Guidance producer subject to accreditation:

National Institute for Health and Clinical Excellence Centre for Clinical Practice (NICE CCP)

Date: 22 July 2009

Version: 1.4

Draft Accreditation Report – for consultation

Contents

1. Accreditation recommendation

The NHS Evidence Advisory Committee operates as a standing advisory committee of the Board of the National Institute for Health and Clinical Excellence (NICE). The Committee provides advice to the Institute on a framework for accrediting sources of evidence that should be recognised as trusted sources of information for the NHS. The Chair of the Committee is appointed by the Institute's Board and the meetings are conducted by the Chair or in his/her absence the vice chair. The current Chair is David Haslam. A full list of the Advisory Committee membership is available on the NICE website (http://www.nice.org.uk/nhsevidence/nhseac.jsp) and those members present for this accreditation application shown in Appendix A.

The decisions of the Committee will normally be arrived at by a consensus of those members present. The quorum is set at 50% of committee membership. The Committee will submit its recommendations to the Institute's Guidance executive which will act under delegated powers of the Institute's Board in considering and approving its recommendations.

Accreditation recommendation

It is proposed that the process to produce guidance by the **NICE Centre for Clinical Practice (CCP) is recommended for NHS Evidence accreditation**.

Background to the guidance producer

NICE is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. The Department of Health commissions NICE to develop clinical guidelines. The Centre for Clinical Practice (CCP) in NICE produces guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS. The Implementation Directorate helps ensure that NICE guidance is put into practice by developing support tools, demonstrating cost impacts and evaluating guidance uptake. NICE CCP produces approximately 20 clinical guidelines each year across a range of diseases and

conditions (http://guidance.nice.org.uk/CG).

NICE guidance is developed by a number of independent advisory groups made up of health professionals, those working in the NHS, patients, their carers and the public. Most clinical guidelines are commissioned by NICE from the National Collaborating Centres, with the exception of short clinical guidelines which are produced by NICE when rapid development of an urgent aspect of only part of a care pathway is required. The process for short clinical guidelines follows that for standard guidelines (Appendix N of 'The Guidelines Manual January 2009'). This accreditation overview therefore applies to both processes for producing standard and short clinical guidelines. The advice in the Guidelines Manual utilised by NICE is based on the criteria of quality in the Appraisal of Guidelines Research and Evaluation (AGREE) instrument.

Advisory committee consideration

The Advisory Committee considered that the guidance producer meets most of the criteria for accreditation. The documentation underlying the guidance producer's processes is robust, comprehensive and up to date. The Committee was therefore satisfied overall with the guidance producer's application, with the exception of two criteria.

The initial analysis indicated some uncertainty about criteria 5.2 (Discussion of potential organisational and financial barriers in applying its recommendations) and 5.3 (Guidance is current, with review criteria for monitoring and/or audit purposes within each product).

External advisors agreed that there was uncertainty around these criteria, and identified further uncertainty around criteria 3.1 (systematic methods to search for the evidence), 3.3 (strengths and limitations described and areas of uncertainty acknowledged), 3.4 (method used to reach recommendations), 3.5 (balance of benefits and harms considered), 6.3 (records and states any potential conflicts of interest) and 6.4 (potential for bias in recommendations or conclusions are taken into account). Further supporting

information was requested to resolve uncertainty around these criteria.

Feedback from the guidance producer resolved uncertainty about criteria 3.1, 3.3, 3.5, 5.2, 6.3 and 6.4. These criteria were judged to be met by the guidance producer.

However, uncertainty remains around criteria 3.4 and 5.3. The uncertainty around 3.4 may reflect the difficulty in accurately describing the process used by the guidance producer in translating evidence into recommendations, and the disparity in processes used depending on the membership of the groups used to make recommendations, rather than a lack of process itself. It is recommended that this area of uncertainty is tolerated in the accreditation decision.

In response to uncertainty about criterion 5.3, the guidance producer reiterated its process for updating guidance to ensure it is current. However, it did not address the specific issue raised, which was uncertainty around criteria for monitoring and audit within each guidance product. This therefore remains an area of uncertainty. It is recognised that criterion 5.3 is ambiguous and it is recommended that it focuses only on criteria for monitoring and audit.

Summary and recommendations

In summary, the Advisory Committee considers that the guidance producer NICE Centre for Clinical Practice (CCP) is accredited.

The guidance producer has a documented process for producing guidance, which is very robust. The process meets 23 of the 25 accreditation criteria, and there is evidence that it is consistently implemented in its guidance.

