NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Process for accrediting guidance producers and recommendations for practice

A user guide for submission of information for accreditation

Final version

Review date: March 2015

Please note: *Prior to completing the accreditation application form, please check that you are eligible for the accreditation scheme. To check eligibility please read the statement from the Process Manual.*

1. Introduction

We will consider accrediting organisations that produce guidance and advice for practice – for the purposes of the accreditation process, guidance is defined as **'systematically developed statements to guide decisions about appropriate health and social care to improve individual and population health and wellbeing.'**

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.

This definition covers any guidance and advice for health and social care professionals that is 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, medicines information guidance, safety guidance and social care guidance and advice.

Content produced via accredited processes is clearly visible in search results on NHS Evidence, identified by a prominently displayed Accreditation Mark. Users of NHS Evidence are able to easily identify trusted sources and have the confidence of knowing that information has been produced to a high standard.

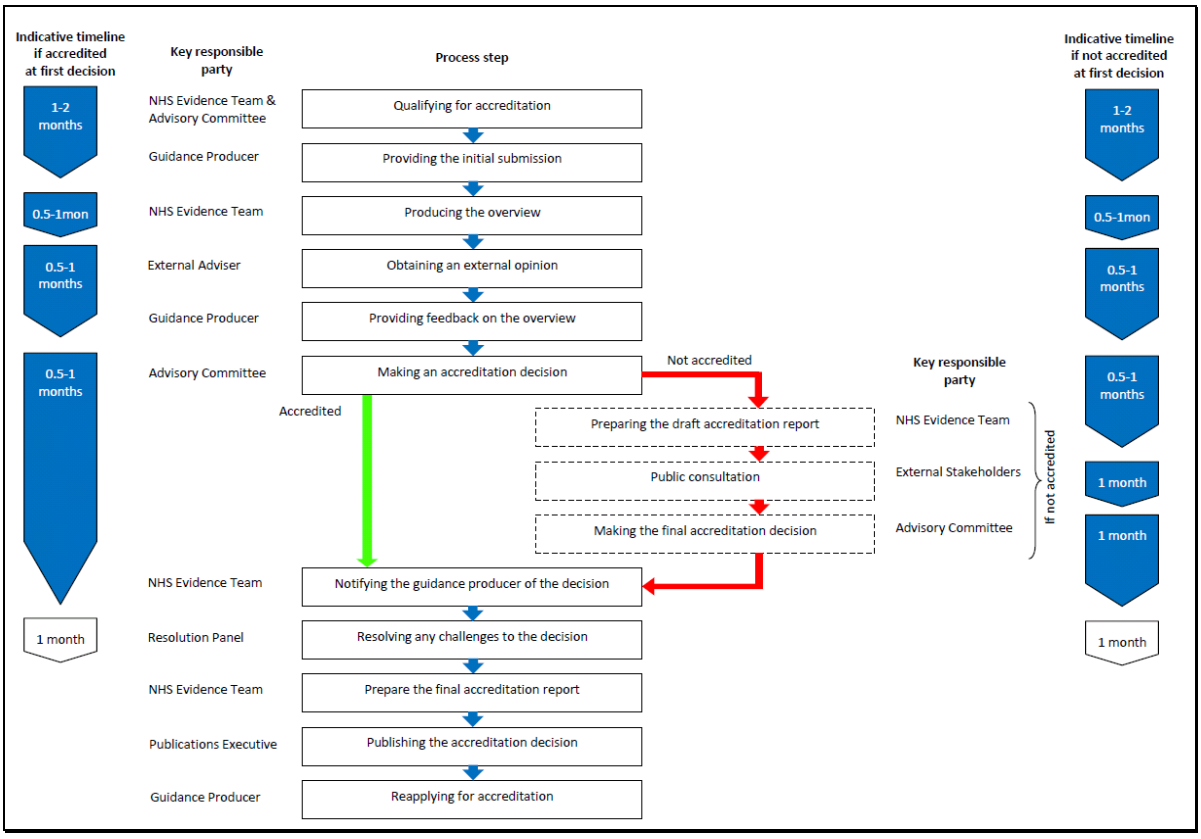
The processes by which organisations produce guidance and advice are accredited rather than individual pieces of guidance and advice or guidance content.

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). Producers of other types of guidance and advice that fits the definition above can apply for accreditation and will be considered at the discretion of the Accreditation Advisory Committee.

