NICE National Institute for Health and Care Excellence

Accreditation process manual

Process manual for accrediting producers of guidance, advice and recommendations for practice: a guide for producers and stakeholders

Final version
Updated: November 2014
Review date: November 2017

About this document

This document is for accreditation applicants and all those interested in the NICE accreditation process. It describes the types of guidelines eligible for accreditation and NICE's procedure to assess the quality of the processes guidance producers follow to develop guidance for practice.

The document replaces 'Process manual for accrediting producers of guidance, advice and recommendations for practice (published May 2013).

Nothing in this document shall restrict any disclosure of information by NICE that is required by law (including in particular but without limitation the Freedom of Information Act 2000).

National Institute for Health and Care Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester M1 4BT

Produced by the National Institute for Health and Care Excellence
First issued September 2009 (Last updated November 2014)

Contents

1 Introduction

NICE, established under the Health and Social Care Act 2012, is the executive Non Departmental Public Body responsible for providing guidance and advice to support health and social care commissioners, providers and others to make sure that the care and preventative services provided are of the best possible quality and offer the best value for money. NICE has a statutory role that encompasses the development of quality standards, advice, information and recommendations about NHS, public health and social care services. NICE provides independent, evidence-based guidance on the most effective ways to prevent, diagnose and treat disease and ill health and reduce health inequalities and variations. NICE guidance on public health topics makes recommendations for populations and individuals on activities, policies and strategies that can help prevent disease or improve health.

The accreditation programme assesses the quality of the processes followed by **guidance producers** to develop **guidance**. This enables users to recognise information sources of the highest quality, and to raise guidance standards in the longer term. A seal of approval – the Accreditation Mark – is awarded to guidance producers if their processes meet the accreditation criteria. Accreditation does not accredit guidance content.

For the purposes of the 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 might include products described in a number of ways, for example:

- clinical and public health guidelines
- healthcare technology guidance
- referral guidelines
- policy guidance
- clinical summaries
- commissioning guidance
- medicines practice guidance

- social care guidance
- clinical decision support content
- safety guidance

This manual describes the procedure for accrediting the processes used by guidance producers to develop guidance. It covers, but is not limited to, the scope for accreditation, the criteria used in the accreditation assessment, the main steps in the process for reaching an accreditation decision, and the notification and publication of an accreditation decision.

Information about accreditation can be found on the NICE website. It includes the documents needed to make an application, hints and tips to prepare an application, case studies of accredited organisations, information on the **Accreditation Advisory Committee**, an overview table detailing all organisations that have applied for accreditation, the status of each application and those organisations that have been accredited.

Words and phrases in bold are explained in the glossary (appendix B).

2 Aims, scope and approach

2.1 Aims and scope

The purpose of **accreditation** is to help users identify the most trusted sources of guidance that have been developed using critically evaluated high-quality processes. In the long term, this will improve the quality of information produced for health and social care decision-makers and used in **NICE Quality Standards**. This should ultimately result in improved patient outcomes.

The accreditation programme assesses the processes by which guidance is developed and not the content.

The accreditation programme assesses the processes by which guidance is developed and not the guidance content. However, individual pieces of guidance produced via an accredited process will bear the **Accreditation Mark**.

2.2 Eligibility and qualifying for accreditation

To be eligible for accreditation, guidance producers must:

- Produce guidance for practice. Products must be developed following systematic processes that are informed by the best available evidence.
- Provide, with their application, both a comprehensive list of all guidance developed to the process under assessment and also example(s) of guidance. Where possible, a minimum of two guidance examples is requested.

It is recommended that guidance producers contact the accreditation team at NICE to verify their eligibility for accreditation before completing and submitting the application form. If eligible, the guidance producer will be invited to enter the accreditation process. In cases of uncertainty, the Accreditation Advisory Committee will decide whether guidance producers qualify for the accreditation process.

A guidance producer may apply to be accredited for more than one guidance development process. In most cases, a separate application needs to be submitted for each process. The accreditation team can advise when a separate application is required.

Commercial organisations that produce guidance are eligible to apply for accreditation but a fee may be incurred. All non-UK applicants will be charged a registration fee to apply. Please refer to section 3.3 for further information about fees.

The accreditation team may also directly invite guidance producers to enter the accreditation process. This invitation may be based on advice from the Accreditation Advisory Committee, taking into account a number of factors, including support for other NICE programmes such as Quality Standards, target audience, type of guidance produced, coverage of topic areas and estimated usage. In some cases, this invitation may apply to a process to produce an individual product only.

2.3 Accreditation recommendations

Accreditation recommendations are made by the Accreditation Advisory Committee, which operates as a standing advisory committee of the NICE Board. The committee submits its recommendations to the NICE Publications Executive, which acts under delegated powers of the NICE Board in considering and approving its recommendations. The committee advises NICE on a framework for accrediting the processes to produce guidance that should be recognised as trusted sources of information for people working in health and social care. The Chair of the committee is appointed by the NICE Board; meetings are conducted by the Chair or, in his/her absence, the Vice-Chair.

2.4 Criteria to achieve accreditation

The **accreditation criteria** are based on the Appraisal of Guidelines Research and Evaluation (AGREE) II instrument. The AGREE instrument was developed to assess the quality of individual clinical guidelines, and has been expanded to encompass other types of guidance that fit the definition for NICE accreditation (see section 2.2). The assessment criteria may be applied according to the focus of the guidance product under consideration. This allows for a complete assessment on a case-by-case basis. Please see appendix A for the types of guidance products and adaptation of the focus of the criteria where applicable. Please note that the list of guidance is not exhaustive and may be added to or amended over time.

2.5 Term of accreditation

The term of Accreditation lasts for 5 years from the date of the accreditation decision. Decisions also apply retrospectively to guidance produced under the accredited process in the previous 3 years, or from the time the process was instated in the previous 3 years. For example, if the guidance development process began, or was updated in 2009 and accreditation was achieved in 2010, the accreditation period would include any guidance produced from 2009 to 2015.

Four years into the 5-year accreditation period, a guidance producer will be contacted to consider accreditation renewal. Please see section 3.19 for further information on the renewal process.

2.6 Core principles of accreditation

NICE operates to a set of core principles of transparency, inclusiveness, independence, timeliness and regular review. In terms of the accreditation process, this means that:

- Recommendations for accreditation will be based on review and discussion of comprehensive information submitted by guidance producers. All information submitted is subject to rigorous assessment and analysis against a set of defined criteria designed to assess the processes used to develop guidance.
- Input from relevant external experts and health and social care professionals forms part of all processes.
- An independent Accreditation Advisory Committee makes accreditation recommendations on behalf of NICE and holds its meetings in public.
- Patients and carers are involved as lay members of the Accreditation Advisory Committee.
- Regular review of accreditation decisions and the process manual ensures that accreditation decisions are of continuing value.
- All recommendations are reviewed by the **NICE Publications Executive**, which ensures that due process has been followed in reaching the recommendations.

2.6.1 Equality statement

NICE is committed to eliminating discrimination, advancing equality of opportunity, and fostering good relations.

NICE's equality scheme sets out how it is meeting these obligations on equality and discrimination and what it still needs to do.

3 Overview of the accreditation process

3.1 Summary of key stages in the process

Figure 1 summarises the key stages in the accreditation process, and the key party responsible for each stage. From acceptance of the application to publication of the final decision, the accreditation process takes on average 5 months for positive accreditation decisions and 8 months for negative accreditation decisions,.

Further detail on each of the steps in the accreditation process is provided in sections 3.2 to 3.4.

For transparency, information is published on the accreditation website summarising the applications that have been or are being considered for accreditation and the stage they are at. This information will remain in the public domain, even if the guidance producer decides to withdraw from the accreditation process.

