlock or disagreement as to the correct recommendation. The process should also describe how the management of any conflicts of interest affects how recommendations are made.

Examples

Common examples of processes used to arrive at final recommendations are voting systems or consensus techniques. Voting systems include open ballots and secret ballots, with or without the option to abstain. Consensus techniques may be informal, such as an unstructured discussion resulting in agreement, 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. Whatever process is used, it must be documented and should explain how the guidance producer routinely arrives at a recommendation based on the assessed evidence, and what happens if there is a difference of opinion.

The process used to manage conflicts of interest may affect how recommendations are made, in terms of who is involved and to what degree. Examples include experts with a declared research interest may be allowed to take part in a discussion, but not vote, whereas those with a financial interest may not take part in the discussion unless asked a direct question by the Chair.

This criterion is rarely documented in the guidance. In some cases, the methods used to formulate the recommendations are described in an appendix to the guidance, or more often within the process documentation.
Examples of sections in the guidance where this information may be found include the methods or a description of the guidance development process.

Questions and considerations

Is it clear what process was used to arrive at the recommendations?
Were the methods appropriate? How does the process used to manage any conflicts of interest affect how recommendations are reached? A description of the methods used to formulate the recommendations and how final decisions were arrived at should be provided. Areas of disagreement and methods of resolving them should be specified. For example, in a voting system what is the resolution process? Does the chair have the power of veto?

Suggestions for guidance content include:
• a description of the recommendation development process (for example, steps used in modified Delphi technique, voting procedures that were considered)
• the outcomes of the recommendation development process (for example, extent to which consensus was reached, outcome of voting procedures)

• a description of how the process influenced the recommendations for example, results of Delphi technique influence final recommendation, alignment with recommendations and the final vote.

DOMAIN 3: RIGOUR OF DEVELOPMENT

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

NICE interpretation

The guidance should consider health benefits, side effects, and risks when formulating the recommendations. These may include: survival, quality of life, adverse effects, harms and symptom management or a discussion comparing one treatment option to another. There should be evidence that these issues have been addressed.

Examples

The process should explicitly require the guidance producer to consider the risks and benefits of different courses of action, including doing nothing, in arriving at the final recommendations. This may be evident in the final product, for example guidance on the management of breast cancer may include a discussion of the potential effects of different treatment options on various final outcomes. The paragraphs/chapters describing the guidance development process should contain a description of the body of evidence, its interpretation, and the translation into practice recommendations. Examples of commonly labelled sections or chapters in the guidance where this information can be found include: methods, interpretation, discussion, and recommendations.

Questions and considerations

Is the discussion of benefit versus risk 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? This may only be noted in the recommendations. For example, this may be done by comparing treatments or describing the risks for each treatment considered or simply an explanation as to why the guidance recommends a treatment even if the risks are significant.

Suggestions for guidance content include:
• supporting data and report of benefits/harms/side effects/risks
• reporting of the balance/trade-off between benefits and harms/side effects/risks
• recommendations reflect considerations of both benefits and harms/side effects/risks.

DOMAIN 3: RIGOUR OF DEVELOPMENT

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 guidance, and should include experts in the relevant area. Target population (patients, service users, public) representatives may also be included. A description of the methodology used to conduct the external review should be described by the process and may be presented in guidance, for example a list of the reviewers and their affiliations.

Examples

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

Questions and considerations

Are the external reviewers relevant and appropriate to the scope of the guidance? Was there a rationale given for choosing the included reviewers? How was information from the external review used by the guidance development group? The methodology by which the process of external peer review is performed should be documented. External reviewers should be independent from the specific guidance production process.

Suggestions for guidance content include:
• purpose and intent of the external review (for example, to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence)
• methods taken to undertake the external review (for example, rating scale, open-ended questions)
• description of the external reviewers (for example, number, type of reviewers, affiliations)
• outcomes/information gathered from the external review (for example, summary of key findings)
• description of how the information gathered was used to inform the guidance development process and/or formation of the recommendations (for example, guidance panel considered results of review in forming final recommendations).