The Accreditation Advisory Committee bases its accreditation decision on the guidance producer meeting the relevant and necessary criteria, and is not based on an absolute or threshold scoring system. The committee considers the weight, strength and consistency of the processes used by the guidance producer, demonstrated by the presence of documented procedures, the rigour of its processes, and how consistently these are implemented in guidance examples, respectively.

Figure 1: Flowchart summarising the accreditation process



- The Accreditation Team will perform an initial assessment to ensure that all relevant information has been received to allow a complete assessment for accreditation. Please note that failure to submit all relevant supporting information will result in a delay in your application being accepted.

- Once all information is received the application is accepted and assigned to an Accreditation Technical Analyst for the duration of the process. The TA will assess your application against the criteria and prepare an overview report.
- Once complete, the overview is peer reviewed at least 2 independent external advisers for a period of 15 working days. If any substantial comments are received from external advisers the TA may revise the initial overview and may amend some of their initial findings.
- The guidance producer is then given the opportunity to review and comment on the Accreditation Team's overview and external advisers' reports for a period of 20 working days. This is the first opportunity to provide any additional supporting information or detail that may not be evident in your initial application.
- The Accreditation Advisory Committee considers all information submitted from the guidance producer, external advisers and Accreditation Team and makes an accreditation recommendation.
- Following ratification by the NICE Publications Executive, if the decision is to not accredit, the decision is available for public consultation for a period of 20 working days. Public consultation is a valuable opportunity for providing any additional information or comments to support your application.
- All comments received during public consultation will be considered. If no substantial comments are received the decision will be upheld and ratified by the Accreditation Advisory Committee.
- Following ratification by the NICE Publications Executive, if the decision is to accredit no Public consultation takes place and a final report is then produced.

Please see the Accreditation process manual for full process details.

It is advisable that content produced via an accredited process is accessible on the NHS Evidence website, either in full or as structured abstracts (for example, as defined by CONSORT). Content included in NHS Evidence should meet the inclusion criteria found here.

The Accreditation Team works closely with the team responsible for adding content to the site, who are notified when applications are received from guidance producers whose content is not included on NHS Evidence.

Commercial, for-profit organisations that produce guidance and advice are eligible to apply for accreditation. Ideally, their content should be freely accessible through NHS Evidence, either in full or as structured abstracts. However, it is recognised that in some instances this may not be possible and in order to meet its objective of raising the quality of information used by health and social care professionals in decision making, it may be necessary to evaluate guidance and advice that is available through subscription or pay per view via channels other than NHS 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. 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 target audience, type of guidance and advice produced, coverage of topic areas and estimated usage.

As part of the accreditation scheme an application form (in Microsoft Word) has been developed for the submission of information for accreditation from guidance producers. You can download the application form here.

This user guide is designed to provide further information for guidance producers regarding the requirements of the application form and submission of appropriate and relevant information required by NICE to evaluate accreditation applications. This document provides details on each section of the application form to be completed and the issues and concepts addressed by the domains and criteria of accreditation.

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

submit one application for each process used in your organisation to develop different guidance products.

Although the Accreditation Team checks samples of guidance to see if processes are consistently implemented, it does not comment on the clinical information contained within the guidance and advice. The individual pieces of guidance and advice produced via an accredited process will bear the Accreditation Mark.

It is recommended that guidance producers contact the Accreditation Team to verify their eligibility for accreditation before completing and submitting the application form. If considered eligible, 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 determined by the Accreditation Advisory Committee.

It is important that the accreditation application is complete before it is submitted. Incomplete applications may be returned, resulting in a delay in your application.

2. Your name and contact details

Please provide a named contact, contact details (email and telephone number) and organisation details. Please identify the most appropriate person to act as liaison with the Accreditation Team during the accreditation process, for example, key contact within the guidance development team. These fields are mandatory.

If you are submitting a joint application on behalf of a collaboration or partnership to produce a specific guideline, please identify a lead organisation who will act as the main point of contact and will be responsible for signing the terms and conditions, should accreditation be granted.

3. Guidance Product Details

Please select a type of guidance product from the available list. For example ‘clinical guidelines’, public health guidelines, clinical summaries, etc. If the type of guidance product you require is not available on the list please choose ‘Other’.

Please provide details on:

- The subject area covered by the guidance, for example disease, condition, therapeutic area/topic, type of patient population, safety, policy.