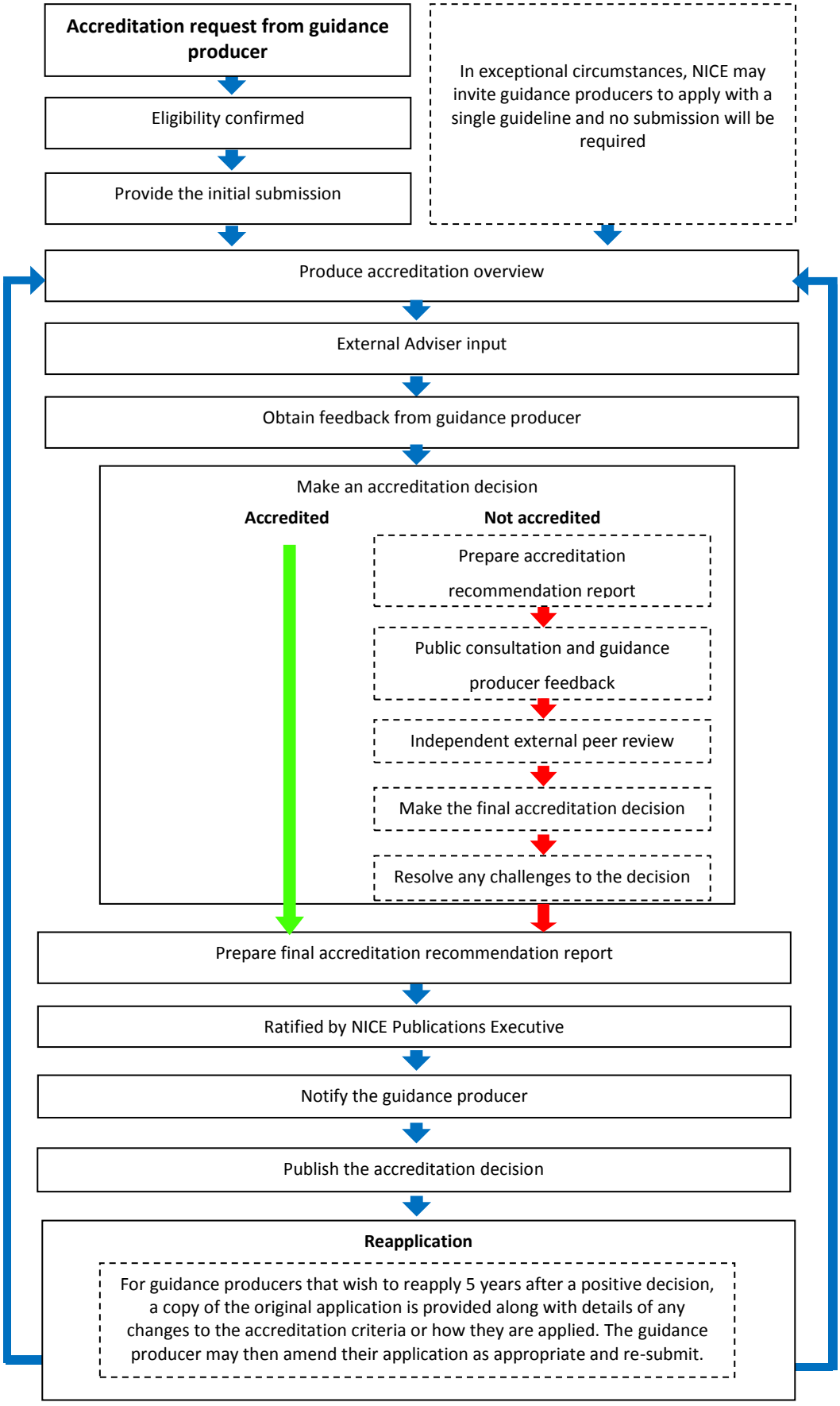
3.2 Pre-application support and advice

To help guidance producers assess their readiness for accreditation and understand how to apply, NICE has developed a range of pre-application support and advice services including:

- regular workshops in London and Manchester where the accreditation process, assessment criteria and pattern of decisions are explained in detail
- an advice service for eligible applicants, offering advice that is generic and based on experience of the accreditation process
- online tools and materials, available under tips and support on accreditation on the NICE website

A pre-application assessment can be performed at any point. However, all pre-application assessments are advisory only, based on learning from previous decisions and discussions: they do not constitute a recommendation to accredit. Only the NICE Accreditation Advisory Committee can recommend accreditation after consideration of the evidence put forward by a guidance producer.

Figure 1 Flowchart summarising the accreditation process



Commercial organisations will be charged for the pre-application service as detailed in section 3.3 on fees

3.3 Accreditation fees

Generally, applicants whose guidance content is freely available to the public will not incur a fee.

Commercial organisations that meet the definition for guidance, but whose guidance can not be made freely available via NICE Evidence services, will incur fees to access formal pre-application support and advice and to apply for accreditation.

On first contact, the accreditation team will confirm whether an organisation is commercial or not-for-profit and advise on next steps. For advice about fees and if they apply to your organisation, please search for 'accreditation service fees' on the NICE website and/or contact us at accreditation@nice.org.uk

Accreditation applications are welcome from non-UK English-language international guidance producers. Please note that there is a registration fee for all international applicants.

3.4 Providing the initial application submission

Eligible guidance producers are requested to complete an application form and provide evidence to show that they meet the criteria for accreditation. The guidance producer should ensure that all responses to the criteria are evidenced where possible. All evidence should be included with the submission.

In exceptional circumstances NICE may identify a single guideline that could be useful for NICE quality standards, if accredited. This may result in an invitation to apply. The assessment of the single guideline follows the same methodology, but no application is required. All subsequent assessment steps are followed, and if the process used to produce the guideline is of suitable quality it will be accredited.

The criteria are considered on a case-by-case basis depending on the type of guidance product under consideration. (See appendix A for a description of how the criteria may be interpreted for different guidance types.) In exceptional circumstances, not all criteria used to evaluate guidance processes may be applicable, and the degree of applicability may vary with the type of guidance product. In these cases, the Accreditation Advisory Committee will evaluate the extent of non-compliance and consider its effect on the accreditation decision. Guidance producers should give a full description of the reasons why they consider a criterion does not apply to their guidance. If a large number of criteria are judged not to apply to a particular guidance producer, the application may be deferred until a more suitable assessment instrument has been developed.

Particular attention should be paid to the searching and synthesis of the evidence on which the guidance is based, the processes around the involvement of patients and lay groups in the guideline development process and the removal of bias from all processes. The guidance producer should provide a documented policy or process for the production of guidance, a comprehensive list of guidance developed using this process and evidence that the process is implemented (such as audit information). The accreditation team will aim to look in detail at a representative sample (for example, 10%) of guidance produced using the process under consideration, to ensure consistent implementation.

The completed application is reviewed and any missing or additional information is requested from the guidance producer. The guidance producer may be requested to resubmit its application in some circumstances, for example:

- Multiple processes are described in a single application: the guidance producer will be asked to submit separate applications for each process.
- The accreditation criteria are not considered appropriate for the process or product that is the subject of the application (for example, if there are several non-applicable criteria): the guidance producer may be contacted at a later date if a

suitable accreditation instrument is developed, but will need to withdraw from the process in the interim.

Incomplete applications will not be accepted. Once all information required to complete an assessment is received, the application is accepted and an analyst assigned to begin the accreditation assessment. Withdrawal of the application can be made by the guidance producer at any time.

An accreditation user guide is available on the NICE website to provide further information on how to complete an application.

3.4.1 Guidance development collaborations

Guidance produced by collaboration may follow a unique process. Accreditation allows for the following different scenarios in which guidance producers may collaborate to produce co-badged guidance:

Scenario	Process for accreditation
A unique guidance development process is followed by 2 or more guidance producers (such as a joint working group).	An accreditation application is requested. In cases of joint guidance production, it is helpful to identify a lead guidance producer that will be the main point of contact for any queries that arise during the accreditation assessment process. The lead guidance producer will also be responsible for signing the terms and conditions of accreditation, should accreditation be awarded.
A guidance producer already seeking accreditation for a guidance development process is also actively involved as a	The specific guideline(s) should be covered by the accreditation decision for that process. To facilitate this, applicants

stakeholder in the development of another guideline that follows the same guidance development process.	should list in their application any co-badged guidance produced entirely according to the process under consideration so that the guidance is automatically covered if accreditation is granted.
An accredited guidance producer is either: a) collaborating with another guidance producer(s) to develop a guideline(s), or b) actively involved as a stakeholder on a guideline(s) being developed by another guidance producer and in both circumstances the guideline(s) is developed entirely according to the accredited process.	No application is needed. This will be covered by the existing accreditation. Confirmation must be received from the accreditation team before the Accreditation Mark can be used. To enable this, the accredited guidance producer must provide the accreditation team with full details of the guideline(s) and any relevant documentation. It is the sole responsibility of an accredited guidance producer to ensure its process is fully adhered to in guidance collaborations. Any new guideline(s) covered by an existing accreditation can be used to assess continued compliance with accreditation terms and conditions. If any guideline(s) bearing the Accreditation Mark breach the accredited process, accreditation will be revoked.
All other scenarios.	The guidance producer must contact the accreditation team for advice, detailing the nature of the collaboration and their involvement.

