NICE National Institute for Health and Care Excellence

Guidance producer:	**Guidelines & Audit Implementation Network**
Guidance product:	**Clinical Guidelines**
Date:	**24 February 2017**
Version:	**1.2**

Accreditation Decision Report – for consultation

Contents

Introduction

The NICE Accreditation Programme recognises organisations that demonstrate high standards in producing health or social care guidance. Users of the accredited guidance may therefore have high confidence in the quality of the information. Organisations can publicly display a seal of approval called an Accreditation Mark for 5 years after their processes have been accredited. The process for accrediting producers of guidance and recommendations for practice is described in the process manual.

Accreditation recommendation

It is proposed that the process used by the **Guidelines and Audit Implementation Network** to produce **Clinical Guidelines** is **not recommended for accreditation.** This draft decision is subject to further external peer review and public consultation before a final decision is made.

Background to the guidance producer

The Guidelines and Audit Implementation Network (GAIN) provides funding and project support for the development of guidance in Northern Ireland. All guidance is developed according to a standard process, which is the subject of this assessment. Its main function is to promote leadership in safety and quality care through the development and integration of regional guidelines and audit and their implementation to improve outcomes for patients, clients and carers. On the 1st April 2015, responsibility for GAIN transferred to the Regulation and Quality Improvement Authority (RQIA).

The funding application process is open to anyone in the health and social care community in Northern Ireland who can demonstrate a need for particular guidance and who can adhere to the GAIN methodology for guidance development.

This process involves systematic reviews of the evidence to develop recommendations and requires a multidisciplinary approach including patients or patient representatives. This is followed by a process of wider consultation and peer review before the final

version is published. The resulting guidelines are branded as GAIN guidelines according to a standard format, and are freely available via the GAIN website.

Summary

The Accreditation Advisory Committee considered that the processes used by the Guidelines and Audit Implementation Network to produce clinical guidelines demonstrated compliance with 17 of the 25 criteria for accreditation, with 8 criteria not fully met.

The scope and purpose of the guidelines are clear, and the content and style is suitable for the target audience to which the example guidelines are directed. The recommendations are provided in reference to specific circumstances. The process includes relevant stakeholders and patient groups throughout the guideline development process as members of the Guideline Development Group (GDG) and where relevant by the use of qualitative research such as surveys. Patients' views and preferences are included. Intended users are also represented throughout the process.

There are systematic methods for evidence searches and guideline developers consider health benefits, side effects and risks of recommendations made in guidelines. The recommendations are specific, clearly identifiable in guidelines and in a language suitable for the target audience. Where relevant, guidelines contain treatment and management options. There is a requirement to provide support tools to aid in the implementation of guidelines, as well as the inclusion of monitoring or audit information. Organisational and financial barriers are considered in the guideline development process. Guidelines include publication and review dates but there are inconsistencies in the documentation of dates for literature searches.

The guideline development process is editorially independent. Funding mechanisms are transparent. Interests are required to be declared and managed according to a policy that currently, only requires GDG members to complete a declaration of interests form. It is unclear if any conflicts arose in the development of the example guidelines and how they were managed. There is therefore still some possibility of bias.

There are also inconsistencies in the application of the process between the guidelines examined, across a range of areas including inclusion and exclusion criteria, consideration of strengths of evidence, methods to arrive at recommendations, the peer review process and review and updating of guidelines.

Suggestions for improving the process used to develop GAIN clinical guidelines include:

- Documentation and implementation of an editorial oversight process to ensure consistency across published guidelines.
- Implementation of the updates to the review process for published guidelines and ensuring the process for reviewing and updating guidance is adhered to.
- The inclusion of a statement in the guidelines to document, either that no conflicts were declared or an indication of the type(s) of any conflicts declared and how they were managed.
- Adding a requirement for peer reviewers to complete a declarations of interest form.

This draft decision now goes for further external peer review and to public consultation. The decision will be reviewed if it is not supported at peer review or if significant additional information is provided during consultation.

Professor Martin Underwood

Chair, Accreditation Advisory Committee

February 2017

Appendix A: NICE Accreditation analysis

The Advisory Committee considered the following analysis of the guidance producer's compliance with NICE Accreditation criteria, which covers 6 discrete domains. The full analysis leading to the accreditation decision is shown below.

