

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

NHS EVIDENCE

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

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1 Introduction

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. As part of the next stage review 'High Quality Care for All' report from Lord Darzi, NICE was given the responsibility of managing the synthesis and spread of knowledge through NHS Evidence – a web-based portal through which all healthcare professionals will be able to access authoritative clinical and non-clinical evidence and best practice.

NHS Evidence provides access to a comprehensive evidence base for everyone in health and social care who makes decisions about treatments or the use of resources. It will inform patient care, commissioning and service management. NHS Evidence also quality-assesses guidance producers in order to allow users to recognise sources of information of the highest quality and to drive up standards in the longer-term. NHS Evidence will not accredit the content of individual products, but will award a seal of approval – 'the accreditation mark' – to guidance producers that show compliance with a defined set of accreditation criteria that reflect the processes used to develop their products. In the first instance, producers of guidance and recommendations for practice will be accredited. To be comprehensive and ensure access to all relevant materials, NHS Evidence will not aim to accredit everything covered via its search facility, for example, local producers or practical tools.

The purpose of this manual is to describe the process for accrediting producers of guidance and recommendations for practice, thereby determining which information will be quality assured by NHS Evidence. Details on the scope for accreditation and what types of guidance producers are accredited, the criteria used to perform the accreditation assessment, the main steps in the process for reaching an accreditation decision and the notification and publication of an accreditation decision are also covered in this document.

For details on where to find additional background material and briefing documents please refer to section 7.

(See Appendix A for a glossary of terms used in this document.)

2 Accrediting guidance producers

2.1 *What information will be accredited by NHS Evidence?*

NHS Evidence will accredit organisations that produce guidance and recommendations for practice – these are referred to in this document as ‘guidance producers’. For the purposes of the NHS Evidence accreditation process, guidance is defined as **'systematically developed statements to guide decisions about appropriate health and social care to improve individual and population health and wellbeing.'**

This definition would cover, for example, clinical guidelines, referral guidelines, public health guidelines, policy guidance, clinical summaries and best practice statements. Examples of relevant producers are likely to include Royal Colleges and professional societies. NHS Evidence will accredit English-language guidance producers – normally those that have produced guidance within the past three years. Producers of other types of guidance that fits the definition above can apply for accreditation, and will be considered at the discretion of the Advisory Committee.

It is anticipated that additional accreditation processes will be introduced over time to include other categories of information (for example, care pathways and systematic reviews). Additional process manuals will be published for each new category.

2.2 *Core principles of NHS Evidence accreditation*

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

- A comprehensive set of supporting information (comprising the guidance producer’s submission) is used to inform the development of recommendations for accreditation. All information submitted is subject to rigorous assessment and analysis against a set of defined criteria designed to assess the processes used to develop guidance.