	Where there is uncertainty about which process guidance production is following, an accreditation application may be requested at the discretion of the Accreditation Advisory Committee.

3.5 Producing the overview

The submission provided by the guidance producer is assessed and validated against the accreditation criteria by an accreditation technical analyst. The analyst prepares an overview document that describes how the guidance producer's processes for guidance development meet the assessment criteria. The overview is an analysis of compliance with the criteria, not an accreditation recommendation.

Assessment against the criteria may be different, depending on the process used to develop the guidance and the type of guidance product under consideration. Because of the variety of guidance producers eligible to apply for accreditation, appendix A demonstrates how the criteria may be applied to allow a full and robust evaluation of the processes used for different types of guidance. The accreditation technical analysts evaluate whether the criteria that are considered relevant and necessary for the type of guidance product have been met.

When the assessment is of a process used to produce only one guideline, there may be a requirement to ask the guidance producer for further evidence of the process.

3.6 External adviser input

In order to provide an independent and reliable assessment, the overview and original submission are seen by at least 2 external advisers.

External advisers are selected to review an application based on their expertise and experience. The pool of external advisers is reviewed annually and new advisers will be recruited when required. A list of the current advisers can be found on the NICE website.

Typically, external advisers have up to 3 weeks to review the overview document produced by the analysts, depending on whether the guidance development process is for producing single or multiple guidelines. They provide a report that evaluates the assessment of the guidance producer's process and adherence to accreditation criteria. The external advisers also have access to the application form and supporting information submitted by the guidance producer. Their responses are made available to the Accreditation Advisory Committee and are further information to aid decision-making.

The external advisers have expertise and experience in guidance development and methodology, and may have experience in one or more of the following: implementation or evaluation in a clinical, practice, commissioning, social care, public health, or healthcare industry setting, and may also have expertise in a specific topic or subject area. People wishing to become an external adviser should check their eligibility and apply to be an adviser.

The names, job titles and professional affiliations of the external advisers involved in a specific accreditation decision are published in the accreditation decision reports (see sections 3.9 and 3.12).

3.7 Obtaining feedback from guidance producers

Guidance producers are invited to review the overview and external adviser reports before submission to the Accreditation Advisory Committee. The guidance producer is sent copies of the documents and a response template by the accreditation team and is requested to respond, typically within 20 working days. The actual amount of time allocated depends on the application under consideration. The guidance producer's feedback is provided to the Accreditation Advisory Committee along with the overview document and external advisers' reports. Depending on the nature of the feedback and accompanying evidence, some of the criteria assessments may change.

3.8 Making an accreditation decision

A submission report summarising the findings of the initial **accreditation overview**, the external advisers' comments and the guidance producer's feedback is prepared by the accreditation technical analyst and provided to the Accreditation Advisory Committee.

In the committee meeting the analyst summarises the key findings from the assessment and feedback. Public attendees are welcome to observe the Accreditation Advisory Committee meetings. Members of the public can register to attend a meeting as an observer. People interested in observing an Accreditation Advisory Committee meeting can check availability and view dates of forthcoming meetings on the meetings in public section of the NICE website. For the benefit of the public attendees slides that summarise key discussion points in each submission are shown at the Accreditation Advisory Committee meeting.

The Accreditation Advisory Committee is a group of experts providing authority, expertise, advice and guidance on accreditation. The committee members assess the information on guidance development processes and implementation prepared by the accreditation technical analyst and commented on by external advisers. Committee members discuss any issues, questions or concerns about a guidance development process and implementation from the information provided. The meetings provide a forum for open debate, authoritative questioning and active involvement in highlighting any areas of uncertainty.

The Accreditation Advisory Committee considers all of the evidence provided and makes a recommendation on whether to accredit the guidance producer. The recommendations of the committee will normally be arrived at by an informal consensus of those members present. The use of consensus as a method of arriving at a recommendation allows for all issues to be discussed. In line with the Terms of Reference, the committee makes its decisions on the weight and strength of the process information provided by a guidance producer in its response to the accreditation criteria and the consistency of implementation of this process.

The Chair of the committee will ensure all relevant factors are discussed with the committee, and instruct them to take these into account. In exceptional circumstances, when a decision cannot be made on the basis of consensus, there will be voting by secret ballot. In the event of a tie, the Chair of the committee has a second casting vote.

Accreditation Advisory Committee meetings may be held entirely in public or split into a part 1 session, for which the public are present, and a part 2 session, from which the public are excluded. The Accreditation Advisory Committee discusses the accreditation submission in a part 1 session but takes a decision on the accreditation recommendation in a part 2 session. For further information regarding what would constitute a part 1 or part 2 session, see section 5.1.2.

The quorum is set at 50% of committee membership. The decision-making process during each committee meeting is moderated by the Chair. All decisions made in a meeting are publicly announced at the next available meeting and recorded in the minutes of that meeting.

During the decision-making session, the Chair invites the committee to sum up the key reasons for reaching an accreditation decision. The accreditation technical analyst ensures that this information is incorporated into the **accreditation report** to be relayed to the guidance producer.

The Accreditation Advisory Committee's decision-making is underpinned by the core principles of accreditation (see section 2.6). The decision is based on the guidance producer meeting the relevant and necessary accreditation criteria for the type of guidance product, and is not based on an absolute or threshold scoring system.

The guidance producer may be asked to provide more information or respond to points of clarification before a recommendation can be made. Guidance producers are therefore encouraged to attend part 1 of the Accreditation Advisory Committee meeting in person where their application will be discussed, so that they will be able to answer questions on points of clarification if asked. Up to 2 representatives will be

allowed for any 1 accreditation application. The Chair will ask guidance producers to respond to questions from the Accreditation Advisory Committee. For further information regarding what constitutes a part 1 or part 2 session, see section 5.1.2.

Each representative will be expected to have:

- relevant detailed knowledge of the guidance process under discussion to engage effectively with the Accreditation Advisory Committee
- knowledge and understanding of the accreditation programme, particularly the assessment criteria
- knowledge and understanding of the guidance producer's responsibilities when attending a committee meeting, particularly any confidential aspects of the discussion.

Further information about registering to attend committee meetings is available in section 5.1.1.

When the committee needs further information to make a recommendation and this cannot be provided by the guidance producer at the meeting, the recommendation will be postponed. The guidance producer will be asked to respond to specific issues and provide further information to address the remaining concerns of the committee. Once the extra information has been received by the analyst, it is reviewed at the next Accreditation Advisory Committee meeting to allow a recommendation to be made.

3.9 Preparing an accreditation recommendation report

After the Accreditation Advisory Committee meeting, the accreditation technical analyst prepares an accreditation recommendation report that summarises the reasons for the committee's recommendation on the guidance producer's submission for accreditation.

Accreditation Advisory Committee recommendations to accredit a guidance producer's process are considered final decisions; there is no public consultation, and the process proceeds to notifying the guidance producer of the final decision

(section 3.13). If the committee recommendation is not to accredit, the process continues to public **consultation** and guidance producer feedback (section 3.10).

3.10 Public consultation and guidance producer feedback

Public consultation will only be requested for cases where the committee recommends not to accredit. This allows both the guidance producer and all interested parties the opportunity to comment and if necessary provide further information for consideration by the Accreditation Advisory Committee.

The draft accreditation report, including the draft accreditation decision and a consultation comments proforma, is published on the accreditation section of the NICE website for public consultation for 20 working days.

Subject experts, specialist patient groups and potential service/end users of guidance will be identified, contacted and invited to comment on the consultation.

The accreditation recommendation report is also sent for independent external peer review (section 3.11).

3.11 Independent external peer review

To ensure an independent, impartial view, the negative recommendation report is sent to a minimum of 2 new independent external advisers. External advisers have 1 week to peer review the information and complete a peer review recommendation report advising whether they agree or disagree with the committee recommendation and why.

If the committee recommendation is not supported at peer review, or if significant additional information is provided by the guidance producer, the application is taken back to committee for further discussion before making a final decision (section 3.12). If the committee recommendation is supported, and there is no significant additional information from the guidance producer or consultation, the application does not go back to committee; instead, the recommendation is sent to the NICE

Publications Executive for approval. The process then proceeds to ‘Notifying the guidance producer’ (see section 3.13).

3.12 Making the final accreditation decision

If the recommendation not to accredit is not supported at peer review, the committee will consider any comments, review their decision and make an informal consensus decision as in section 3.8. Once again, a vote will be taken in exceptional circumstances. This decision is incorporated into a final accreditation report and sent to the NICE Publications Executive for approval. The accreditation recommendation report and peer review recommendation report will be summarised in the published final report.

