NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

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

Final version

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About this document

This document describes the procedure for accrediting the processes used by guidance producers to produce guidance, advice and recommendations for practice.

The document replaces 'Process manual for accrediting producers of guidance and recommendations for practice: a guide for producers and stakeholders (published September 2009).

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).

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Contents

1 Introduction

The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care. NICE also manages the synthesis and spread of knowledge through NICE Evidence – a service that enables access to authoritative clinical and non-clinical evidence and best practice through a web-based portal.

NICE Evidence provides access to a comprehensive evidence base for everyone in health and social care who makes decisions with their **patients** or **service users** about treatments or the use of resources. It informs patient care, commissioning and service management.

Accreditation assesses the quality of the processes followed by guidance producers so that users can recognise sources of information of the highest quality, and to raise guidance standards in the longer term. Accreditation does not accredit the content of individual products, but awards a seal of approval – the Accreditation Mark – to guidance producers that show they meet a defined set of accreditation criteria in processes used to develop their products.

This manual describes the procedure for accrediting the processes used by guidance producers to produce guidance, advice and recommendations for practice. 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 on Accreditation can be found on the NICE website (www.nice.org.uk/aboutnice/accreditation). The website includes accreditation application documents, 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 not granted accreditation.

(Words and phrases in bold are explained in Appendix B Glossary.)

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 and advice that have been developed using critically evaluated high-quality processes. This will, in the long term, improve the quality of information produced for health and social care decision-makers and be used in **NICE quality standards**. This should ultimately result in improved patient outcomes.

2.2 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 Institute's Board in considering and approving its recommendations. The Committee advises NICE on a framework for accrediting sources of evidence 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.

2.3 Eligibility and validity

NICE will consider accrediting the processes used by organisations that produce guidance, advice and recommendations for practice. These organisations are referred to in this document as 'guidance producers'. For the purposes of the accreditation process, guidance and advice is defined as 'systematically developed statements to guide decisions about appropriate health and social care to improve individual and population health and wellbeing.'

This definition covers any recommendations for practitioners that are based on a systematic review and synthesis of the most relevant evidence base, and includes for example, clinical and practice guidelines, referral guidelines, public health guidelines, policy guidance and advice, clinical summaries, commissioning guidance and advice, medicines information guidance and advice, safety guidance and social care guidance and advice. The Accreditation Mark clearly identifies content

produced via accredited processes in search results on NICE Evidence. Users of evidence can easily identify trusted sources and have the confidence of knowing that information is of a high standard.

The processes by which organisations produce guidance and advice are accredited rather than individual pieces of guidance and advice or guidance content.

Accreditation does not relate to the content of the guidance and advice, but the processes used to produce it. However, individual pieces of guidance and advice produced via an accredited process will bear the Accreditation Mark.

Not all NICE Evidence content is eligible for accreditation. For example, NICE Evidence hosts sources of information such as Current Controlled Trials and patient information that are not eligible for the accreditation programme as they do not meet the definition of guidance and advice. Guidance producers seeking accreditation must ensure that their content meets the inclusion criteria for the accreditation programme (see section 3.2).

2.4 Accreditation criteria

The accreditation criteria are based on the Appraisal of Guidelines Research and Evaluation (AGREE) II instrument[1], and can be interpreted in different ways to enable a broad range of guidance and advice products to be included in the accreditation programme. The AGREE instrument was developed to assess clinical guidelines, and has been expanded to encompass other types of guidance and advice that fit the definition (see section 2.3). 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 and advice products and adaptation of the focus of the criteria where applicable.

[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 Journal182 *(http://www.agreetrust.org)*

2.5 Term of accreditation

Accreditation decisions are valid for 5 years from the date of accreditation. Decisions also apply retrospectively to guidance and advice 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 was begun or updated in 2009 and accreditation is achieved in 2010 the accreditation period for guidance and advice produced following the accredited process would range from 2009 to 2015. Because accreditation is valid for a retrospective 3-year period, guidance producers should have published new or updated guidance and advice in the previous 3 years to be eligible. Guidance producers that have updated their process in the past 3 years must provide information on the changes between previous and updated processes for evaluation. See section 3.13 of this manual for further information.