The guidance producer needs to improve in the following areas:

- More detail around the different processes used to reach recommendations in its guidance
- More detail around how its guidance is audited and monitored when it is implemented

Compliance with these criteria will be reviewed when the guidance producer reapplies for accreditation in 3 years.

David Haslam

Chair, Advisory Committee

July 2009

2. NHS Evidence accreditation analysis

The Advisory Committee considered the following analysis of the guidance producer's compliance with NHS Evidence accreditation criteria, summarised below. The extent of compliance with each domain and criteria is shown in Appendix B: Overview Summary Table. Appendix C lists the additional information taken into account in the analysis and considered by the Committee. The process for accrediting producers of guidance and recommendations for practice is described in the process manual which can be found here http://www.nice.org.uk/nhsevidence/aboutaccreditation/aboutaccreditation.jsp?domedia=1&mid=27C232A0-19B9-E0B5-D4A11FA899F4C219.

2.1. Scope and purpose

Does the guidance producer have a policy in place that requires them to specifically detail the domain criteria?

The guidance producer meets the criteria in this domain, described in 'The Guidelines Manual January 2009'. Evidence for the application of these criteria was found in two examples of guidance (CG79: Rheumatoid arthritis, Feb 2009 and CG81: Advanced breast cancer, Feb 2009). The external advisors agreed with this assessment.

2.2. Stakeholder involvement

Does the guidance producer have a policy in place that means it includes information detailed in the domain criteria?

The guidance producer meets the criteria in this domain, described in 'The Guidelines Manual January 2009'. Evidence for the application of these criteria was found in two examples of guidance (CG79: Rheumatoid arthritis, Feb 2009 and CG81: Advanced breast cancer, Feb 2009). The external advisors agreed with this assessment.

2.3. Rigour of development

Does the guidance producer have a clear policy in place that means it includes information detailed in the domain criteria?

The external advisors felt that there were areas of uncertainty around some of the criteria in this domain.

3.1 (systematic methods to search for the evidence): the external advisors asked if the guidance producer is intending to use the GRADE system.

In its feedback, the guidance producer reiterated that 'The Guidelines Manual January 2009', specifies that elements of GRADE are being used when approaching questions about interventions in guidelines [Chapter 6, section 6.2.1.1 'The GRADE (Grading of Recommendations Assessment, Development and Evaluation) Approach to Assessing the Quality of Evidence'.]

The guidance producer submitted one further example of the use of GRADE [guideline CG85 Glaucoma, Chapter 6 'Overview of Treatment'. (http://www.nice.org.uk/nicemedia/pdf/CG85FullGuideline.pdf)]. The use of GRADE is being phased in so it may take some time for it to be used in all guidelines.

After considering the guidance producer's feedback, the criterion was judged to have been met.

3.3-3.5 (strengths and limitations described and areas of uncertainty acknowledged; method used to reach recommendations; and balance of benefits and harms considered): the external advisors requested a sample description of the path from evidence to recommendation.

The guidance producer submitted one further example describing the path from evidence to recommendations [guideline CG85 Glaucoma, Chapter 6 'Overview of Treatment'. (http://www.nice.org.uk/nicemedia/pdf/CG85FullGuideline.pdf)].

After considering the guidance producer's feedback, the uncertainty around these

criteria was judged to have been resolved and the criteria met.

3.4 (method used to reach recommendations): the external advisors stated that the informal consensus techniques used by the guidance producer require methods for resolving disagreements, and that formal techniques require further elaboration and supporting information from a previously developed guideline.

Feedback from the guidance producer was that the process of informal and formal consensus is described in the guidelines development manual Chapter 3 section 3.5 'Making Group Decisions and Reaching Consensus'. There are many different approaches to making group decisions, and there is no blueprint about which approach should be used in which circumstances. Also, they felt that because Guideline Development Groups (GDGs) used by the guidance producer function in different ways to reflect their individual membership, it is difficult to be prescriptive about the approach that should be used. The Delphi technique may be used as an approach for formal consensus. For the process of informal consensus, technical staff draft recommendations, the GDG then debate the draft recommendations and agree the final wording. The guidance producer cited the example of CG47 'Feverish Illness in Children' chapter 1 section 1.7 'Guideline Development Methodology' (http://www.nice.org.uk/nicemedia/pdf/CG47Guidance.pdf).

After considering the guidance producer's feedback, there is still some uncertainty around this criterion. However, this may be a function of the difficulty in quantifying the process of reaching recommendations rather than a failing in the processes used.