Depending on the nature of the peer review recommendation report, the final accreditation decision may differ from the earlier recommendation.

3.13 Notifying the guidance producer of the final decision

Once a final accreditation decision has been reached and the report approved by the NICE Publications Executive, the guidance producer is sent a copy of the final accreditation report with a covering letter as notification of the decision. The guidance producer has 20 working days from the date the report is sent to challenge the decision.

3.14 Publishing the final accreditation decision

If accreditation has been granted, the guidance producer is invited to sign up to the necessary **terms and conditions** (provided separately). This document includes a statement about ensuring the same processes will continue to be used to produce the guidance documents that were considered during the accreditation assessment, and that any deviation from this process will be notified to the accreditation team. The final accreditation report, incorporating the final accreditation decision, is submitted to the NICE Publications Executive for sign-off before publication. The NICE Publications Executive ensures that due process has been followed in the development of the accreditation decision.

If the NICE Publications Executive authorises publication, the final accreditation report is published on the accreditation pages of the NICE website, regardless of the accreditation decision. If accreditation has been granted, the guidance producer's current guidance which has been produced following the accredited process, may bear the Accreditation Mark. Content that is developed by guidance producers that do not receive accreditation continues to be available through NICE Evidence, where applicable (non-accreditation does not result in a producer's content being removed from NICE Evidence).

If the NICE Publications Executive requests a clarification, the final accreditation report is updated as required and the accreditation decision may be reconsidered by the Accreditation Advisory Committee. Depending on the request, amendments may be approved by the Accreditation Advisory Committee Chair.

3.15 Resolving any challenges to the decision

The **resolution process** is a final quality assurance step, intended to ensure that the accreditation process is fair and that accreditation decision-making has not unreasonably deviated from the process described in this document.

3.15.1 Resolution grounds

The **Resolution Panel** (see section 3.15.4) will only consider resolution requests made by the guidance producer on the grounds that there has been a 'breach of process'. See section 3.20 for the procedure for queries, feedback and complaints.

3.15.2 Resolution requests

Guidance producers have 20 working days from the date they are notified of the final accreditation decision to request resolution by email, fax or letter to the Associate Director for accreditation. The guidance producer may also request a resolution at any point in the accreditation process. The request should specify the breach of process and provide supporting information so that NICE can fully understand the nature of the concern and provide an appropriate remedy if there has been a breach

of process. The Resolution Panel will not consider a resolution request unless the grounds for resolution are clearly identified and stated.

If a resolution request is received, publication of the accreditation decision is suspended pending an investigation of the request. If no request is received, the accreditation decision is published as soon as possible thereafter.

3.15.3 The initial scrutiny process for resolution requests

All resolution requests are subject to an initial scrutiny process. The Director of Health and Social Care will decide whether the request falls within the scope of the resolution process, that is, a breach of process has been identified. The initial scrutiny process will be completed within 20 working days of the close of the resolution period.

If on initial scrutiny the Director of Health and Social Care considers that there has been no breach of process, or that the request does not have a reasonable prospect of success, the Associate Director for accreditation relays this decision to the guidance producer and the accreditation decision proceeds to publication. If the Director of Health and Social Care considers that there has been a breach of process, a meeting of the Resolution Panel is convened within 20 working days of the conclusion of the initial scrutiny process.

More than one resolution request may be received for an accreditation decision, but not all requests are referred to the Resolution Panel. For the requests that have been referred to the panel, the guidance producer will be informed that the panel is to be convened, and that they will be told of the outcome of their request at a later date, when the outcome of the panel is known. This is to avoid pre-empting the outcome of resolution.

3.15.4 The Resolution Panel

The Resolution Panel consists of three NICE Board members (including a non-executive director and an executive director not previously involved in the accreditation decision). The Resolution Panel decides whether there has been a

breach of process and, if so, what action is appropriate. The Resolution Panel will be chaired by the Director of Health and Social Care. In the event of there being a resolution request that relates to NICE guidance, an independent panel will be convened.

3.15.5 Meetings of the Resolution Panel

The accreditation team prepares a briefing for the Resolution Panel which forms the basis for its consideration of the resolution request. This involves establishing the events or omissions that have been alleged by the party requesting resolution on breach of process grounds.

The Accreditation Advisory Committee Chair and Associate Director for accreditation attend the Resolution Panel meetings to provide clarification, if needed. The Accreditation Advisory Committee Chair is not a member of the panel and does not formulate the outcome of resolution. Members of the accreditation team may also be required to attend to answer questions from the Resolution Panel members.

3.15.6 The outcome of resolution

The Resolution Panel will find either that there has been no breach of process and that the final accreditation decision can be published as proposed, or that there has been a breach of process.

If there has been a breach of process, the Resolution Panel decides what action is appropriate to remedy the breach. This is likely to mean repeating the accreditation process from a certain step, including, where necessary, consideration of the decision by the Accreditation Advisory Committee.

The decision reached by the Resolution Panel is final.

3.15.7 Communicating the outcome of resolution

The Associate Director for accreditation implements the panel's decision and informs the guidance producer of the outcome of resolution. This normally occurs 3 working days before the publication of the final accreditation decision. When resolution is

requested before the final accreditation report stage, the Associate Director for accreditation will inform the guidance producer of the outcome of the resolution no later than 2 working days. If the Accreditation Advisory Committee needs to reconsider the accreditation, the guidance producer will be notified.

3.16 Interim visit

An interim visit, between relevant member(s) of the accreditation team and the guidance producer, will take place between 36 and 48 months after accreditation is awarded. The purpose of this visit is to discuss and review the following:

- any changes/developments to the guidance producer's accredited process
- progress with any recommendations made by the Accreditation Advisory Committee when accreditation was awarded
- readiness to apply for accreditation renewal.

The timing of the interim visit will be guided by discussions with the guidance producer and arranged by the accreditation team. In advance of the meeting an 'interim visit form' will be sent to the guidance producer for completion. Following the interim visit any identified process changes will be reviewed by the technical team to ensure that the process continues to comply with accreditation terms and conditions. Guidance producers are also encouraged to contact the accreditation team ahead of the interim visit if they need any support or advice on process changes.

3.17 Notifying process changes

Throughout the accreditation period, accredited guidance producers are expected to inform the accreditation team if there are any changes in their process that may require an assessment to ensure that there is no lowering of previous standards. Guidance producers must inform the accreditation team of any change to a process, organisation or governance that may affect the fulfilment of the relevant accreditation criteria within 30 days of that change occurring.

If an accredited guidance producer concludes that there is a reasonable possibility that any of the relevant accreditation criteria are no longer met, it will notify the accreditation team with an explanation of what change has occurred and how the fulfilment of the accreditation criteria may be affected. The guidance producer must complete a 'Change to process' notification document, which clearly outlines the changes in the process and describes the intent and impact of the changes. The guidance producer should show that the changes do not affect compliance with the accreditation criteria. When the changes do affect the accreditation criteria, the guidance producer must explain how and why in order to allow reassessment to ensure that the process change is not detrimental to the guidance development process. Where the changes may affect the accreditation decision, a submission report outlining the changes to process is produced describing the impact on the criteria and accreditation decision. These reports may be considered by the Accreditation Advisory Committee and, if required, the NICE Publications Executive, and are published on the accreditation pages of the website.

The accreditation team may review process and developed guidance if at any point concerns are raised about changes that do not meet previous standards, or if evidence is provided that challenges the accreditation decision. Please see section 3.20 for the feedback and complaints procedure. The assessment procedure will take the form of an assessment of the criteria affected by the change in process. If the outcome of the assessment upholds the concern, the Accreditation Mark may be removed.

3.18 Reapplying for accreditation

Guidance producers that are not accredited after the accreditation process have the opportunity to reapply. It is assumed that the guidance producer will have addressed any concerns highlighted in the original assessment before reapplying. The accreditation team provides a debrief meeting for constructive feedback and advice to help the guidance producer address these issues. Following a negative decision a guidance producer will be contacted 3 months before the date of acceptable reapplication. The process of reapplication is the same as that used for the initial

accreditation application. The Accreditation Advisory Committee will consider the circumstances and advise on whether a reapplication within 1 year is acceptable.

3.19 Accreditation renewal

Twelve months before the end of the 5-year accreditation period, the guidance producer will be contacted by the accreditation team to inform them of the upcoming expiry of the accreditation term. The guidance producer will be asked to confirm if it intends to apply for accreditation renewal.