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 and advice.
- Input from relevant experts and healthcare 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.
- For negative draft accreditation decisions a 1-month (20 working days) public consultation allows external stakeholders to comment on and inform the Accreditation Advisory Committee's accreditation recommendation.
- 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 Disclaimer

Only information produced from a process that has successfully been through the accreditation assessment process will be awarded accreditation. Information that has not been produced following an accredited process will also be available on NICE Evidence. This may be because accreditation has not been applied for, because an organisation did not meet the eligibility criteria or because accreditation was not awarded following assessment. The Accreditation team proactively seeks, assesses for eligibility and encourages applications from guidance producers. Where guidance producers are considered eligible and have applied for accreditation the status of each application can be seen on the status table on the accreditation website. Application for accreditation is voluntary; therefore not all guidance producers will necessarily apply for accreditation. The Accreditation team will identify guidance and advice producers whose production processes have undergone rigorous scrutiny.

Accreditation does not refer to the content of the guidance and advice, but the processes used to produce it.

2.6.2 Equality Statement

NICE is committed to promoting equality, eliminating unlawful discrimination and actively considering the implications of its recommendations for human rights. It aims to comply fully with all legal obligations to:

- promote race and disability equality, and equality of opportunity between men and women, and

- eliminate unlawful discrimination on grounds of race, disability, age, gender, sexual orientation, and religion or belief in the way it carries out its functions and in its employment policies and practices.

NICE's equality scheme sets out how it is meeting these obligations on equality and discrimination and what it still needs to do[2].

[2] The equality scheme and action plan are available at www.nice.org.aboutnice/howwework/NICEEqualityScheme.jsp

3 Overview of the accreditation process

3.1 Summary of key stages in the process

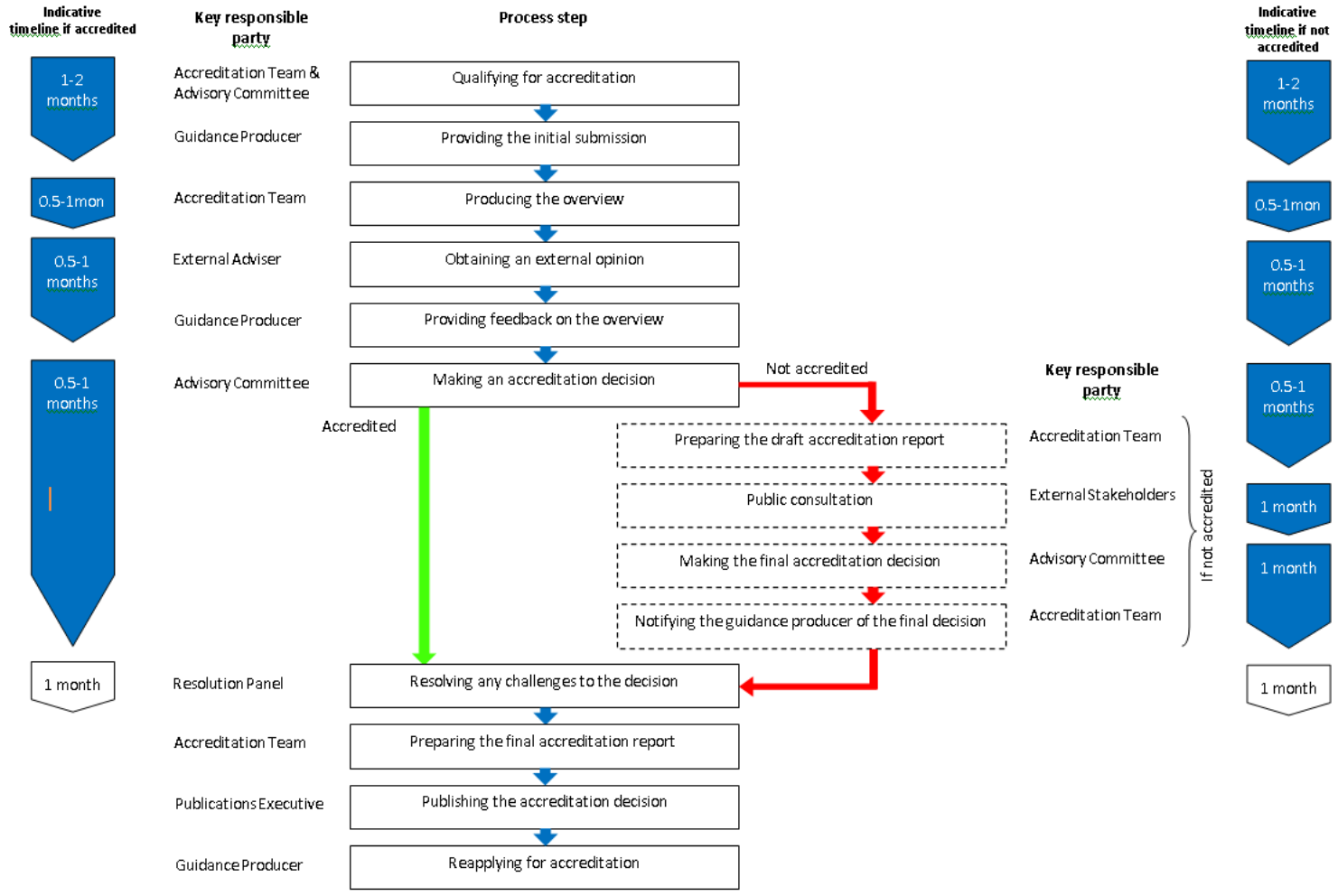
Figure 1 summarises the key stages in the accreditation process, the key party responsible for each stage, and an indicative timeline. The accreditation process takes on average 4–5 months for positive accreditation decisions and 7–8 months for negative accreditation decisions, from acceptance of the application to publication of the final decision.