DOMAIN 3: RIGOUR OF DEVELOPMENT

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 guidance production processes to ensure the quality of process outputs is maintained or improved. For this criterion we look within the process documents to see if the guidance has a regular updating schedule. In addition does the process also address unscheduled updates such as updating guidance after feedback or important new evidence is published. The guidance examples commonly bear the date for the next update.

Examples

A timescale may be given or a standing panel established that receives regularly updated literature searches and makes changes to the guidance as required. The process should describe the conditions for a scheduled or unscheduled update, for example when significant new evidence emerges, 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 within the process documentation, with instructions on how this review will be conducted. Examples of commonly labelled sections in the guidance where this information can be found include: methods, update, and date of guidance.

Questions and considerations

Is enough information provided to know when an update will occur or what criteria would trigger an update for a piece of guidance? Is the updating schedule documented for the guidance development process?
A clear statement about the procedure for updating the guidance should be provided. The timescales for reviews of process should also be documented. There may be an internal review group which aims to look at the quality of the guidance development process at defined intervals.

Suggestions for guidance content include:
• a statement that the guidance will be updated, and a description of what would cause an update
• the explicit time interval or criteria to guide decisions about when an update will occur
• the methodology for the updating procedure is reported.

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

DOMAIN 4: CLARITY OF PRESENTATION

4.1 The recommendations are specific, unambiguous and clearly identifiable

NICE interpretation

The process documentation should state how the recommendations will be displayed to differentiate them from the rest of the information included in the guidance. In the guidance examples reviewed the recommendations are commonly summarised at the start or end of a section or the guidance document.
Users should be able to find the most relevant recommendations easily. These recommendations answer the main question(s) that have been covered by the guidance.

Examples

Many submissions provide a style guide which helps to address this criterion. The style guide may stipulate that recommendations use precise, unambiguous wording, and be clearly identifiable, for example in a summary box, bold or underlined typeface, or presented through flowcharts or algorithms. Some guidance may provide separate summaries with key recommendations, for example a quick reference guide. In order to ensure the recommendations are specific, the process should require a clear link between circumstances and recommendations so that it is clear what action is required. Within the guidance, evidence of implementation may be found in the following commonly named sections: the executive summary, conclusions, and recommendations. For some guidance recommendations may be in the form of implications for practice or care rather than prescriptive statements.

Questions and considerations

Are the key recommendations appropriately selected and do they reflect the questions and issues intended to be addressed by the guidance?
Are the recommendations precisely worded to avoid ambiguity?
Are the circumstances and recommendations clearly linked so that it is clear what action is required under the circumstances?
Are recommendations displayed prominently or highlighted in the relevant sections?

Suggestions for guidance content include:
• a description of recommendations highlighted in some way to ensure they are clearly identifiable
• specific recommendations that are grouped together in one section
• identification of the intent or purpose of the recommended action (for example, to improve quality of life, to decrease side effects)
• identification of the relevant population (for example, patients, public)
• caveats or qualifying statements, if relevant (for example, patients or conditions for whom the recommendations would not apply)
• an explicit statement reflecting any uncertainty in the interpretation and discussion of the evidence, within the recommendations.

DOMAIN 4: CLARITY OF PRESENTATION

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

NICE interpretation

Guidance that targets the management of an issue, such as a disease, safety issue or intervention should consider the different possible options for screening, prevention, diagnosis or treatment of the issue. These alternatives with their relative benefits, harms and supporting evidence should be clearly presented in the guidance.
The process documents should specify that where an issue can be treated in different ways within a specific area, all of the options are stated. These may be further broken down into the specific circumstances as to when one option may be preferred over another with a link to the evidence base.

Examples

A recommendation on the management of a condition may contain a statement or list of treatment alternatives (or other interventions, for examples social care), or present them as options within a flowchart or pathway.
Examples of commonly labelled sections or chapters in the guidance where this information can be found include: executive summary, recommendations, discussion, treatment options, and treatment alternatives.

Questions and considerations

This criterion may be more relevant to guidance that is broad in scope (for example, covering the management of a condition or issue rather than focusing on a particular set of interventions for a specific condition/issue). Is the guidance broad or narrow in scope?
In the event of multiple recommendations (for example, management guidance), is it clear what each recommendation applies to?