- Year methodology for developing guidance product was introduced, that is, the year methodology and process to be accredited was first used for developing guidance.

- Year methodology for developing guidance product was last updated. Please note when the methodology was last updated. If it has not been updated since it was developed, please insert the year in which it was originally developed.

- How frequently the guidance is produced. Approximate number of guidance products produced annually using the process that is the subject of the accredited application, along with the timeframe for updates.

- Please list all guidance products which have been produced via the process which is under assessment for accreditation. For example if two guidelines per year are produced and the process under review for accreditation was updated last year there may only be two or three products to list here. A representative sample of recently published examples of guidance will be examined in detail by the Accreditation Technical Analysts, taken arbitrarily from the list provided. In addition the list is required so that the Accreditation Mark can be added to the identified guidance products on NHS Evidence if accreditation is achieved.

- Please also list any guidance produced in conjunction with other organisations that entirely follows the process under consideration. Any co-badged guidance can be covered by the accreditation decision, as long as there is assurance that the same process has been used in all areas. Where there is any uncertainty, a separate application submitted jointly by the organisations involved in developing the joint guidance may be required.

4. Supporting Information

Guidance producers are asked to provide the following information against all criteria within each domain; all criteria should be addressed and evidenced where applicable.

- Explanatory information in the ‘Enter information here’ section covering how each criterion has been met.

  Where explanatory information can be evidenced by a policy and/or process document, please reference the relevant policy and/or process sections.

  Please keep answers concise and relevant, where possible not exceeding 4000 characters. A summary of the process you use to produce guidance is helpful; please document in the ‘additional information’ section at the beginning of the application form.

- Please submit all relevant policy or process documents which address the requirements of the domain criteria. Details of how to submit documents are in section 7.

  Please highlight all relevant paragraphs/sections and provide references in your response to facilitate the Accreditation Technical Analysts to identify relevant sections.

Guidance producers should attempt to identify all information about the guidance development process prior to submission. This information may be contained in the process document or it may be summarised in a range of documents, such as separate technical reports, in published papers, meeting minutes, audit information, on the website or in policy reports (e.g. guideline programmes).

5. Meeting accreditation domains and criteria

Where relevant please provide information against all criteria within each domain.

Please describe how your policies and processes for producing guidance meet the criteria, and provide supporting information as evidence of your application. If you need any help, please contact Accreditation@nice.org.uk

Not all of the criteria used to evaluate guidance and advice processes may be applicable in all cases. The relative importance of some criteria may therefore vary according to the specific guidance process and product being evaluated, and in some circumstances, although the guidance producer will be eligible, not all of the accreditation criteria may be applicable. The committee will debate the impact of non applicable criteria on a case by case basis. Where the degree of variance from the accreditation criteria is considered significant, then the guidance producer may be considered ineligible for accreditation using the current criteria, and new criteria may need to be developed. Similarly, for some types of guidance, certain criteria may take on greater importance; for example the rigour of development for a secondary source needs to be very robust. The guidance producer may be requested to provide more information before a decision can be made.

Where a criterion is designated as not applicable by a guidance producer a full description of the reasons why should be provided. If a large number of criteria are judged to be not applicable for a particular guidance producer, the application may be deferred until a more suitable assessment instrument has been developed.

Table 1 Accreditation domains and criteria

The accreditation criteria are based on the AGREE Instrument, which was developed to assess the quality of clinical/practice guidelines. NICE 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. Section 2 of this document examines the requirements for each criterion.

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
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 recommendations 3.6 Describes the processes of external peer review 3.7 Describes the process of updating guidance and maintaining and improving guidance quality

Domain	Criteria
4. Clarity and presentation deals with the language and format of the guidance.	These criteria consider whether the guidance producer ensures that: 4.1 The recommendations are specific, unambiguous and clearly identifiable 4.2 The different options for management of the condition or options for intervention are clearly presented 4.3 The date of search, the date of publication or last update and the proposed date for review are clearly stated 4.4 The content and style of the guidance is suitable for the specified target audience. If the public, patients or service users are part of this audience, the language should be appropriate
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
6. Editorial Independence is concerned with the independence of the recommendations, acknowledgement of possible conflicts of interest, the credibility of the guidance in general and their recommendations in particular.	These criteria consider whether the guidance producer: 6.1 Ensures editorial independence from the funding body 6.2 Is transparent about the funding mechanisms for its guidance 6.3 Records and states any potential conflicts of interest of individuals involved in developing the recommendations 6.4 Takes account of any potential for bias in the conclusions or recommendations of the guidance

6. Further supporting information

Please complete the text box with any further relevant information regarding the application for accreditation, including any economic evidence and modeling where relevant.