Further detail on each of the steps in the accreditation process is provided in sections 3.2 to 3.15.

NICE has developed methods to assist guidance producers in their understanding of how to apply and to assess their readiness for accreditation. The accreditation team holds regular workshops at which the accreditation process, assessment criteria and pattern of decisions are explained in detail. An advice service is also provided by the accreditation team. The advice provided is generic and based on experience with the accreditation process. A pre-accreditation assessment cannot be performed.

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.

Figure 1 Flowchart summarising the accreditation process



3.2 Qualifying for accreditation

3.2.1 Types of guidance and advice

To be considered for accreditation, guidance producers need to meet the eligibility criteria given in section 2.4. It is important to note that in all cases products must be evidence based and produced following systematic processes.

It is acknowledged that this is a broad definition. Examples of health and social care guidance and advice products can include, but are not limited to:

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

Examples of relevant producers include Royal Colleges, professional societies and voluntary sector organisations. Accreditation applications are welcome from non-UK English-language international guidance producers (please note that there is a registration fee for international guidance producers wishing to apply for accreditation). Applications from guidance producers from the UK do not incur a registration fee. Producers of other types of guidance and advice that fit the definition of guidance and advice can apply for accreditation and will be considered at the discretion of the Accreditation Advisory Committee. Because accreditation is valid for a retrospective 3-year period, guidance producers should have published new or updated guidance and advice in the previous 3 years.

In some cases only one piece of guidance or advice is produced following a unique process. The eligibility of a process used to produce a single guidance or advice product will be considered by the Accreditation Advisory Committee. The committee considers whether the topic of the guidance and advice addresses an area of unmet need, underpins any Quality Standards[3] and the uniqueness of the guideline. Any questions regarding the eligibility for a guidance and advice production process will be raised by the accreditation team with the Accreditation Advisory Committee if required.

When a guidance and advice production process produces several pieces of guidance and advice, it is requested that at least two pieces of guidance and advice produced following the process under assessment are provided with the application.

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

Commercial, for-profit organisations that produce guidance and advice are eligible to apply for accreditation. If accredited, the guidance producer will be allowed to display the Accreditation Mark in accordance with accreditation terms and conditions.

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 Quality Standards, target audience, type of guidance and advice produced, coverage of topic areas and estimated usage.