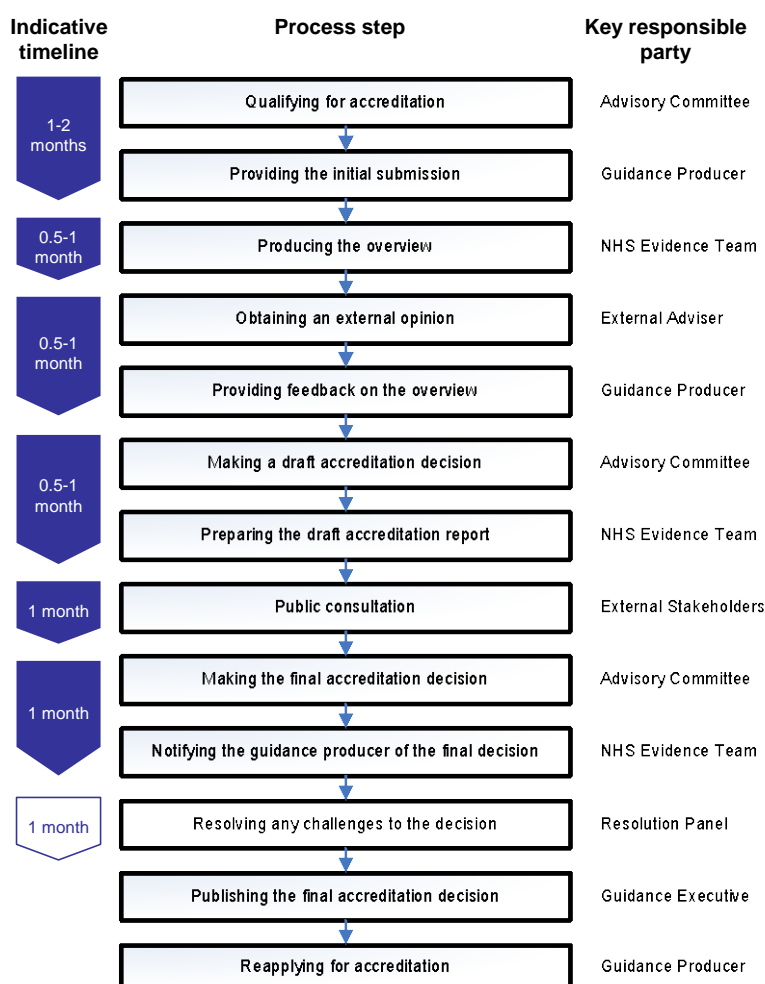
- Input from relevant experts and healthcare professionals forms part of all processes.
- Patients and carers have the opportunity to be involved.
- An independent Advisory Committee makes accreditation decisions on behalf of NICE.
- A transparent process and method underpins the development of all accreditation decisions. This includes open access to Advisory Committee meetings.
- A one-month public consultation allows external stakeholders to comment on and inform the development of the Advisory Committee's accreditation decision.
- A process of regular review to update the accreditation decisions and the process manual ensures that accreditation decisions are of continuing value.

3 Overview of the accreditation process

3.1 Summary of key stages in the process

Figure 1 below summarises the key stages in the accreditation process, the key party responsible for each stage, and an indicative timeline. It is hoped that, once the accreditation process is established, most guidance producers will receive an accreditation decision within six months of submitting their accreditation application.

Figure 1 Flowchart summarising the accreditation process



In order to be fully transparent, information is published on the NHS Evidence website summarising the guidance producers currently being accredited and the stage they are at in the accreditation process.

Further detail on each of the steps in the accreditation process is provided in sections 3.2 to 3.14.

3.2 *Qualifying for accreditation*

To be considered for accreditation, guidance producers must first qualify to enter the accreditation process by meeting the definition in 2.1. Guidance producers can proactively apply to NHS Evidence to be considered for accreditation via the NHS Evidence website. If considered to meet the criteria, the guidance producer will be invited to enter the formal accreditation process. A decision on which guidance producers qualify for the accreditation process will, in cases of uncertainty, be ratified by the Advisory Committee.

The NHS Evidence Accreditation Team may directly invite guidance producers to enter the accreditation process. This invitation will be based on advice from the Advisory Committee, taking into account a number of factors, including the volume of guidance produced, coverage of a range of topic areas and estimated usage.

3.3 *Providing the initial submission*

Guidance producers that qualify for accreditation are sent a standard proforma that reflects the accreditation criteria (See Appendix B for the criteria for the accreditation of guidance producers). Guidance producers are required to complete the proforma and provide evidence to show that they meet the necessary criteria (examples of evidence include policy or process documents). In addition, guidance producers are expected to provide a comprehensive list of guidance developed using this process; at least two recently published examples of guidance may be examined in detail.

The guidance producer is expected to make a submission within two months of an invitation from NHS Evidence. If they do not respond within this time, the NHS Evidence Accreditation Team will follow up with a reminder. The completed submission is reviewed by the NHS Evidence Accreditation Team and any missing or additional information is requested from the guidance producer.