Please note: If you are providing further information regarding one of the criteria listed, please state the criteria number.

7. Attach supporting material

You will need to submit supporting information and documents with your application form. Please email relevant supporting information documents to us at Accreditation@nice.org.uk early stating which application it relates to.
Please ensure all relevant documents are sent through at the time of submission.

These should include:

- All relevant policy or process documents and manuals which detail the requirements of the domain criteria
- A comprehensive list of guidance developed using this process.
- A list of all available support tools
- Any supporting information which evidences your application, such as meeting minutes, organisational policies, website details or audit information.

8. Next steps

Following the submission of information for accreditation, the team will take the following steps in the accreditation process:

Section 2:

Domain 1: Scope and purpose

The following is offered as a guide to demonstrate 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 should be clearly stated. For example for commissioning guidance, objectives such as including 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 safety guidance it may be to keep a population safe or for policy guidance it could be specific to a training standard, population or a set of methods to follow.

- A detailed description of the key questions answered in the guidance, particularly for the key recommendations, such as a description of how processes for topic selection and scoping guidance take into account issues related to equality (by identifying issues related to race, disability, sex/gender or age while defining the population and/or target audience, and by promoting equality). The key question covered by guidance may be relate to the efficacy or safety of a medicine or group of medicines, a more general health or wellbeing issue or a safety question. However the description should include how these key questions were reached.

- The patient populations and/or target audience to whom the guidance and advice applies should be stated. For example, the age range, gender, clinical description and co-morbidities.

- Clear recommendations specific to the clinical/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 (which deals with the language and format of guidance). 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.

- Where recommendations are translated from a primary guideline it is important to ensure that the original objectives and scope are retained.

- Commissioning guidance does not always have explicit recommendations in the same way that other guidance 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

The term ‘stakeholder involvement’ refers to professional groups, patient representatives, patients and intended 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/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 response 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.

Various methods exist for ensuring that patients' and carers' perspectives directly inform guidance development.

- Direct involvement of individual patients and carers in developing the guidance – the views of individual patients, carers and lay people can be sought in a number of ways. These include:
    - patients and carers as members of the group developing guidance,
    - consultation,
    - 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 rather to characterise their own views and experiences.

Involvement of organisations representing patients' and carers' interests – patient and carer organisations can represent the views of 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 are ‘representing’ a particular group or constituency, and where they are participating as expert individuals. Where the views of patients, or other lay people are not directly taken into account, the reasons must be explained. If the guidance is a summary of other guidelines or information, the guidance producer should verify that patients’ views have been considered. Where available, patient defined and reported outcomes should also be identified.

Please consider:

- who you involve – for example, patients with direct experience, patient organisations etc
- why do you involve those particular groups/patients?
- what support do you provide for them and how are they involved?
- at what stage(s) in the guidance development process are they involved?

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

Representative intended users covers both the clear definition of target users in the guidance and advice product so they can immediately determine if the guidance is relevant to them. The guidance should have been pre-tested for further validation amongst its intended end users prior to publication, for example through testing and piloting.

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:

- 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, such as local data sets and population information, and proven best practice that inform the guidance and advice should also be described.

- The details of the search strategy including search terms used, sources consulted and dates of the literature covered should be described. Sources may include electronic databases (for example, MEDLINE, EMBASE, CINAHL), databases of systematic reviews (for example, the Cochrane Library, DARE), articles identified through hand searching through the review of conference proceedings and other sources (for example, the US National Guidance Clearinghouse, the German Guidance Clearinghouse) should be described. Recommendations should be based on best available evidence. For safety evidence the evidence search should be fit for purpose such as searching well known sources of safety information (such as the MHRA).

- The processes that describe the identification, evaluation, synthesis and validation of the evidence used to develop guidance and advice should be provided. Normally evidence of the process will be demonstrated 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.

- Identification and inclusion of evidence from patients, carers and other lay people should be detailed. This evidence may include good quality

qualitative research, literature reviews of patients' 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 (RCT), and in some cases can offer entirely new data on which guidance recommendations can be based.