[3] Information on NICE Quality Standards is available at http://www.nice.org.uk/aboutnice/qualitystandards/qualitystandards.jsp

3.2.2 Inclusion in NICE Evidence

It is advisable that content produced via an accredited process is accessible on the NICE Evidence website, either in full or as structured abstracts (for example, as defined by CONSORT).

Content included in NICE Evidence should meet the following criteria:

- clearly identify the provenance, ownership and authorship of content
- ensure information is current and accurate
- meet data format and metadata tagging standards that will be provided when considered for inclusion.

NICE Evidence reserves the right to exclude content sources and providers if:

- access to an abstract or evidence summary through the host website incurs a cost to the user (for example, pay per view full text)
- content is predominantly written in a language other than English
- the evidence provider is sponsored by an entity with a financial interest that is deemed likely to affect the objectivity of the evidence
- content focuses on raw data that are not integral to another type of publication, such as a toolkit
- content is exclusively personal opinion (for example, blogs)
- content is temporary and therefore of short-term interest only (for example, news stories or event information)
- content is a professional code of ethics
- content has been archived by an evidence producer

However, NICE recognises that in some instances, for commercial, for-profit organisations, this may not be possible and that it may be necessary to evaluate guidance and advice that is available through subscription or pay-per-view channels rather than NICE Evidence (for example, in clinical decision-support systems). In these circumstances, an application fee will be incurred by the guidance producer for an accreditation application.

3.3 Providing the initial application submission

Guidance producers that are eligible for accreditation are requested to complete an online 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.

The criteria that are considered relevant and necessary are considered on a case-by-case basis depending on the type of guidance and advice product under consideration. (See Appendix A for a description of the interpretation of the criteria for different guidance and advice types.) Not all criteria used to evaluate guidance and advice processes may be applicable in all cases, and the degree of applicability may vary with the type of guidance and advice product. In such circumstances, 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 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 and advice 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 policy or process for the production of guidance and advice, a comprehensive list of guidance and advice developed using this process and evidence that the process is implemented

(such as audit information). The Accreditation team will endeavour to look at in detail a representative sample (for example 10%) of guidance and advice produced after assessment to ensure consistent implementation.

A guidance producer may apply to be accredited for more than one process, with supporting information and a comprehensive list of guidance and advice developed using each specific process.

Guidance and advice that has been produced by more than one guidance producer may follow different processes to guidance and advice produced by any of the single guidance producers alone. Accreditation allows for the different scenarios in which organisations may cooperate to produce co-badged guidance and advice:

- Where a unique guidance and advice development process is followed by two 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.
- Where a guidance producer is involved as a stakeholder on a guideline(s) being developed by another guidance producer using an accredited process, the specific guideline(s) should be covered by the existing accreditation decision for that process. To facilitate this, applicants should list any co-badged guidance produced entirely according to the process under consideration, along with the full list provided with the accreditation application, so that the guidance is automatically covered if accreditation is granted.
- 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.

The guidance producer is requested to make a submission within 2 months of eligibility confirmation or invitation from accreditation. If a submission is not received within this time, the accreditation team will follow up with a reminder. The completed application is reviewed by the accreditation team 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 is assigned to begin the accreditation assessment. Withdrawal of the application can be made by the guidance producer at any time.

A user guide and self-assessment tools are available on the website to provide further information on how to complete an application. These tools can be found here.

3.4 Producing the overview

The submission provided by the guidance producer is assessed and validated against the accreditation criteria by the accreditation technical analysts. The analysts prepare an overview document that assesses how the guidance producer's processes for guidance and advice development meet the assessment criteria. The overview is an analysis of compliance with the criteria, rather than an accreditation recommendation.

Assessment against the criteria may be different, depending on the process and the type of guidance and advice product under consideration. Due to 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 and advice. Not all of the criteria used to evaluate guidance and advice processes may be applicable in all cases. The accreditation technical analysts evaluate whether the criteria which are considered relevant and necessary for the type of guidance and advice product have been met.

3.5 Obtaining an external opinion

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

External advisers have up to 3 weeks to review the overview document produced by the analysts and 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 form an additional piece of information to aid decision-making.