3.4 *Producing the overview*

The submission provided by the guidance producer is assessed and validated by the NHS Evidence Accreditation Team, and an overview is prepared. This overview includes a qualitative assessment of the extent to which the guidance producer is compliant with the assessment criteria.

3.5 *Obtaining an external opinion*

In order to provide an independent and reliable assessment, the overview is subject to external scrutiny by at least two external advisers. Their response is made available to the Advisory Committee and forms an additional piece of information to aid decision-making.

The external advisers have expertise and experience in guidance development, and may also have expertise in a specific topic or subject area. The choice of external adviser for a particular submission will take into account the specific topic or subject area under consideration, where possible. The names and professional affiliations of the external advisers involved in a specific accreditation decision are published during the public consultation on the draft decision (see section 3.9).

3.6 *Providing feedback on the overview*

Guidance producers are invited to review the overview before it is submitted to the Advisory Committee. A response must be received within 20 working days of receipt of the overview. The guidance producer's feedback is provided to the Advisory Committee along with the overview document.

3.7 *Making a draft accreditation decision*

The overview, the external advisers' report and feedback from the guidance producer are provided to the Advisory Committee at their first meeting. The Advisory Committee considers all of the evidence provided and makes a draft decision on whether to accredit the guidance producer. The decision is based upon the guidance producer meeting the relevant and necessary criteria and is not based on an

absolute scoring system. The decision-making process during each Advisory Committee meeting is moderated by the chair.

The Advisory Committee's decision-making is underpinned by the core principles of NHS Evidence accreditation (see section 2.2). It is not based on a threshold scoring system.

3.8 *Preparing the draft accreditation report*

The draft accreditation decision and supporting documentation is used to prepare the draft accreditation report. This report includes a summary of the external advisers' opinions.

3.9 *Public consultation*

The draft accreditation report, including the draft accreditation decision, is published on the NHS Evidence website for a one month public consultation. The purpose of the consultation is to validate the evidence provided by the guidance producer and the draft accreditation decision of the Advisory Committee.

3.10 *Making the final accreditation decision*

A summary of the consultation feedback is presented at the next meeting of the Advisory Committee and makes a final decision on whether to accredit the guidance producer. This decision is incorporated into a final accreditation report.

3.11 *Notifying the guidance producer of the final decision*

When the Advisory Committee has reached a final accreditation decision, the guidance producer is notified in writing and is sent a copy of the final accreditation report. If the guidance producer wishes to challenge the decision, they must do so within 15 working days.

3.12 *Resolving any challenges to the decision*

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

Process manual for accrediting producers of guidance and recommendations for practice

3.12.1 Resolution grounds

The Resolution Panel (see section 3.12.4) will only consider resolution requests on the grounds that there has been a 'breach of process'.

3.12.2 Resolution requests

Guidance producers have 15 working days to request resolution by e-mail, fax or letter to the Associate Director for Accreditation. The request should specify the breach of process and provide supporting information so that NHS Evidence 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 accreditation decision is suspended pending an investigation of the request. If no request is received, the accreditation decision is reviewed by the NICE Guidance 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 Associate Director for Accreditation will investigate the request and the Programme Director for Content and Quality will decide whether the request falls within the scope of the resolution process. The initial scrutiny process will be completed within 15 working days of the close of the resolution period.

If on initial scrutiny the Programme Director for Content and Quality considers that the breach of process ground does not appear to have been met, or 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 Programme Director for Content and Quality considers that the breach of process ground appears to have been met, 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 not 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 made known. This is to avoid pre-empting the outcome of resolution.

3.12.4 The Resolution Panel

The Resolution Panel consists of two 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 Resolution Panel will be chaired by the Executive Director.

3.12.5 Meetings of the Resolution Panel

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

3.12.6 The outcome of resolution

In relation to requests for resolution on breach of process grounds, 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 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 two days before the publication of the final accreditation decision. If the 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. This includes a statement about ensuring the same processes will continue to be used, and that any deviation will be notified to the NHS Evidence Advisory Committee. The final accreditation report, incorporating the final accreditation decision, is then submitted to the NICE Guidance Executive for sign-off prior to publication. The NICE Guidance Executive ensures that due process has been followed in the development of the accreditation decision.