3.5 (balance of benefits and harms considered): the external advisors asked for confirmation that the guidance producer specify the basis on which judgements are made.

The guidance producer confirmed that this was the case.

This criterion was judged to be met.

2.4. Clarity and presentation

Has the guidance producer submitted sufficient detailed information to ensure the domain criteria are met?

The guidance producer meets the criteria in this domain, described in 'The Guidelines Manual January 2009'. Evidence for the application of these criteria was found in two examples of guidance (CG79: Rheumatoid arthritis, Feb 2009 and CG81: Advanced breast cancer, Feb 2009). The external advisors agreed with this assessment.

2.5. Applicability

Has the guidance producer submitted sufficient detailed information to evidence routine consideration of the domain criteria?

5.2 (discussion of potential barriers to implementation): The external advisors agreed with the NHS Evidence accreditation assessment that there was uncertainty on this criterion requiring more supporting information, and that barriers to implementation are routinely included in all guidance not just where appropriate.

In their feedback, the guidance producer stated that Chapter 13 of the Guideline Development Manual, 'Implementation Support for Clinical Guidelines', describes how the uptake of NICE recommendations is promoted and encouraged. This chapter describes how any barriers to implementation are identified and whether any potential significant changes in resource use are likely to arise from implementation of the guideline. The implementation support tools are developed by staff from the Implementation Directorate at NICE, in consultation with the Guideline Development Group (GDG), the National Collaborating Centre (NCC), the Centre for Clinical Practice (CCP) Guidelines Commissioning Manager and the Patient and Public Involvement Programme lead for the guideline.

This supporting information resolved the uncertainty around this criterion, which was judged to be met.

5.3 (guidance is current, with review criteria for monitoring and/or audit): The external

advisors agreed with the NHS Evidence accreditation assessment that there was uncertainty on this criterion. The criterion appears to address two issues: currency and monitoring/audit. Currency is met by the guidance producer, but there is uncertainty around monitoring/audit.

In its feedback, the guidance producer did not specifically address this uncertainty.

2.6. Reliability and trustworthiness

Has the guidance producer submitted sufficient detailed information to evidence achievement of the domain criteria?

The external advisors felt that there were areas of uncertainty around some of the criteria in this domain.

6.3 (records and states any potential conflicts of interest): the external advisors stated that information is lacking in how potential conflicts are managed and it is unclear what the process is when these are fall outside what is acceptable in NICE's policy.

6.4 (potential for bias in recommendations or conclusions are taken into account): the external advisors stated that the producer provides no evidence of a process for handling bias and that issues of potential bias should be addressed in all guidance documents.

The guidance producer responded by stating that both of these issues relating to conflict of interest and potential bias are addressed. Chapter 3 of the Guideline Development Manual has a section on how potential conflicts of interest should be declared and handled, 'Code of Conduct and Conflicts of Interest'. This procedure is in accord with the NICE policy for handling conflicts of interest, 'A Code of Practice for Declaring Interests and Resolving Conflicts' (http://www.nice.org.uk/niceMedia/pdf/boardmeeting/brdjul06item5.pdf). The policy applies to the chair and other non-executive and executive directors of the NICE board, the members of its advisory bodies, the experts who assist advisory bodies, NICE's employees and the employees of those organisations which provide the Institute with

the evidence on which it forms it recommendations. It describes the circumstances in which they should declare an interest which might conflict, or be seen to conflict, with their duties and responsibilities to the Institute. The policy sets out, for each group, when a declaration of interest should be made and summarises the action which should be taken when interests are declared. Declarations of interests from the guideline developers are published in the final full guideline; for an example, see Appendix B of guideline CG85 Glaucoma (http://www.nice.org.uk/nicemedia/pdf/CG85FullGuidelineAppendices.pdf).

3. Implementation

Following a final accreditation decision being made, guidance from the accredited producer will be identified on NHS Evidence by a graphic – the accreditation mark. The accredited guidance producer is also granted a royalty-free, worldwide licence to use the NHS Evidence accreditation mark in accordance with the Conditions and Terms of Use (http://www.nice.org.uk/nhsevidence/?domedia=1&mid=5AE1D938-19B9-E0B5-D471CA81220F57DA) for the duration of their accreditation for a category of evidence. Provided these conditions are complied with, a guidance producer's accreditation will last for three years from when NHS Evidence's decision to award accreditation is published on the NHS Evidence website.