If the guidance producer confirms that it will apply for accreditation renewal, the accreditation team will return the previous application form and any other relevant documentation to the guidance producer. The guidance producer is expected to update and resubmit the application form, which will include any changes to its process or organisation (if significant). The guidance producer should state which version of its process manual is current, provide a copy for assessment, and produce a full list of guidance produced following this process. The accreditation team will undertake a full review as for the initial accreditation. Guidance producers are expected to demonstrate maintenance and continuing progress in their guidance development process; otherwise, accreditation may not continue.

The accreditation renewal application may be submitted up to 6 months before the accreditation term expires. In exceptional circumstances, where there is an organisational barrier to applying for renewal before accreditation expires, a grace period may be granted. To request this, the guidance producer must submit a formal request to the Accreditation Team, at least 6 months before accreditation expires, clearly outlining the reasons. Grace periods are granted at the discretion of the Accreditation Advisory Committee Chair.

If the guidance producer confirms it will not apply for accreditation renewal at the end of the term, the guidance producer will be expected to stop using the Accreditation Mark at the appropriate expiry date in line with the agreed accreditation terms and conditions. Existing guidelines already carrying the Accreditation Mark will remain

accredited as they were produced to an accredited process. Any guidelines produced to this process after the expiry date will not carry the Accreditation Mark.

NICE keeps the accreditation criteria under review and criteria may be updated (for example, in line with an update to the AGREE criteria) in the future as part of a review of this process manual. Guidance producers will be notified of any changes to the accreditation criteria at the earliest opportunity to ensure that they can make any necessary amendments or developments to their processes. The timing of any changes in relation to application for renewal will also be considered.

Any changes will not be applied to guidance producers that are already accredited until they are required to apply for renewal of accreditation.

3.20 Feedback and complaints procedure

The accreditation team routinely seeks feedback on the accreditation process from guidance producers that have been through the accreditation process. An accredited guidance producer may be contacted and asked to provide further feedback on the benefits of accreditation.

More general feedback, in the form of queries or complaints about the accreditation processes or decisions, may be sent to accreditation@nice.org.uk or nice@nice.org.uk. A response will be sent within 20 working days.

If the comment is a complaint about an accreditation decision or evidence is provided that challenges a decision, the accreditation team may undertake a review of a guidance producer's process. A review may take place at any time if a complaint is received, and may justify an interim reassessment and presentation to the Accreditation Advisory Committee before formal expiry of the 5-year accreditation award. If the complaint is upheld, accreditation may be removed.

4 Who is involved in the accreditation process?

Table 1 Key participants in the accreditation process

Accreditation Advisory Committee	The Accreditation Advisory Committee operates as a standing committee. It receives, considers and reviews information on guidance producers and independently accredits guidance development processes. The Accreditation Advisory Committee submits its accreditation recommendation to the NICE Publications Executive which acts on behalf of the NICE Board to consider and approve the recommendation. The Accreditation Advisory Committee comprises up to 30 members with a range of expertise including at least 2 lay members, all independent of NICE. The Committee meets up to 6 times per year. Committee meetings are open to members of the public and agendas and minutes of the meetings are made publicly available. The minutes are a summary record of the main points discussed at the meeting and recommendations made. The key roles of the Accreditation Advisory Committee include: • determining which guidance producers qualify to enter the accreditation process • reviewing the overview, the opinion of the external advisers, and any feedback from the guidance producer to reach a draft accreditation recommendation • reviewing feedback from external advisers to make the final accreditation recommendation.
Guidance producer	The guidance producer is the accreditation applicant. Guidance producers prepare 'systematically developed statements to guide decisions about appropriate health and social care to improve individual and population health and wellbeing.' The key roles of the guidance producer include: • submitting an application for accreditation • providing the information necessary to perform the accreditation assessment (proforma and supporting documentation) • reviewing the overview document prepared by the accreditation team and providing feedback • reviewing the final accreditation report and decision • complying with the Terms and Conditions.
Accreditation team	The accreditation team comprises the Associate Director for accreditation, technical and project staff and coordinators. The

	accreditation team is accountable to the Director of Health and Social Care. Key roles of the accreditation team include: • engagement with guidance producers before, during and after the accreditation process • reviewing and validating the information provided by guidance producers and requesting additional information if necessary • preparing the overview based on the guidance producer's submission, which provides an analysis of compliance with the criteria • preparing the submission report for consideration by the Accreditation Advisory Committee • preparing the draft and final accreditation reports, incorporating the outcomes and decisions from the Accreditation Advisory Committee meetings • notifying the guidance producer of the Accreditation Advisory Committee's draft and final accreditation decision.
External advisers	The external advisers are individuals who have expertise and experience in guidance development. They may also have expertise in a specific subject or topic area. The key role of the external advisers is to review the overview of the guidance producer's submission and provide an independent opinion on the content and findings before and after committee decision.
Resolution Panel	The Resolution Panel consists of three NICE Board members (a non-executive director and an executive director not previously involved in the accreditation decision). The Resolution Panel decides whether there has been a breach of process and, if so, what action is appropriate. The key role of the Resolution Panel is to resolve any legitimate challenges to the final accreditation decision.
NICE Publications Executive	The NICE Publications Executive is an executive committee that acts under delegated authority of the NICE board to review and approve documents for publication and ensure the accreditation process has been followed. The key role of the NICE Publications Executive is to review and approve the publication of the final accreditation reports.

4.1 Membership of the Accreditation Advisory Committee and appointing members

The Accreditation Advisory Committee comprises up to 30 voting members, including the Chair. The Accreditation Advisory Committee Chair and members are recruited through open advertising and are appointed initially for a 3-year term. Membership represents potential users of the services such as clinicians, commissioners, health and social care practitioners and experts in relevant areas of work including research, evidence, methodology and knowledge. It also includes lay representation.

Membership may be extended for a further 3 years by mutual agreement, up to a maximum of 10 years. A list of current members is published on the NICE website. Full details of membership recruitment can also be found.

NICE is committed to the values of equality and diversity and welcomes applications for membership of the Accreditation Advisory Committee from all sections of the community.

Members of the Accreditation Advisory Committee and other individuals attending the committee meeting must declare any interests. This is recorded in the minutes. For further information on how NICE deals with conflicts of interest, please see the NICE policy on conflicts of interest.

The Accreditation Advisory Committee membership does not include individuals from groups who have a significant commercial interest in the development of competitor knowledge products or other evidence suppliers.

Membership may vary in accordance with the needs of the Committee. Additional specialist committee members may be invited to join the standing members for an accreditation application decision. Standing and specialist committee members will have full voting rights and will count towards the quorum.

Additional experts may also be invited to attend to advise the Accreditation Advisory Committee meeting on a topic-specific basis to assist in the consideration and interpretation of evidence. They do not have voting rights and do not count towards the quorum.

5 Transparency

NICE is committed to making the process of accreditation transparent to its stakeholders.

5.1 Public access to meetings of the Accreditation Advisory Committee

Holding the Accreditation Advisory Committee meetings in public supports NICE's commitment to openness and transparency, and demonstrates that the process of accreditation is rigorous and independent. It helps **stakeholders** to understand the basis for accreditation decisions, and illustrates how the Accreditation Advisory Committee takes into account all of the evidence submitted.

Public access to meetings of the Accreditation Advisory Committee is granted in accordance with NICE policies and subject to the standing orders of the Accreditation Advisory Committee.

5.1.1 Arranging attendance

A notice will be published on the NICE website announcing each Accreditation Advisory Committee meeting 20 working days before the meeting. The notice includes:

- the date, time and place of the meeting
- a list of all agenda items
- the contact details of the coordinator responsible for meetings in public

Members of the public may apply to attend a meeting through the NICE website or by post. Up to 20 places are available for each meeting, depending on the size of the venue.

To enable wider public access, up to 2 representatives per organisation are allowed to attend; however, when a meeting is oversubscribed, attendance may be limited to 1 representative per organisation.

When the meeting agenda has been finalised, the applicants are contacted to let them know whether or not a place has been made available to them. The invitation includes information on admission to the building where the meeting is to be held and also how the meeting will be conducted.

If due to unforeseen circumstances the agenda is changed, the meeting is cancelled or the meeting time or location has to be moved, this will be posted on the NICE website as soon as possible, and registered delegates will be contacted.