It is important to note that in some instances, evidence is not always clear cut and there may be uncertainty about the best care option(s). In this case, the uncertainty should be stated in the guidance with supporting evidence

Suggestions for guidance content include:

- a description of options
- a description of population or situation most appropriate to each option
- a link back to the specific questions and issues covered by the guidance

DOMAIN 4: CLARITY OF PRESENTATION

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 dates of the evidence searches should also be evident in either the guidance or accompanying documentation such as evidence tables.

Examples

The date of publication or last update may be found within the guidance or on the hosting website. There may be a 'master schedule' used internally by the guidance producer to monitor the updating schedules for guidance. Examples of commonly labelled sections or chapters in the guidance where this information can be found include: front and back cover of the guidance, executive summary, publication information and the search strategy.

Questions and considerations

From looking at the guidance can you clearly see:
• the date of publication
• the date the guidance was last updated
• the date the guidance is to be reviewed
• the dates covered by the evidence search?
Does the process documentation provide a coherent structure for how the dates are monitored? Does the process describe with reasoning how any dates are decided and where the evidence for these dates will be found in guidance examples?

Suggestions for guidance content include:
• dates of production and publication
• date of next review and updating schedule (for example, a three year updating schedule is followed)
• dates of all searches covered (for example if the guidance is an update there may be more than one set of dates of search indicated).

DOMAIN 4: CLARITY OF PRESENTATION

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, 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 documents are in a format accessible to people with differing needs where appropriate, for example patients or a non-specialist audience. Where specific patients or service users are part of the target audience, the specific needs should have been considered, for example different formats tailored to the partially sighted. If an equality impact assessment has been performed, the formats for the guidance should show the outcomes of this assessment.

Examples

For the health or social care professional specialist terminology may be used, but if the guidance includes information for the general public, jargon should be avoided and replaced by more easily understood terms.
Examples of different formats for diverse audiences may include: executive summary patient information, large print and different languages.

Questions and considerations

Does the language used in the guidance match the target audience (as defined in response to criterion 1.3)? Technical language used in guidance may be appropriate if the target audience is a technical one, for example policy guidance for a laboratory audience.

Suggestions for guidance content include:
• a description of target audience, including patients where appropriate
• evidence that different formats have been considered, linking to the equality impact assessment.

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

DOMAIN 5: APPLICABILITY

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 the implementation of guidance will be assisted in each case, for example, by providing tools (by this we mean any tool which can be used in conjunction with and assists the implementation of the guidance) and aids to implementation. The process may describe what form these support tools/aids may take and provide a list of products that are produced with the guidance. The guidance producer should show evidence that support tools have been considered in their guidance.

Examples

Any from a broad range of tools/aids may be appropriate, these include: a summary document, a quick reference guide, educational tools, results from a pilot test, patient leaflets, or computer support. Any additional materials should be provided with the guidance.

These items may be provided through specific accompanying materials produced to support the dissemination and implementation of the guidance. Within the guidance, examples of commonly labelled sections or chapters where this information can be found include: tools, resources, implementation, and appendices. This information may also be found on the guidance producer's website.

Questions and considerations

Is there information about the development of the implementation tools and validation procedures? Has the use of each piece of guidance been considered? For example if the guidance is designed for use at a hospital bedside are the support tools appropriate for this rather than producing the same support tools in all cases.

Suggestions for guidance content include:
• an implementation section, or reference to where this can be found
• tools and resources to facilitate application, for example:
    - guidance summary documents
    - links to check lists, algorithms
    - links to how-to manuals
    - solutions linked to barrier analysis (see criterion 5.2)
    - outcome of pilots and lessons learned
• directions on how users can access tools and resources.

DOMAIN 5: APPLICABILITY

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

NICE interpretation

The recommendations may affect resources or service delivery when applied, including increasing or decreasing costs, with implications for budgets. The process should take this into account and there should be a discussion of the potential impact of the recommendations on resources.
Does the process describe how it considers the financial and organisational implications of implementing the guidance? Evidence of this discussion should be found in the guidance. For example if a recommendation has resource issues for an organisation has the guidance producer addressed this in the guidance?
There may be existing facilitators and barriers that will impact the application of guidance recommendations.