Accredited guidance producers must take reasonable steps to ensure that processes approved by NHS Evidence are followed when generating the type of evidence for which they are accredited. Accredited guidance producers should have quality assurance mechanisms in place to ensure compliance with accredited procedures. Accredited guidance producers shall inform NHS Evidence of any change to a process which may impact on the fulfilment of the relevant accreditation criteria within 30 days of that change occurring.

Appendix A: Advisory Committee members, external advisors and NHS Evidence accreditation team

NHS Evidence Advisory Committee Members

The Advisory Committee is a standing advisory committee. The members have been appointed for a period of 18 months. This may be extended by mutual agreement to a further term of 3 years and up to a maximum term of office of 10 years. A list of the committee members who took part in the discussions for this accreditation decision appears below.

Committee members are asked to declare any interests in the guidance producer to be accredited. If it is considered that there is a conflict of interest, the member(s) is excluded from participating further in the discussions.

Title	Name	Surname	Role	Organisation
Mr	Richard	Brownhill	Clinical Development & Nurse Practitioner	Calderdale & Huddersfield NHS Trust & Kirklees PCT
Sir	Iain	Chalmers	Coordinator - James Lind Initiative	James Lind Library
Ms	Amanda	Edwards	Head of Knowledge Services	Social Care Institute for Excellence (SCIE)
Mr	Lester	Firkins	Chair – James Lind Alliance – Strategy and Development Group	James Lind Alliance
Dr	Brian	Fisher	General Practitioner	NHS Alliance (GP and national patient/public lead)
Ms	Diane	Gwynne Smith	Head of Knowledge Management	Social Care Institute for Excellence (SCIE)
Professor	David	Haslam	National Clinical Advisor to the Care Quality Commission	Care Quality Commission
Dr	Bobbie	Jacobson	Director of London Health Observatory, Vice Chair of Association of PH Observatories	London Health Observatory
Dr	Monica	Lakhanpaul	Senior Lecturer in Child Health / Consultant Paediatrician	
Professor	Nigel	Mathers	Professor of General Practice Sheffield, and RCGP	Northern General Hospital
Ms	Catherine	Mercer	Midwife	Royal Shrewsbury Hospital
Professor	Jon	Nicholl	Professor of Health Services Research	School of Health and Related Research (ScHARR)
Professor	Sandy	Oliver	Professor of Public Policy, Deputy Director Social Science Research Unit	Cochrane Consumers and Communication Review Group, University of London
Dr	Carl	Parker	General Practitioner	Hartlepool and North Tees PCT

Advisory Committee Deputies

Professor	Stuart	Logan			For John Tooke
Ms	Parul	Desai			For Mark Davies
Dr	Norma	O'Flynn	Clinical Director National Collaborating Centre for Primary Care	Royal College of General Practitioners	For Nigel Mathers
Dr	Edward	Wozniak	Paediatric Advisor	Department of Health	For Sheila Shribman

External Advisors for NICE CCP accreditation application

Dr Faith McLellan, Guidelines Review Committee Secretariat, World Health Organization, Geneva, Switzerland

Dr Suzanne Hill, Medicines, Access and Rational Use, Essential Medicines and Pharmaceutical Policies, World Health Organization, Geneva, Switzerland

NHS Evidence accreditation team for NICE CCP accreditation application

Dr Paul Chrisp, Associate Director Accreditation, NHS Evidence, National Institute for Health and Clinical Excellence, Manchester, UK

Carrie Thomson, Project Manager - New Developments, National Institute for Health and Clinical Excellence, Manchester, UK

Appendix B: Overview Summary Table

Domain	1 **Scope and purpose** is concerned with the overall aim of the guidance, the specific clinical questions and the target population.	***Draft accreditation decision***
Criteria	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	Green
	1.2 The clinical questions covered by the guidance	Green
	1.3 The patients and/or target audience to whom the guidance applies	Green
	1.4 That the producer ensures guidance includes clear recommendations in reference to specific clinical circumstances.	Green
Domain	2 **Stakeholder involvement** focuses on the extent to which the guidance represents the views of its intended users.	***Draft accreditation decision***
Criteria	These criteria consider whether the guidance producer has a policy in place that means it includes:	
	2.1 Individuals from all relevant professional groups	Green
	2.2 Patient representatives and seeks patients views and preferences	Green
	2.3 Representative intended users in developing guidance.	Green
Domain	3 **Rigour of development** relates to the process used to gather and synthesise information and the methods used to formulate recommendations and update them.	***Draft accreditation decision***
Criteria	These criteria consider whether the guidance producer has a clear policy in place that:	
	3.1 Requires the technical team to use systematic methods to search for evidence and provide details of the search strategy	Green
	3.2 Requires the guidance producers to state the criteria and reasons for inclusion or exclusion of evidence identified by the evidence review	Green
	3.3 Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty	Green
	3.4 Clarifies the method used to arrive at recommendations (for example, a voting system or formal consensus techniques like Delphi consensus)	Yellow
	3.5 Requires the guidance producers to balance the health benefits against the side effects and risks	Green
	3.6 Details the processes of external peer review	Green