5.1.2 How meetings are conducted

Meetings of the Accreditation Advisory Committee are normally held at NICE's offices in London or Manchester. Provision will also be made at all Accreditation Advisory Committee meetings for any attendees with audio or visual impairments, such as hearing loops and papers in alternative formats.

Accreditation Advisory Committee meetings may either be held entirely in public or split into a part 1 session, for which the public are present, and part 2 sessions, from which the public are excluded. The Accreditation Advisory Committee discusses the accreditation submission in a part 1 session but takes a decision on the accreditation recommendation in a part 2 session. The reasons for holding part 2 sessions are because:

- the accreditation recommendation should remain confidential until the guidance producer is informed
- the Accreditation Advisory Committee may be considering commercial- or academic-in-confidence information
- the Accreditation Advisory Committee may be considering guidance producer submissions where these have been submitted under conditions of confidentiality
- the decisions made by the Accreditation Advisory Committee are commercially sensitive.

All decisions are announced publicly at the next available meeting.

5.2 Access to documents used in accreditation process

To ensure that the process is as transparent as possible, evidence relevant to the Accreditation Advisory Committee's discussions and decisions is made publicly available. All draft and final accreditation reports are therefore published on the accreditation pages of the website. The Accreditation Advisory Committee agendas and minutes are also published. Slides summarising key discussion points for draft and final recommendations are available to public attendees of committee meetings to allow public attendees to understand the issues for discussion.

5.3 Use of confidential data

Normally, the accreditation decision is made based on publicly available information. However, occasionally it may be necessary for the Accreditation Advisory Committee to review confidential data in order to assess a guidance producer. This may happen at any stage in the accreditation process. If a guidance producer considers that unpublished data should be marked as either 'commercial' or 'academic in confidence', the rationale for doing so should be clearly stated and should be consistent with the principle set out below.

The accreditation team will ask data owners to reconsider restrictions on release of data when there appears to be no obvious reason for the restrictions, or when such restrictions would make it difficult or impossible for the accreditation team to show the evidential basis for its accreditation decisions.

In order to be ‘confidential’ the information must be:

- of limited public availability, and
- capable of clear definition, and
- disclosed to the accreditation team in a situation that entails an obligation of confidence (this includes information that is passed to the accreditation team where NICE has undertaken, by virtue of a confidentiality agreement, to keep that information confidential or where the circumstances are such that it is clear that NICE should keep the information confidential for a third party).

5.4 Freedom of Information Act 2000

Nothing in this document will restrict any disclosure of information by NICE that is required by law (including, in particular but without limitation, the Freedom of Information Act 2000).

6 Updating the accreditation process manual

The accreditation team will review and update (if required) this document every 3 years. If significant changes are needed before the 3-year review date, the revised process will be subject to a 3-month public consultation.

It may also be necessary to make minor changes to the accreditation process before 3 years. Minor changes that may be made without consultation are those that:

- do not add or remove a fundamental stage in the process
- do not fundamentally alter the criteria used for accreditation
- do not add or remove a fundamental technique or step
- will not disadvantage one or more stakeholders
- will improve the efficiency, clarity or fairness of the process or methodology

Changes meeting these criteria will be published on the accreditation pages of the NICE website 20 working days before their implementation. The electronic version of this document will also be updated at that time and a note to this effect placed on the front page.

Any other changes will only be made after a 3-month public consultation.

Final version: November 2014

Review date: November 2017

Appendix A: Criteria for the accreditation programme

The accreditation criteria provide a framework for assessment by the accreditation team and the Accreditation Advisory Committee of the quality and rigour of the process used by guidance producers to develop guidance. These criteria are based on the AGREE Instrument[1]. The criteria focus on the process used for developing guidance rather than the content of individual guidance or products. Nevertheless, as part of the assessment process, guidance producers are expected to provide a comprehensive list of guidance developed using this process; a number of examples of guidance (approximately 10% of all examples available produced via the process under assessment for accreditation) may be examined in detail to assess the practical application of their methodology and process.

There are 25 key assessment criteria, organised in 6 domains. Each domain is intended to capture a separate dimension of the quality of the process used to develop guidance. Table 2 describes each of the 6 accreditation domains and their associated assessment criteria. Guidance producers are assessed to review the extent to which their process for developing guidance meets these criteria. In addition, the accreditation technical analysts evaluate an arbitrarily selected sample of guidance to ensure that the guidance producer's processes are implemented consistently.

To ensure the methodology and criteria are based on the best available evidence and able to consistently improve the standard of guidance produced, the NICE accreditation team will regularly scan international criteria.

The accreditation criteria are based on the AGREE Instrument, which was developed to assess the quality of clinical or practice guidelines. The NICE accreditation team has adapted the instrument to cover a wider range of guidance, and to focus on

[1] The AGREE Collaboration. Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al for the AGREE Next Steps Consortium (2010) AGREE II: Advancing guideline development, reporting and evaluation in healthcare. Canadian Medical Association Journal

development processes. Please note that this is a guide only and each application is considered on its own merits according to the type of guidance, audience and organisation.

Table 2 Accreditation domains and criteria

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
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	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 producer 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 producer to consider the health benefits, side effects and risks in formulating recommendations 3.6 Describes the processes of external peer review 3.7 Describes the process of updating guidance and maintaining and improving guidance quality
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
5. Applicability deals with the likely organisational, behavioural and cost implications of applying the guidance.	These criteria consider whether the guidance producer routinely considers: 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 Reviewing criteria for monitoring and/or audit purposes within each product

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 1: Scope and purpose

The following is a guide to how accreditation criteria are applied to the processes used to develop guidance.

The Accreditation Advisory Committee is looking for explicit statements and supporting information that describe the processes used to define the scope and purpose of guidance. In addition to the information covered in any policy or process manuals, the Accreditation Advisory Committee will be looking for examples within guidance documents that clearly illustrate:

- The overall objectives of the guidance. For example, for commissioning guidance, objectives such as quality outcomes, patient experience and deliverables expected should be stated. For medicines information, this may be specific to a particular drug or drug class, or be wider in the case of a formulary. The overall objective may be a high-level organisational objective – for example, for safety guidance it may simply be to keep a population safe or for policy guidance it may be specific to a training standard, population or a set of methods to follow.
- A detailed description of the key questions answered in the guidance, particularly for the key recommendations. For example, there should be descriptions of how processes for topic selection and scoping guidance take into account issues related to equality (race, disability, gender or age in defining the population and/or target audience, and by promoting equality in guidance). The key question covered by guidance may be a more general question relating to the efficacy or safety of a medicine or group of medicines, more general health or wellbeing issue or a safety question. However, the description should include how these key questions were reached, for example, in reaction to adverse events for a drug. This should specify user groups covered, exclusion criteria, geographical coverage and location, what is provided, interventions, referral and discharge processes.
- The patient populations and/or target audience to whom the guidance applies, for example, the age range, sex, clinical description, comorbidity. The needs

assessment is robust and describes the population affected by the guidance, its needs, size and expected population impact. Where relevant, the guidance should describe the care pathway and identify programme budgets, service interfaces and other agencies, and advice should align with local and national strategic context and priorities.

- Clear recommendations specific to the clinical or practice circumstances covered by the guidance. A recommendation should provide a concrete and precise description of what is appropriate, in which situation and in which patient group, as permitted by the body of evidence. Note that this is different from the issue of clarity and presentation of recommendations, which is covered in criterion 4.1. Recommendations may be a more general review of the evidence of the efficacy or safety of a medicine or group of medicines and involve a range of interventions and strategies, that may be presented as practice points and be more instructive than directive.
- Recommendations may be described in the body of the document and may describe a standard practice.
- The original objectives and scope are retained when recommendations are translated from a primary guideline.
- In the example of commissioning guidance, it does not always have explicit recommendations in the same way other guidance does, and may be more instructive or indicative than directive. However, for commissioning guidance, outcomes should be clearly specified and quantified.

Domain 2: Stakeholder involvement

Stakeholder involvement refers to professional groups, patient representatives, patients and service users who are involved at some stage of the guidance development process. Guidance producers are requested to describe how processes for stakeholder involvement address issues related to equality (for example, by ensuring that those affected by guidance are involved in its production, giving proper weight to various relevant equality considerations, ensuring diversity in the membership of advisory groups).

In common with other guidance, development of commissioning guidance needs to be multidisciplinary, with clear evidence of input from a range of stakeholders, such as the local community, members of the public, patients, service users, secondary care, GP commissioners, social care and other agencies. This may include clinical networks, reference groups, inter-agency working parties and national surveys.