- Commissioning guidance and advice needs to be informed by clinical evidence and, where available, accredited clinical/practice guidance and advice and quality standards.

- The evidence base used to inform social care guidance and advice may not be as strong as that used in clinical/practice medicine. Nevertheless, the criteria used for accreditation still apply, as the Accreditation Team 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 from observational or case series research. Organisations producing social care guidance and advice should be able to demonstrate or describe a process for indentifying, evaluating and synthesising evidence to inform practice. Information from health economic modeling and evaluation should be detailed.

- Criteria for including or excluding evidence for recommendations identified by the evidence review should be clearly shown. All criteria should be explicitly described and reasons for including and excluding evidence should be stated. For example, guidance producers may decide to only include evidence from RCTs 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/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.

- Search strategies and inclusion and exclusion criteria should 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, along with details of any system used in the assessment of strengths and weaknesses (for example, an evidence grading system) should be stated. An acknowledgement of any areas of uncertainty including areas where there is a lack of quality evidence should be provided.

- The processes for ensuring the relevance and validity of the data sets used as evidence should be described.

- 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 by the use of a voting system or formal consensus technique, like Delphi consensus should be described. 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.

- For a clinical summary, please describe in your process manual how you 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.

- Sometimes recommendations 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).

- The balance of health benefits against side effects and risks of the recommendations should always be considered. 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 versus benefits will clearly be an important criterion for safety guidance and advice and this discussion should be clearly explained and robust.

- A description of the process of external peer review of guidance and advice prior to publication is important. External reviewers should not have been involved in the development group but should include experts in the clinical/practice area along with methodological experts. Patients' representatives may also be included. A description of the methodology used to conduct the external review should be presented, which may include a list of the reviewers and their affiliations.

- Peer review includes 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 should be explained. For example, a timescale should be given or details about how a standing panel receives updated literature searches and improves its methodology should be included. This could include processes for updates following post-hoc review procedures, for example the 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 should be described, for example, continuous review based on audit of outcomes, evidence review, or routine updating schedule.

- Because the evidence base for guidance (especially for medicines information) can change rapidly, the process for updating guidance should be clearly described.

- As a clinical summary is normally based on both primary guidelines and clinical evidence, please ensure that the updating process describes when and how an update of any evidence type may trigger an update of the clinical summary.

Domain 4: Clarity and presentation

The Accreditation Advisory Committee is looking for explicit statements and supporting information that describes how a guidance producers advice is clear and unambiguous. In addition to the information covered in 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 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.

- Producers of clinical summaries should ensure that the meaning behind a recommendation is not lost when translating from a primary guideline into a recommendation in the clinical summary.

- For some guidance and advice products, recommendations may be more instructive and in the form of practice points or standards rather than clearly identifiable discrete statements.

- In the example of commissioning guidance and advice the scope and recommendations for service providers should clearly describe the different needs of the population. This should be evident through the guidance recommendations 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 for instance.

- The date of search, the date of publication or last update and the proposed date for review.

- 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 clinical and financial terminology. Considerations of different formats should be noted to allow patients with differing needs to be able to address their own safety concerns.

- For commissioning guidance, the factors and processes that might impact on quality of service user experience can be incorporated into the commissioning process and 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 and slides highlighting 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 implementation and ongoing utilisation of commissioning guidance and advice should be described. These may include benchmarking tools, data for comparison, and modeling tools. For safety guidance, there may be no discussion of barriers to implementation or tools to assist implementation as safety guidance and advice should always be heeded.

- Discussion of potential organisational and financial barriers in applying recommendations should be evident. For example evidence of cost impact assessment, provision of costing tools, health economic modeling and evaluation, service redesign (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), how the guidance and advice addresses quality and productivity issues. For commissioning guidance, the ability to estimate and match service supply capability (size and skills) with demand should be considered. For example in a gap analysis or business case consideration of the potential impact 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 monitor may include examination of prescribing patterns and services commissioned. The specified quality standards should be detailed; measures should link back 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 that support the implementation and ongoing utilisation of guidance in the original guideline should be shown to be fit for the purpose.

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 details of external funding or a statement that explains that guidance was developed without external funding. Processes for procurement and contracting need to be specified. The required regulatory and legal frameworks need to be considered.

- An explicit statement that all individuals involved in guidance production have declared whether they have any potential conflicts of interest including pecuniary and non-pecuniary, specific and non-specific and personal and non-personal. 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 multiparty 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.