The external advisers may have expertise and experience in guidance and advice development, methodology, 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. The choice of external adviser for a particular accreditation submission takes into account the specific topic or subject area under consideration, where possible. [4]

[4] People wishing to become an external adviser should check their eligibility and apply to be an adviser (see http://admin.nice.org.uk/sys/preview/062A25C6-A513-44A4-76E5759087AFB2AB.jsp?CFID=2390338&CFTOKEN=64933765).

The names, job titles and professional affiliations of the external advisers involved in a specific accreditation decision are published in the draft and final accreditation decision reports (see sections 3.9 and 3.10).

3.6 Providing feedback on the overview

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 within 20 working days. 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. If no feedback is received from the guidance producer in this period only the overview and external adviser response documents are submitted to the Accreditation Advisory Committee for draft decision-making.

3.7 Making an accreditation decision

A submission report that summarises the findings of the initial accreditation overview, the external advisers' comments and the guidance producer's feedback is prepared by the accreditation analysts 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.[5] For the benefit of the public attendees slides that

[5] If you are interested in observing an Accreditation Advisory Committee meeting, check availability and view dates of forthcoming meetings on the NICE Evidence Accreditation website.

summarise key discussion points in each submission are shown at the Accreditation Advisory Committee meeting.

The Accreditation Advisory Committee acts as a group of experts providing authority, expertise, advice and guidance on accreditation. The committee members assess the information on guidance and advice development processes and implementation prepared by the accreditation technical analysts and commented on by expert external advisers. The Accreditation Advisory Committee meetings allow the committee members to raise any issues, questions or concerns about a guidance and advice 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 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, where 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 one session, for which the public are present, and a part two session, from which the public are excluded. The Accreditation Advisory Committee discusses the accreditation submission in a part one session but takes a decision on the accreditation recommendation in a part two session. For further information regarding what would constitute a part one or part two session see section 5.1.2.

The quorum is set at 50 per cent 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 which are 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 analysts ensure that this information is incorporated into the accreditation reports 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 and advice product, and is not based on an absolute or threshold scoring system. The guidance producer may be asked to provide more information before a decision can be made. Where the committee requires further information to make a recommendation, the committee will discuss the specific issues that are thought to lack information or are unclear. This allows the further information requested from the guidance producer to be specific and address the remaining concerns of the committee for a particular guidance and advice production process. Once the extra information has been received by the analysts it is reviewed at the next Accreditation Advisory Committee meeting to allow a recommendation to be made. In certain circumstances, at the request of the committee, a guidance producer may attend a meeting to provide further information.

3.8 Preparing an accreditation report

After the Accreditation Advisory Committee meeting, the accreditation technical analysts prepare an accreditation report that summarises the committee's recommendation on the guidance producer's submission for accreditation. The accreditation recommendation and supporting documentation are used to prepare the accreditation report.

If the committee recommends accreditation, the accreditation team prepares a final accreditation report, there is no public consultation, and the guidance producer is notified (see section 3.11). If the recommendation is not to accredit, the accreditation report is a draft recommendation and proceeds to public consultation (section 3.9).

3.9 Public consultation

Public consultation will only be requested for cases where the committee recommends not to accredit. This allows 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, is published on the accreditation website for public consultation for 20 working days.

The guidance producer is notified of the draft decision 3 days before the public consultation starts. Any individual or organisation can submit comments via the consultation process. All comments received during public consultation are summarised by the accreditation team and responses prepared for consideration by the Accreditation Advisory Committee, which are reviewed at the next committee meeting. The comments and responses are published when the final accreditation report is published.

3.10 Making the final accreditation decision

Accreditation Advisory Committee recommendations to accredit a guidance producer's process are considered final decisions (see section 3.8).

If substantive comments are received during consultation the committee will consider the comments and discuss them in detail before making a final decision. Slides are provided summarising the key discussion points and an informal consensus decision made, as in section 3.7. Once again, a vote will be taken in exceptional circumstances. If the comments received during public consultation are not substantive and do not affect the draft accreditation decision the Chair will ratify the draft decision. This decision is incorporated into a final accreditation report. The

comments and responses received during consultation are published alongside the final report.