Professional groups may include members of a steering group, a research team involved in selecting and reviewing or rating the evidence and individuals involved in formulating the final recommendations. This item excludes individuals who have externally reviewed the guidance. Information about the composition, discipline and relevant expertise of the guidance development group should be provided.

Patient representatives refers to the inclusion of information about patients' experiences and expectations of health care (and those of carers, where appropriate) to inform the development of guidance. There should be evidence that this process has taken place even where the guidance is produced in reaction to an adverse event. It is also an essential aspect of guidance development, alongside a rigorous interrogation of any research evidence on patients' views and experiences.

There are various methods for ensuring that patients' and carers' perspectives directly inform guidance development. These include:

- involving patients and carers as members of the group developing guidance
- involving patients and carers during consultation
- using focus groups, interviews and other qualitative methodological approaches.

In these cases, the patient or carer would not be expected to represent the views of other people in the same patient population, but to characterise their own views and experiences.

Patient and carer organisations can represent the views and interests of a group of patients with a health condition and can be involved in the ways outlined above.

Best practice recommends that guidance producers demonstrate a range of patient and public involvement activities in the development of their guidance. It is important to be clear about the extent to which individual patients or patient organisations involved in guidance development represent a particular group or constituency, and when they are participating as expert individuals.

If the views of patients or other lay people are not taken directly into account, the reasons must be explained. If the guidance is a summary of other guidelines or information, the guidance producer should verify that patients' views have been considered. When available, patient-defined and reported outcomes should also be identified.

Patient and public involvement in developing commissioning guidance should be clear. For example, ensuring that patients and service users and the public can share their experiences of services through routine mechanisms for input provides clear channels of communication. Commissioning guidance could provide recommendations on how to involve patients and the public in the local processes to ensure that services will be suited to the local population. Processes for developing commissioning guidance may also assume that the clinical or practice guidance on which it is based has adequately involved patients and service users, in which case it should be clear that this has been verified. As well as showing how patients and service users are consulted, processes should also outline how the opinions gathered during consultation are used to formulate guidance.

Representative intended users are the target users of the guidance product who can immediately determine if the guidance is relevant to them. There should be evidence that the guidance has been pre-tested for further validation among its intended end users before publication, such as with a pilot. If the views of patients, or other lay people are not directly taken into account, the reasons must be explained. If the guidance is a summary of other guidelines or information, the guidance producer should verify that patients' views have been considered. When available, patient-defined and reported outcomes should also be identified.

Domain 3: Rigour of development

The Accreditation Advisory Committee is looking for explicit statements, policies and supporting information that describe in detail the processes used to gather, appraise, synthesise, and summarise evidence and generate recommendations. In addition to the information covered in the policy documents, the Accreditation Advisory Committee is looking for examples within the guidance document that clearly illustrate:

- Identification and inclusion of evidence from patients, carers and other lay people. This evidence may include good-quality qualitative research, literature reviews of patient experiences, patient surveys, audit data and patient questionnaires. Evidence may also be available from patient and carer organisations. Such evidence can provide context to the quantitative data from, for example, a randomised controlled trial, and in some cases can offer entirely new data on which guidance recommendations can be based.
- The details of the search strategy including search terms used, sources consulted and dates of the literature covered. Sources may include electronic databases (for example, MEDLINE, EMBASE, CINAHL), databases of systematic reviews (for example, the Cochrane Library, DARE), hand searching journals, reviewing conference proceedings and other guidance (for example, the US National Guidance Clearinghouse, the German Guidance Clearinghouse). Recommendations need to be based on best available evidence. For safety evidence the search should be fit for purpose and include well-known sources of safety information (such as the MHRA).
- The focus is on the processes that describe the identification, evaluation, synthesis and validation of the evidence used to develop guidance. Normally evidence of the process will be seen in examples of guidance, for example in evidence tables. However, where this is inappropriate (for example, in concise summary guidance or clinical decision-support systems), other supporting information showing the development process is welcome.

- Commissioning guidance needs to be informed by clinical evidence and, where available, accredited clinical or practice guidance and quality standards.
- There should be evidence that the guidance is based on best available evidence, for example identified through a literature search. The process to identify other evidence that informs the guidance, such as local data sets, population information and proven best practice, should also be described.
- The evidence base used to inform social care guidance may not be as strong as that used in clinical or practice medicine. Nevertheless, the criteria used for accreditation still apply, as we evaluate the processes used to find the best available evidence, rather than the evidence itself. For example, in social care guidance the best available evidence may be observational or case series. Organisations producing social care guidance should be able to demonstrate or describe a process for identifying, evaluating and synthesising evidence to inform practice. Health economic modelling and evaluation information should be detailed.
- If cost effectiveness is part of the guidance development, the evidence of searching specifically for information about cost effectiveness should be documented. This may mean searching specific databases such as the Cochrane NHS Economic Evaluation Database.
- Criteria for including or excluding evidence for recommendations identified by the evidence review. These criteria should be explicitly described and reasons for including and excluding evidence should be clearly stated. For example, guidance producers may decide to include only evidence from randomised controlled trials and to exclude articles not written in English. The evidence base for clinical summaries is likely to include primary guidelines which may be supplemented by other evidence, the methods for inclusion and exclusion and evaluating strengths and weaknesses need to be clear and robust.
- Evidence may need to be put into a local context. Where commissioning guidance focuses on particular parts of the care pathway, the methods used to include or exclude information (including clinical opinion) should be described, along with

how strengths and weaknesses are considered and any uncertainties that may affect the expected outcomes.

- There may be no exclusion data for safety topics. All relevant information regarding a particular drug or device should be included.
- That search strategies and inclusion and exclusion criteria consider issues related to equality (for example, by ensuring that issues related to race, disability, sex/gender or age are represented in the evidence base).
- If economic evidence has been searched for and found, specific exclusions for this type of evidence should be documented.
- The strengths and limitations of evidence, details of any system used in the assessment of strengths and weaknesses (for example, an evidence grading system) and acknowledgement of any areas of uncertainty including areas where there is a lack of quality evidence.
- The processes for ensuring the relevance and validity of the data sets used as evidence.
- The strengths versus weaknesses of the evidence may require context as all safety evidence may be considered strong. If a tailored evidence hierarchy is used this should be described in full.
- The assessment of the strength or weakness of the economic evidence should also be explicitly described, including demonstration of the methods/appraisal checklists used in the assessment.
- The process by which data and evidence have been generated and synthesised either formally by analytical methods or informally. Details of any systematic reviews underpinning the application, together with examples, should be provided.
- Clear description of the methods used to formulate the recommendations and how final decisions were arrived at, for example, a voting system or formal consensus techniques like Delphi consensus. Areas of disagreement and methods of resolving them should be specified. There should be an explicit link between the recommendations and the evidence on which they are based.

- Describe in the process manual how to ensure that when translating a recommendation from a primary guideline into a recommendation in the clinical summary the meaning behind the original recommendation is not lost.
- Recommendations may simply arise out of the safety information and level of risk. For example if a particular drug was found to be fatal in certain circumstances the recommendations would be not to use and there would be no need for consensus to arrive at a recommendation. All methods used to arrive at recommendations should be described.
- It is recognised that because of the type of evidence used in social care guidance it may be more difficult to categorically link recommendations or practice points with hard evidence in the same way as in clinical medicine. However, there should be a clear rationale for recommendations based on the best available evidence wherever possible, and how these are formulated (for example, an iterative consensus process).
- Consideration of the balance of health benefits against side effects and risks of the recommendations. These may include: survival, quality of life, cost effectiveness, adverse effects, and symptom management or a discussion comparing one treatment option with another. There should be explanation of how the balance was assessed and evidence of how any identified issues have been addressed. The risks and benefits will clearly be an important criterion for safety guidance and this discussion should be well explained and robust.
- A description of the process of external peer review of guidance before publication. External reviewers should not have been involved in the development group and should include experts in the clinical or practice area and methodological experts. Patient representatives may also be included. A description of the methodology for external review should be presented, which may include a list of the reviewers and their affiliations.
- Peer review may constitute external review or feedback from individuals not involved in developing the commissioning guidance.
- The procedure for updating the guidance and maintaining and improving guidance quality. For example, a timescale has been given or a standing panel receives

regularly updated literature searches and makes changes as required. This may also include any process for updates following post-hoc review procedures, for example process for updating guidance in light of feedback.