If the NICE Guidance Executive authorises publication, then the final accreditation report is published on the NHS Evidence website¹. If accreditation has been granted, the guidance producer's current content (that is, content published within a defined time period²) is highlighted on the NHS Evidence website with an 'accreditation mark'. Content that is developed by guidance producers that do not receive accreditation continues to be available through the NHS Evidence website (that is,

¹ Note that all reports are published on the NHS Evidence website regardless of the final accreditation decision.

² The definition of current content will vary by guidance producer, and will be subject to review and approval by the Advisory Committee as part of the accreditation process.

non-accreditation does not result in a producer's content being removed from NHS Evidence).

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

3.14 Reapplying for accreditation

Guidance producers that are not accredited following the accreditation process have the opportunity to reapply from one year after the previous assessment. It is assumed that the organisation will have addressed any concerns highlighted in the original assessment before reapplying.

Accredited guidance producers are expected re-confirm every three years that their relevant processes have not changed, and they should proactively inform NHS Evidence if there are any changes in the interim (as stated in the terms and conditions of accreditation). If at any point concerns are raised regarding changes to process which do not meet previous standards, a random selection of guidance may be requested and assessed.

4 Who is involved in accrediting guidance producers?

Table 1 outlines the key participants in the NHS Evidence accreditation process.

Table 1 Key participants in the accreditation process

Advisory Committee	The NHS Evidence Advisory Committee operates as a standing committee. It receives, considers and reviews information on guidance producers and independently accredits them to ensure that NHS staff have access to authoritative clinical and non-clinical evidence and best practice. The Advisory Committee submits its accreditation decision to NICE's Guidance Executive which acts on behalf of the NICE Board to consider and approve the decision.
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	<p>The Advisory Committee is made up of approximately 30 members with a range of expertise, all independent of NICE. The Advisory Committee meets every six to eight weeks (excluding August). Members of the public may request attendance at the meeting. Agendas and minutes of Advisory Committee meetings are made publically available. The minutes are a contemporaneous note of the business of the meeting.</p> <p>The key roles of the Advisory Committee include:</p> <ul style="list-style-type: none"> • 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 decision • reviewing feedback from the public consultation to make the final accreditation decision.
<p>Guidance producer</p>	<p>The guidance producer is the organisation applying for accreditation.</p> <p>Guidance producers prepare 'systematically developed statements to guide decisions about appropriate health and social care to improve individual and population health and wellbeing.'</p> <p>Key roles of the guidance producer include:</p> <ul style="list-style-type: none"> • 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 NHS Evidence Accreditation Team and providing feedback • commenting during the public consultation • reviewing the final accreditation report and decision • reapplying for accreditation.
<p>NHS Evidence Accreditation Team</p>	<p>The NHS Evidence Accreditation Team comprises the Associate Director for Accreditation and a team of technical analysts and information experts. The Accreditation Team is accountable to the Programme Director for Content and Quality for NHS Evidence.</p> <p>Key roles of the NHS Evidence Accreditation Team include:</p> <ul style="list-style-type: none"> • 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