Depending on the nature, extent and volume of public consultation comments, the final accreditation decision may differ from the draft decision.

3.11 Notifying the guidance producer of the final decision

Once a final accreditation decision has been reached, the guidance producer is sent a copy of the final accreditation report with a covering letter as notification of the decision. Regardless of the accreditation decision the guidance producer has 20 working days from the date the report is sent to challenge a decision.

3.12 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.

3.12.1 Resolution grounds

The Resolution Panel (see section 3.12.4) will only consider resolution requests made by the guidance producer on the grounds that there has been a 'breach of process'. See section 3.15 for the procedure for queries, feedback and complaints.

3.12.2 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 reviewed by the NICE Publications Executive and is published as soon as possible thereafter.

3.12.3 The initial scrutiny process for resolution requests

All resolution requests are subject to an initial scrutiny process. The Director of Evidence and Practice 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 Evidence and Practice 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 Evidence and Practice 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.

3.12.4 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 Evidence and Practice. In the event of there being a resolution request that relates to NICE guidance, an independent panel will be convened.

3.12.5 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 required. 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.

3.12.6 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 or reopening consultation.

The decision reached by the Resolution Panel is final.

3.12.7 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. Where 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.

3.13 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 and advice 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 Publications Executive ensures that due process has been followed in the development of the accreditation decision.

If the Publications Executive authorises publication the final accreditation report is published on the Accreditation[6] pages of the website. If accreditation has been granted, the guidance producer's current guidance and advice 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 (that is, non-accreditation does not result in a producer's content being removed from NICE Evidence).

If the 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.

[6] Note that all reports are published on the NICE Evidence portal regardless of the final accreditation decision.

3.14 Reapplying for accreditation

Guidance producers that are not accredited after the accreditation process have the opportunity to reapply from 1 year after the final decision. 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. In exceptional circumstances a guidance producer may be allowed to reapply for accreditation within 1 year after a negative decision. The Accreditation Advisory Committee will consider the circumstances and advise on whether a reapplication within 1 year is acceptable. Following a negative decision a guidance producer will also 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.

Six months before the end of the 5-year accreditation period the guidance producer is contacted by the accreditation team to inform them of the upcoming expiry of the accreditation conditions. As part of this contact the accreditation team will return the original (or previous) application form to the guidance producer. The guidance producer is expected to reapply by explaining how their process has changed. The guidance producer should state which version of their process manual the guidance producers are working to and produce a full list of guidance and advice produced following this process. The accreditation team will undertake a full review as for the initial accreditation. Guidance producers are expected to demonstrate continuing progress in their guidance development process otherwise accreditation may not continue.

Throughout the accreditation period accredited guidance producers are expected to re-confirm that their accredited processes have not adversely changed. Producers should inform accreditation if there are any changes in the interim resulting in a lowering of previous standards. Guidance producers must inform Accreditation 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. Eighteen and 36 months after accreditation the guidance producer will be asked to complete a

‘Process validation form’ stating that no changes have affected the accredited process adversely thereby endangering compliance with the accreditation criteria.

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 and advice 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 and advice 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 3.15 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. Please see Conditions of accreditation, provided separately.

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. Any changes will not be applied to guidance producers who are already accredited until they are required to reapply for accreditation.

3.15 Feedback and complaints procedure

The accreditation team routinely seeks feedback on the accreditation process from guidance producers that have been through the accreditation process. Twelve months after accreditation is awarded the 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 NICE via the NICE Evidence feedback facility[7]. 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.

[7] For feedback please see the NICE Evidence website.