- Processes to ensure that the validity of the guidance is maintained or updated. For example, continuous review based on audit of outcomes, evidence review, or routine updating schedule.
- The process for updating guidance, because the evidence base in medicines information often changes rapidly.
- A description of when and how an update of any evidence type may trigger an update of the clinical summary, because a clinical summary is normally based on both primary guidelines and clinical evidence.

Domain 4: Clarity and presentation

The Accreditation Advisory Committee is looking for explicit statements and supporting information that describe how it ensures that its guidance is clear and unambiguous. In addition to the information covered in the policy documents, the Accreditation Advisory Committee will be looking for examples within guidance documents that clearly illustrate:

- Specific, unambiguous and clearly identifiable recommendations including a description in each recommendation of what is appropriate, in which situation and in which patient group, as permitted by the body of evidence.
- Recommendations are in a form that are accessible to people with additional needs (for example, physical, cognitive or sensory disabilities) and are culturally appropriate.
- That the meaning behind a recommendation is not lost when translating from a primary guideline into a recommendation in the clinical summary due to house style.
- In the example of commissioning guidance, the scope and recommendations for service providers should meet the different needs of the population, for example, referrals, interventions and outcomes.

- Consideration of different possible options for the management of a condition, for example, screening, prevention, diagnosis or treatment of the condition. However, different options may not be applicable if the guidance is about one particular drug or device.
- The date of search, the date of publication or last update and the proposed date for review.
- The suitability of content and style for the specified target audience. For example, if patients or service users are part of the audience, the language and format should be appropriate. The content and language should be understandable to those delivering the guidance and, if relevant, to the wider stakeholder group and service users as guidance is likely to have disparate target audiences with different levels of understanding of technical clinical and financial terminology. Considerations of different formats should be noted to allow for all patients with different needs to be able to address their own safety concerns.
- The factors and processes that might affect quality of service user experience in the commissioning process. These should be clearly stated and linked to outcomes (for example, post-discharge communication). Guidance should clearly articulate structure, process and outcomes.

Domain 5: Applicability

The Accreditation Advisory Committee is looking for explicit statements and supporting information that describe how the implementation of the guidance is supported. In addition to the information covered in the guidance and policy documents, the Accreditation Advisory Committee will look for:

- Further information on the provision of support tools, including justification of how appropriate support tools are identified. Guidance producers are to include a list of available support tools in the supporting information provided. Support tool examples may include: algorithms, audit support, costing tools, slides that highlight key messages, summary documents, quick reference guides, educational tools, patients' leaflets and computer support, and should be provided

with the guidance. Tools that support the ongoing implementation of commissioning guidance should be described. These may include benchmarking tools, data for comparison, and modeling tools. For some types of guidance, such as safety guidance, there may be no discussion of barriers to implementation or tools to assist implementation because any safety guidance should always be followed.

- Discussion of potential organisational and financial barriers in applying recommendations. For example, this may include evidence of cost impact assessment, provision of costing tools, health economic modelling and evaluation, service redesign (for example, along care pathways), programme budgeting to understand investment against outcomes, risk assessment, incentives, governance frameworks, accountability arrangements (includes quality and patient experience, not just financial accountability) and how the guidance addresses the Quality and Productivity agenda. The ability to estimate and match service supply capability (size and skills) with demand should be considered, for example in a clear gap analysis and business case. The potential effect of the guidance on service delivery and resource allocation should be considered.
- The guidance should take into account potential financial and organisational barriers to implementation, particularly if it involves other agencies or professionals across a care pathway.
- If cost effectiveness information has been considered as a part of the guidance development process, any outcomes showing that a treatment/intervention is not or may not be cost effective should be described.
- The guidance producer should explain if review criteria for monitoring and/or audit do not apply to its guidance.
- Methods and processes for audit and monitoring may include prescribing patterns and monitoring that commissioned services meet the specified quality standards. Measures should link to desired outcomes, and reference made to where these are published.
- When a primary guideline is used as a part of the evidence base the tools, barriers to implementation and audit information should be shown to have be

assessed as fit for the purpose of the clinical summary if further support tools are considered unnecessary.

Domain 6: Editorial independence

The Accreditation Advisory Committee is looking for explicit statements, policies and supporting information that describe how editorial independence is ensured. In addition to the information covered in the policy documents, the Accreditation Advisory Committee will be looking for the guidance document to contain:

- An explicit statement that the views or interests of the funding body have not influenced the final recommendations.
- Transparency about the guidance funding mechanism, for example detailing external funding systems or specifying when guidance was developed without external funding. Processes for procurement and contracting need to be specified. The required regulatory and legal frameworks need to be considered.

The committee is looking for explicit statements and policies that describe how conflicts of interest are identified, declared, and managed before and during guidance development.

Guidance producers should ensure:

- The method for identifying relevant interests is clear and transparent and is publicly accessible (or available on request).
- Declarations of interest are transparent. Disclosure should include financial and non-financial, personal and non-personal, commercial, specific or non-specific and family interests pertinent to the potential scope of the guideline. The timeframe of conflicts should also be reflected, considering both current and/or planned.
- The process for managing any interests declared, and identifying whether they are a conflict relating to the scope of the guideline, is publicly accessible (or available on request) and up to date (e.g. within 3 years).

- The process (or policy) specifically states how conflicts of interest are avoided or declared and managed. The Chair of the guidance development group should not have financial or non-financial, personal or family interests, specific to the agenda.
- The process outlines when declarations should be made and how often, and when members should be excluded, or excluded from the decision making process (such as voting) but allowed their input as experts to inform the development process.
- They are clear and proportionate in how conflicts are taken into account in the guidance process and development of recommendations (e.g. recusal policy, ethics framework). Whenever possible, members should not have conflicts of interest and members with conflicts of interest should represent a minority of the group. The Chair or co-chairs should not be a person(s) with a conflicts of interest.

The guidance should also contain details on the credibility and any potential bias of the guidance in general, and the conclusions and recommendations in particular.

Potential for bias may be taken into account through a combination of factors, for example, systematic literature review, critical appraisal, peer review, editorial independence and a conflicts-of-interest policy.

Appendix B: Glossary

Accreditation

The process by which credibility, authority and competence are certified, and processes used by a producer of guidance are recognised by NICE as meeting the accreditation criteria.

Accreditation Advisory Committee

Independent standing committee responsible for accreditation recommendations.

Accreditation criteria

The criteria developed by the accreditation team that guidance producers must meet if they are to be accredited. The particular set of criteria that must be met depends on the type of evidence that the guidance producer develops. Different criteria apply to different types of evidence.

Accreditation Mark

The graphic that can be displayed by guidance producers on guidance produced via the accredited process in accordance with the terms and conditions.

Accreditation overview

A report with a qualitative assessment of the extent to which the guidance producer's process meets the accreditation assessment criteria. It is used to inform the Accreditation Advisory Committee about the guidance producer’s process so that the committee can develop the accreditation recommendation.

Accreditation report

Report containing the accreditation decision and supporting documentation including external adviser opinions.

Consultation

A 1-month (20 working days) period in which the public are able to comment on the committee’s accreditation decision and report. Only used if a negative decision is made.

Declaration of interest

A transparent process by which members of a working group or committee declare any personal, professional or financial involvement with an organisation (or related to a technology) that might affect their objectivity (for example, if their position or department is funded by a pharmaceutical company). This may be current and/or planned.

Guidance

Systematically developed statements to guide decisions about appropriate health and social care to improve individual and population health and wellbeing.

Guidance producer

An organisation (or organisations in the case of jointly produced processes and guidance) that owns the process used to produce guidance and recommendations for practice.

NICE Quality Standards

NICE quality standards are a set of specific, concise statements and associated measures. They set out markers of high-quality, cost-effective patient care, covering the treatment and prevention of different diseases and conditions and are based on recommendations in guidance produced via an accredited process.

NICE Publications Executive

An executive committee that acts under delegated authority of the NICE board to review and approve documents for publication and ensure the accreditation process has been followed.

Resolution Panel

Three NICE Board members (including a non-executive director and an executive director) who consider resolution requests on the grounds that there has been a breach of process.

Resolution process

The final quality assurance process undertaken if the guidance producer wishes to challenge the final accreditation decision. Publication of the accreditation decision is suspended pending the resolution investigation process.

Stakeholder

An organisation with an interest in the guidance producer that the accreditation team is considering for accreditation. Stakeholders may be:

- organisations representing health and social care professionals
- NHS organisations
- local authorities
- national patient and carer organisations
- manufacturers of drugs or equipment.

Terms and conditions

The terms and conditions of accreditation set out the rules that guidance producers must comply with when displaying the Accreditation Mark.