	<ul style="list-style-type: none"> • preparing the draft and final accreditation reports, incorporating the outcomes and decisions from the Advisory Committee meetings • consolidating feedback from the consultation process • notifying the guidance producer of the Advisory Committee's final accreditation decision.
External Advisers	<p>The external advisers are individuals that have expertise and experience in guidance development. They may also have expertise in a specific subject or topic area.</p> <p>Key roles of the external advisers include:</p> <ul style="list-style-type: none"> • reviewing the overview of the guidance producer's submission and providing an independent opinion on the content and findings.
Resolution Panel	<p>The Resolution Panel consists of two 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.</p> <p>Key roles of the Resolution Panel include:</p> <ul style="list-style-type: none"> • resolving any legitimate challenges to the Advisory Committee's final accreditation decision.
NICE Guidance Executive	<p>The Guidance Executive comprises NICE's Executive Directors, guidance centre directors and Communications Director. The Guidance Executive considers and approves for publication all guidance and implementation tools. It is also responsible for approving for publication of the final accreditation report and decision of the NHS Evidence Advisory Committee.</p> <p>Key roles of the Guidance Executive include:</p> <ul style="list-style-type: none"> • reviewing the final accreditation report and ensuring that due process has been followed • approving the publication of the final accreditation report.

4.1 Membership of the Advisory Committee and appointing members

The Advisory Committee is made up of approximately 30 voting members, including the Chair. In future, Advisory Committee members will be recruited through open

advertising and are appointed initially for a three-year term. The membership will be drawn from potential users of the services such as clinicians and commissioners and experts in relevant areas of work including research, evidence, methodology and knowledge.

Membership may be extended for a further three years by mutual agreement. A list of current members is published on the NHS Evidence website. Full details of the way members are recruited can be found at

<http://www.nice.org.uk/getinvolved/joinnwc/advisorybodyrecruitmentpack.jsp>.

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

Members of the Advisory Committee and other individuals attending the Committee meeting declare any conflicts of interest. 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/getinvolved/joinnwc/healthandotherprofessionals/invitationtoapplyformembershipoftheguidelinedevelopmentgrouponglaucomaandocularhypertension/conflicts_of_interest.jsp). The 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 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 Advisory Committee*

Holding 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 NHS Evidence accreditation decisions, and illustrates how the Advisory Committee takes into account all of the evidence submitted by stakeholders.

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

5.1.1 Arranging attendance

NHS Evidence will publish a notice on its website announcing each Advisory Committee meeting, at least ten working days before the meeting. The notice will include:

- the date, time and place of the meeting
- a list of all agenda items, showing whether each will be discussed in an open or closed session
- the contact details of the Coordinator responsible for meetings in public.

Members of the public may apply to attend a meeting through the NHS Evidence website, by post or fax. Up to 20 places will be 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, where a meeting is oversubscribed, attendance may be limited to one representative per organisation.

When the meeting agenda has been finalised, the applicants will be contacted to let them know whether or not a place has been made available to them. The invitation will include 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 website as soon as possible and registered delegates will be contacted.

5.1.2 How meetings are conducted

Meetings of the Advisory Committee will normally be held at NICE's offices in London or Manchester, which are accessible to the public including those with limited mobility.

Advisory Committee meetings may either 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 reasons for holding a part two session include situations where:

- the Advisory Committee is considering commercial or academic in confidence information
- the Advisory Committee is considering guidance producer submissions where these have been submitted under conditions of confidentiality
- the decisions made by the Advisory Committee are commercially sensitive.

The decision not to hold a part two session will be at the discretion of the Chair, and will be taken when no confidential or personal data or information will be considered, and when the matters under consideration are not commercially sensitive.

5.2 Access to documents used in accreditation process

To ensure that the process is as transparent as possible, all evidence relevant to the Advisory Committee's decisions should be made publicly available. All final

accreditation reports are therefore published on the NHS Evidence website. The Advisory Committee agendas and minutes are also published.

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 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.

- Information and data that have been put into the public domain anywhere in the world may not be marked as confidential.

NICE 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 NICE 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 process guide

NHS Evidence will review and update this document three years after its publication.

It may be necessary to make minor changes to the accreditation process before three years. Changes to the process guide will be made in accordance with NICE's policy. 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 methods 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 NHS Evidence website four weeks 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 three months' public consultation.

7 More information

More information about NHS Evidence can be found on the NHS Evidence website (TBC) or the NICE website (www.nice.org.uk/ip).

Appendix A: Glossary

Consultation

A one-month period in which the public are able to comment on the committee's draft accreditation decision and report.