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 and advice production 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 31 members with a range of expertise including at least two lay members, all independent of NICE. The Committee meets every 6–8 weeks. 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 the public consultation 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 analysts, a programme manager, project managers and a coordinator. The accreditation team is accountable to the Director of Evidence and Practice. 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 • consolidating feedback from the consultation process • 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 and advice development. They may also have expertise in a specific subject or topic area. Where possible the adviser and specialist area is matched with the 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.
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	The Publications Executive comprises Director of Evidence and Practice, Associate Director of Accreditation, Programme Director for

Executive	Engagement and Management, Chief Technology Officer, and Programme Director for Implementation, Associate Director for Communications, Clinical Adviser and the NICE Clinical and Public Health Director. The 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 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 31 voting members, including the Chair. The Accreditation Advisory Committee 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 professionals 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. A list of current members is published on the accreditation webpage. Full details of membership recruitment can be found at http://www.nice.org.uk/nhsevidence/nhseac.jsp .

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 'A code of practice for declaring and dealing with conflicts of interest'

(http://www.nice.org.uk/media/0B2/B6/DeclaringDealingConflictInterestOct08.pdf). 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.

Additional experts may 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 two representatives per organisation are allowed to attend; however, when a meeting is oversubscribed, attendance may be limited to one 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 one session, for which the public are present and part two sessions, from which the public are excluded. The Accreditation Advisory Committee discusses the accreditation submission in a part one session but takes a decision on the accreditation recommendation in a part two session. The reasons for holding part two 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.

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

(a) of limited public availability; and

(b) capable of clear definition; and

(c) disclosed to Accreditation in a situation that entails an obligation of confidence (this includes information that is passed to Accreditation where we have undertaken, by virtue of a confidentiality agreement, to keep that information confidential or where the circumstances are such that it is clear that we should keep the information confidential for a third party).

This is based on case law and effectively defines what is referred to as the ‘quality of confidence’. If the information is only available to a small group of people that is also relevant.

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

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

Accreditation will review and update this document 3 years after its publication. 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 Evidence 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: 2.5

Review Date: November 2014

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 and advice. These criteria are based on the AGREE Instrument[8]. The criteria focus on the process used for developing guidance and advice rather than the content of individual guidance and advice or products. Nevertheless, as part of the assessment process, guidance producers are expected to provide a comprehensive list of guidance and advice developed using this process; a number of examples of guidance and advice (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 six domains. Each domain is intended to capture a separate dimension of the quality of the process used to develop guidance and advice. Table 2 describes each of the six accreditation domains and their associated assessment criteria. Guidance producers are assessed to review the extent to which their process for developing guidance and advice meets these criteria. In addition, the accreditation technical analysts evaluate an arbitrarily selected sample of guidance and advice to ensure that the guidance producer's processes are implemented consistently.

[8] 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

Table 2 Accreditation domains and criteria

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

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 producers to state the criteria and reasons for inclusion or exclusion of evidence identified by the evidence review. 3.3 Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty 3.4 Describes the method used to arrive at recommendations (for example, a voting system or formal consensus techniques like Delphi consensus) 3.5 Requires the guidance producers to consider the health benefits, side effects and risks in formulating recommendation 3.6 Describes the processes of external peer review 3.7 Describes the process of updating guidance and maintaining and improving guidance quality
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 consider: 5.1 Publishing support tools to aid implementation of guidance 5.2 Discussion of potential organisational and financial barriers in applying its recommendations 5.3 Review criteria for monitoring and/or audit purposes within each product

Domain	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 and advice.

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 and advice. In addition to the information covered in any policy or process manuals, the Accreditation Advisory Committee will be looking for examples within guidance and advice documents that clearly illustrate:

- The overall objectives of the guidance and advice. For example, for commissioning guidance and advice, 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 and advice it may simply be to keep a population safe or for policy guidance and advice 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 and advice, particularly for the key recommendations. For example, there should be descriptions of how processes for topic selection and scoping guidance and advice 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 and advice). The key question covered by guidance and advice 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 and advice applies, for example, the age range, sex, clinical description, co-morbidity. The needs assessment is robust and describes the population affected by the guidance and advice, its needs, size and expected population impact. Where relevant, the guidance and advice 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 and advice. 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 and advice, it does not always have explicit recommendations in the same way other guidance and advice does, and may be more instructive or indicative than directive. However, for commissioning guidance and advice, 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 and advice 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 and advice 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 and advice, development of commissioning guidance and advice 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 and advice. Information about the composition, discipline and relevant expertise of the guidance and advice 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 and advice is a summary of other guidelines or information, the guidance producer should verify that patients' views have been considered. Where available, patient-defined and reported outcomes should also be identified.