	3.7 Mentions the process of updating guidance and maintaining and improving guidance quality	Green
Domain	4 **Clarity and presentation deals with the language and format of the guidance.**	***Draft accreditation decision***
Criteria	These criteria appraise whether the guidance producer ensures that:	
	4.1 Their recommendations are specific, unambiguous and clearly identifiable	Green
	4.2 Different options for the management of the condition are clearly presented	Green
	4.3 The date of search, the date of publication or last update and the proposed date for review are clearly stated	Green
	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.	Green
Domain	5 **Applicability deals with the likely organisational, behavioural and cost implications of applying the guidance.**	***Draft accreditation decision***
Criteria	These criteria measure whether the guidance producer routinely considers:	
	5.1 Publishing support tools to aid implementation of guidance	Green
	5.2 Discussion of potential organisational and financial barriers in applying its recommendations	Green
	5.3 That their guidance is current, with review criteria for monitoring and/or audit purposes within each product.	Yellow
Domain	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.	***Draft accreditation decision***
Criteria	These criteria measure whether the guidance producer:	
	6.1 Ensures independence from the funding body	Green
	6.2 Is transparent about the funding mechanisms for its guidance	Green
	6.3 Records and states any potential conflicts of interest of individuals involved in developing the recommendations	Green
	6.4 Takes account of any potential for bias in the conclusions or recommendations of the guidance	Green

Appendix C: Additional information analysed

List of information taken into account in the accreditation analysis and considered by the Advisory Committee.

Document name	Description	Location
The guidelines manual January 2009 – all chapters	A manual that explains how NICE develops guidelines	http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopmentmethods/GuidelinesManual2009.jsp?domedia=1&mid=5F238D80-19B9-E0B5-D4CB1191544B5D45
The guidelines manual January 2009 – all appendices	Appendices to the 2009 manual	http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopmentmethods/GuidelinesManual2009.jsp?domedia=1&mid=5F247196-19B9-E0B5-D481E895E2E997F9
CG79 Rheumatoid arthritis: full guideline	An example of a full guideline product produced by the guidance producer	http://www.nice.org.uk/Guidance/CG79/Guidance/pdf/English
CG79 Rheumatoid arthritis: full guideline	Appendices to the CG79 full guideline	http://www.nice.org.uk/guidance/index.jsp?action=download&o=43335
CG81 Advanced breast cancer: full guideline	An example of a full guideline product produced by the guidance producer	http://www.nice.org.uk/Guidance/CG81/Guidance/pdf/English
CG79 Rheumatoid arthritis documents	A list of documents showing the different formats and versions of the guidelines produced for different audiences	http://www.nice.org.uk/Guidance/CG79
CG81 Advanced breast cancer documents	A list of documents showing the different formats and versions of the guidelines produced for different audiences	http://www.nice.org.uk/Guidance/CG81

Document name	Description	Location
Rheumatoid arthritis: costing template	A costing template to aid implementation of the CG79 Rheumatoid arthritis guideline	http://www.nice.org.uk/Guidance/CG79/CostTemplate/xls/English
Rheumatoid arthritis: costing report	A costing report to aid implementation of the CG79 Rheumatoid arthritis guideline	http://www.nice.org.uk/Guidance/CG79/CostReport/pdf/English
Rheumatoid arthritis: slide set	A slide set to aid implementation of the CG79 Rheumatoid arthritis guideline	http://www.nice.org.uk/Guidance/CG79/SlideSet/ppt/English
Advanced breast cancer: costing template	A costing template to aid implementation of the CG81 Advanced breast cancer guideline	http://www.nice.org.uk/Guidance/CG81/CostTemplate/xls/English
Advanced breast cancer: costing report	A costing report to aid implementation of the CG81 Advanced breast cancer guideline	http://www.nice.org.uk/Guidance/CG81/CostReport/pdf/English
Advanced breast cancer: slide set	A slide set to aid implementation of the CG81 Advanced breast cancer guideline	http://www.nice.org.uk/Guidance/CG81/SlideSet/ppt/English