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).

Delphi method

A technique used for the purpose of reaching an agreement on a particular issue, without the participants meeting or interacting directly. It involves sending participants a series of postal questionnaires asking them to record their views. After the first questionnaire, participants are asked to give further views in the light of the group feedback. The judgements of the participants are statistically aggregated, sometimes after weighting for expertise.

Guidance

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

Guidance Executive

NICE directors who approve all NHS Evidence accreditation decisions for publication.

Guideline

A systematically developed tool which describes aspects of a patient's condition and the care to be given. A good guideline makes recommendations about treatment and care, based on the best research available, rather than opinion. It is used to assist

clinician and patient decision-making about appropriate healthcare for specific clinical conditions.

Methodology

The overall approach of a research project (for example, the study will be a randomised controlled trial, of 200 people, over one year).

Overview

A document that summarises the findings from the evidence gathered for an NHS accreditation decision. It is used to inform the Advisory Committee about the guideline producer so that the Committee can develop the draft accreditation decision.

Stakeholder

An organisation with an interest in the guidance / guideline producer that NHS Evidence is accrediting. Stakeholders may be:

- manufacturers of drugs or equipment
- national patient and carer organisations
- NHS organisations
- organisations representing healthcare professionals

Systematic review

A review in which evidence from scientific studies has been identified, appraised and synthesised in a methodical way according to predetermined criteria. May or may not include a meta-analysis.

Appendix B: Criteria for the accreditation of guidance producers

The accreditation criteria provide a framework for assessing the quality and rigour of the process used by guidance producers to develop guidance, and are based on an adapted version of the AGREE Instrument³. The criteria focus on the process used for developing guidance rather than the content of individual guidance or products. Nevertheless, as part of the assessment process, each guidance producer is expected to provide at least two recent examples of guidance they have developed in order to demonstrate 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. Table 2 describes each of the six accreditation domains and their associated assessment criteria. Guidance producers will be assessed to ensure that their process for developing guidance meets these criteria.

Table 2 NHS Evidence accreditation domains and criteria

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

³ This framework is adapted from the original AGREE Instrument: The AGREE Collaboration. The Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument, 2001. London: The AGREE Research Trust (<http://www.agreetrust.org>)

Domain	Criteria
<p>2. Stakeholder involvement focuses on the extent to which the guidance represents the views of its intended users.</p>	<p>These criteria consider whether the guidance producer has a policy in place that means it includes:</p> <ul style="list-style-type: none"> 2.1 Individuals from all relevant professional groups 2.2 Patient representatives and seeks patients views and preferences 2.3 Representative intended users in developing guidance.
<p>3. Rigour of development relates to the process used to gather and synthesise information and the methods used to formulate recommendations and update them.</p>	<p>These criteria consider whether the guidance producer has a clear policy in place that:</p> <ul style="list-style-type: none"> 3.1 Requires the technical team 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 recommendations 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 Clarifies 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 balance the health benefits against the side effects and risks 3.6 Details the processes of external peer review 3.7 Mentions the process of updating guidance and maintaining and improving guidance quality
<p>4. Clarity and presentation deals with the language and format of the guidance.</p>	<p>These criteria appraise whether the guidance producer ensures that:</p> <ul style="list-style-type: none"> 4.1 Their recommendations are specific, unambiguous and clearly identifiable 4.2 The different options for management of the condition 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 of the guidance is suitable for the specified target audience. If patients or service users are part of this audience, the language should be appropriate.

Domain	Criteria
<p>5. Applicability deals with the likely organisational, behavioural and cost implications of applying the guidance.</p>	<p>These criteria measure whether the guidance producer routinely considers:</p> <ul style="list-style-type: none"> 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 That their guidance is current, with review criteria for monitoring and/or audit purposes within each product.
<p>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.</p>	<p>These criteria measure whether the guidance producer:</p> <ul style="list-style-type: none"> 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