Examples

The guidance should clearly highlight issues likely to impede or complicate the adoption of its recommendations. This criterion does not consider barriers to accessing the guidance, but focuses on the barriers to implementation of 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.

These may be detailed within separate documents detailing the specific plans or strategies for implementation of the guidance, or within the guidance in sections concerning its dissemination and implementation. Examples of commonly labelled sections or chapters in the guidance where this information can be found include: barriers, guidance utilisation, implementation and quality indicators.

Questions and considerations

Does the guidance suggest specific strategies to overcoming the barriers?
Were appropriate experts or intended users involved in finding and analysing cost/organisational information?

Suggestions for guidance content include:
• identification of the types of cost information that were considered (for example, economic evaluations, drug acquisition costs)
• the methods by which the cost information was sought (for example, a health economist was part of the guidance development panel, the use of health technology assessments for specific drugs)
• identification of the types of facilitators and barriers that were considered
• the methods by which information regarding the facilitators and barriers to implementing recommendations were sought (for example, feedback from key stakeholders, pilot testing of guidance before widespread implementation)
• a description of, or information on the types of facilitators and barriers that emerged from the inquiry (for example, practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography).

DOMAIN 5: APPLICABILITY

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

NICE interpretation

Measuring the application of guidance recommendations can facilitate their ongoing use, and establish if they are effective in meeting their objectives. This requires clearly defined criteria that are derived from the key recommendations in the guidance. The criteria may include process measures, behavioural measures, clinical or health outcome measures. The process should also specify any methods for audit and monitoring of guidance uptake and implementation.

Examples

Specific plans or strategies for monitoring the implementation and effectiveness of guidance may be found in the process rather than the guidance products. Audit or monitoring tools may be found in the guidance however, for example questionnaires to ascertain guidance uptake, or a request for feedback via an online survey or email. There may also be monitoring criteria to measure specific outcomes, if it is possible to link outcomes directly to application of the recommendations.
Examples of commonly labelled sections or chapters in the guidance where this information can be found include: recommendations, quality indicators, and audit criteria.

Questions and considerations

Are a range of criteria provided including process measures, behavioural measures, and clinical, health or social care outcomes?
Is a process in place for audit or monitoring of guidance implementation?
The process documents and/or the guidance should explain how the implementation of each piece of guidance will be assessed as applicable. This may be done by a physical audit, feedback or a data collection tool.

Suggestions for guidance content include:
• identification of criteria to assess guidance implementation or adherence to recommendations
• the criteria for assessing impact of implementing the recommendations
• advice on the frequency and interval of measurement
• descriptions or operational definitions of how the criteria should be measured.

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

DOMAIN 6: EDITORIAL INDEPENDENCE

6.1 Ensures editorial independence from the funding body

NICE interpretation

A description of the ways in which a guidance producer considers its processes editorially independent should be provided. This may include; use of multi-disciplinary personnel and control of the way in which recommendations are arrived at in conjunction with a transparent funding mechanism. However if the process for editorial input is transparent then it should be possible to see if (or the extent to which) the editorial process changed the original decision. There should be an explicit statement that the views or interests of the funding body have not influenced the final recommendations.

Examples

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. Multi-disciplinary panels independent from the guidance producer may be used.

This information may be provided either on the guidance producer's website, and/or within the actual guidance in the sections detailing the authoring process or funding information. Examples of commonly labelled sections or chapters in the guidance where this information can be found include: methodology, authoring and funding source.

Questions and considerations

How did the guidance development group address potential influence from the funding body/people involved in developing the guidance?
A fit for purpose policy on the authoring process is required. It should include an explicit statement that editorial independence has been achieved and explain how it considers that this has been done.

Suggestions for guidance content include:
• a clear description of the authoring process used by the guidance producer
• document the guideline development group to explain its independence from the funding body
• a statement that bias is negated for people involved in the guidance development process and a description as to how this bias has been negated.