Patient and public involvement in developing commissioning guidance and advice 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 and advice 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 and advice may also assume that the clinical or practice guidance and advice 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 and advice.

Representative intended users are the target users of the guidance and advice product who can immediately determine if the guidance and advice is relevant to them. There should be evidence that the guidance and advice 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 and advice is a summary of other guidelines or information, the guidance producer should verify that patients' views have been considered. Where 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 and advice 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 and advice (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 and advice.

Normally evidence of the process will be seen in examples of guidance and advice, for example in evidence tables. However, where this is inappropriate (for example in concise summary guidance and advice or clinical decision-support systems), other supporting information showing the development process is welcome.

- Commissioning guidance and advice needs to be informed by clinical evidence and, where available, accredited clinical or practice guidance and advice and quality standards.
- There should be evidence that the guidance and advice is based on best available evidence, for example identified through a literature search. The process to identify other evidence that informs the guidance and advice, such as local data sets, population information and proven best practice, should also be described.
- The evidence base used to inform social care guidance and advice 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 and advice the best available evidence may be observational or case series. Organisations producing social care guidance and advice 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.
- 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 and advice 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 and advice 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).
- 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 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 and advice 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 to 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 advice and this discussion should be well explained and robust.
- A description of the process of external peer review of guidance and advice 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 and advice.
- The procedure for updating the guidance and advice and maintaining and improving guidance and advice 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 and advice in light of feedback.

- Processes to ensure that the validity of the guidance and advice is maintained or updated. For example, continuous review based on audit of outcomes, evidence review, or routine updating schedule.
- The process for updating guidance and advice, 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 ,as 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 and advice 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 and advice 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 and advice 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 the condition, for example, screening, prevention, diagnosis or treatment of a condition.

However, different options may not be applicable if the guidance and advice 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 advice and, if relevant, to the wider stakeholder group and service users as guidance and advice 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 and advice 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 and advice is supported. In addition to the information covered in the guidance and advice and policy documents, the Accreditation Advisory Committee will be looking 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 and advice. Tools that support the ongoing implementation of commissioning

guidance and advice 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 as any safety guidance and advice 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 and advice addresses QIPP. 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 and advice on service delivery and resource allocation should be considered.
- The guidance and advice should take into account potential financial and organisational barriers to implementation, particularly if it involves other agencies or professionals across a care pathway.
- The guidance producer should explain if review criteria for monitoring and/or audit do not apply to its guidance and advice.
- 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 be assessed as fit for the purpose of the clinical summary if further support tools and 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 and advice 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 and advice funding mechanism, for example detailing external funding systems or specifying when guidance and advice was developed without external funding. Processes for procurement and contracting need to be specified. The required regulatory and legal frameworks need to be considered.
- An explicit conflict-of-interest statement from all individuals involved in the guidance and advice development declaring whether they have any pecuniary and non-pecuniary, specific and non-specific and personal and non-personal interests. For example, a specific personal pecuniary interest involves a current personal payment, which may relate to the manufacturer or owner of a product or service being evaluated. It is recognised that those drawing up commissioning guidance and advice may have some conflicts of interest. Processes that manage bias should therefore be clearly described, for example through a range of multi-party involvement, using the evidence base, procurement processes, governance arrangements and clear accountability. Accountability arrangements should include a governance framework that handles potential conflicts of interest, for example, for those working as both providers and commissioners.
- Details on the credibility and any potential bias of the guidance and advice 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 is certified, and recognised by NICE that processes used by a producer of guidance and advice meet the accreditation criteria.

Accreditation Advisory Committee

Independent standing committee responsible for accreditation recommendations.

Accreditation criteria

The criteria developed by Accreditation 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 licence.

Accreditation Overview

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 process by which members of a working group or committee declare any personal or professional 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).

Guidance and advice

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

Guidance producer

An organisation that owns the process used to produce guidance and advice and recommendations for practice.

Licence

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

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 and advice 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 Accreditation 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.