DOMAIN 6: EDITORIAL INDEPENDENCE

6.2 Is transparent about the funding mechanisms for its guidance

NICE interpretation

Funding of the guidance should be clear; this may mean a statement of the main funding source (s) and governance of the guidance producer. Frequently guidance is 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 printing of the guidance). All mechanisms by which funding is received and disbursed should be documented and transparent for a guidance development organisation.

Examples

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

Questions and considerations

Does the organisation have transparent funding arrangements for its guidance development? Are the processes used to gather and disperse funds been described in enough detail?
The guidance producer should ensure that a full description of how the organisation receives and disburses its funding should be documented and auditable.

Suggestions for guidance content include:
• the name of the funding body or source of funding (or explicit statement of no funding)
• a statement that the funding body did not influence the content of the guidance.

DOMAIN 6: EDITORIAL INDEPENDENCE

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

NICE interpretation

There are circumstances when stakeholders involved in guidance development may have competing interests. These should be recorded and managed according to a defined policy.

A conflicts of interest policy should:

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

Examples

Individuals involved in developing the recommendations may be required to declare any competing interests prior to undertaking work on each specific piece of guidance. If the work is ongoing and involves frequent updates, for example the development and maintenance of 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 individual or their immediate family) or organisational interests, which can be split into financial or 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 the area.

Examples of commonly labelled sections or chapters in the guidance where this information can be found include: methods, conflicts of interest, guidance panel, acknowledgements and appendix.

Questions and considerations

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 individuals from taking part if they can make a valid contribution without compromising the integrity or safety of the recommendations. Some types of guidance will demand more comprehensive policies and will be applied more strictly, because of the overall risk of harm from bias.

One way to evaluate this risk is to assess both the risk of bias occurring, and the potential harm that might arise from any 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 two factors into account, a guidance product with a high risk of bias and the potential for harm, for example a technology appraisal, would need a very robust conflicts of interest policy. Such a policy might prohibit the involvement of individuals deemed to have any conflicts of interest except under controlled circumstances, whereas a policy for guidance with a lower potential for harm might allow greater inclusion or involvement. Ultimately a submitting organisation must be able to explain in the accreditation application why its policy is balanced and appropriate for the type of guidance it produces.

Suggestions for guidance content include:

- who declared an interest and what the interest was
- what action was taken for those declared interests
- information on where the policy for declaring interest can be found

DOMAIN 6: EDITORIAL INDEPENDENCE

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 of the processes the guidance producer follows to ensure that no bias can influence the recommendations of its guidance. A description of all of the checks and balances the process has to ensure the integrity of the recommendations of a piece of guidance should be described in the process.

Examples

A systematic, documented approach to gathering evidence and synthesising recommendations helps to eliminate bias at the search and development stages, particularly when combined with multi-disciplinary teams (for example specialists from a variety of disciplines or organisations) and peer review. Transparent methods and validated tools help to ensure that all relevant evidence is considered and treated appropriately, with results that are reproducible and free from systematic bias. A robust policy to identify and handle conflicts of interest is essential. Peer review by individuals external to the guidance development team can provide scrutiny of the recommendations, and further helps to eliminate bias.

Transparency around the funding mechanisms for guidance development is an important step in establishing the potential for financial considerations to influence the guidance recommendations. If an organisation does not reveal the how its guidance development process is funded, it is difficult to ascertain whether the methods it uses to ensure editorial independence from the funding source are likely to be effective. For this reason, both transparency and editorial independence from the funding body are essential in eliminating bias that may arise from financial interests.

Information that addresses these points may be found on the guidance producer's website, published accounts, or in the guidance in sections describing the development and funding of the product. Examples of commonly labelled sections or chapters in the guidance where this information can be found include: methods, conflicts of interest, guidance panel/team, and appendix.

Questions and considerations

What measures were taken to minimise the influence of competing interests on guidance development or formulation of the recommendations?
Have all areas open to bias been considered and measures put in place to reduce or remove bias?

Suggestions for guidance content include:
• a description of the types of competing interests considered
• the methods by which potential competing interests were sought
• a description of the competing interests
• a description of how the competing interests influenced the guidance production process and development of recommendations.