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
Scope and purpose	**Does the guidance producer have a policy in place and adhered to that requires them to explicitly detail:**		
	1.1 Overall objective	The process manual[1] details the aims and objectives of guidelines. Guideline developers are required to include an introduction section, outlining the need for the guideline and its remit, as part of the formatting of the guidelines. The example guidelines[2,3] both detail the aims and objectives in the relevant section of the document.	Criterion met
	1.2 The clinical, healthcare or social questions covered	The process manual[1] requires guideline developers to detail the question under consideration in both the proposal to GAIN and in the guideline itself. It advocates the use of the Population, Intervention, Comparison, and Outcome (PICO) in formulating the questions to be used in the systematic searches for evidence. The example guidelines[2,3] contain information on the context of the document.	Criterion met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	1.3 Population and/or target audience to whom the guidance applies	The process manual[1] asks guideline developers to identify their key target audience in their development procedure. It also requires guideline developers to define the population the guidance covers including age, social and ethnic groups where appropriate. The example guidelines[2,3] state the patient groups who the guidelines are aimed at and the intended audience.	Criterion met
	1.4 Guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	There is a requirement in the process manual[1] for guideline developers to use the PICO format which results in recommendations being specific to the population and context of the topic. It is clear in the example guidelines[2,3] that the recommendations are specific to particular audiences and circumstances.	Criterion met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
Stakeholder involvement	**Does the guidance producer have a policy in place and adhered to that means it includes:**		
	2.1 Individuals from all relevant stakeholder groups, including patient groups, in developing guidance	The process manual[1] requires guideline development groups to be multi-disciplinary, ensuring full discussion of relevant evidence, service delivery issues, and the construction of appropriate recommendations. It also includes a requirement for developers to consider key external organisations, experts and stakeholders in the development process, from scoping to reviewing the final document. It also advocates the inclusion of patient and carers in the guideline development group, in addition to any relevant patient groups. It is clear that the example guidelines[2,3] have included all relevant stakeholders in the guideline development process.	Criterion met
	2.2 Patient and service user representatives and seeks patient views and preferences in developing guidance	The process manual[1] includes information of the requirements for lay involvement in guideline development by individual guideline developers. It advocates the inclusion of patient and carers in the guideline development group, in addition to any relevant patient groups. GAIN offers support to patients and their representatives by offering training and induction sessions. Patient views were included in the development of the example guidelines[2,3].	Criterion met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	2.3 Representative intended users in developing guidance.	The process manual[1] recommends that the Guideline Development Group (GDG) should consist of a multidisciplinary group including relevant professional stakeholders, specialists, and those who would be involved in implementing the guidance. The suggested format for guidelines includes membership details of the GDG in an appendix. It is clear that there was representation from intended users in the example guidelines[2,3]	Criterion met
Rigour of development	**Does the guidance producer have a clear policy in place that:**		
	3.1 Requires the guidance producer to use systematic methods to search for evidence and provide details of the search strategy	The process manual[1] states that identification and synthesis of evidence should be done using systematic methods. It provides information about the steps required, resources that may be used including named databases, advice on date ranges for searches, and a link to various sections of the **Scottish Intercollegiate Guidelines Network** (SIGN) website relevant to developing a search strategy. The example guidelines[2,3] include a description of the search strategy as well as a reference to further information on the GAIN website.	Criterion met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	3.2 Requires the guidance producers to state the criteria and reasons for inclusion or exclusion of evidence identified by the evidence review	The process manual[1] states that inclusion and exclusion criteria should be developed at the start of systematic reviews. Potential exclusion criteria such as study design, timeframe and language are provided, although the dangers of introducing bias or missing key evidence through exclusion criteria are also explained. It also requires that all decisions taken to include or exclude certain studies or groups of studies should be documented in the guidelines. There is inconsistency in the implementation of the process in the example guidelines[2,3]. While the Northern Ireland Guidelines for the Management of Chronic Kidney Disease (CKD), 2015[2] provides this information in its literature search documentation, it is not available for the Guideline for admission to Midwife-Led units in Northern Ireland & Northern Ireland Normal labour & birth care pathway, 2016[3].	Criterion not fully met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	3.3 Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty	The process manual[1] states that the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the level of evidence allocated to the paper, which will in turn influence the grade of recommendation that it supports. An evidence appraisal system used by the SIGN is provided in the appendix. One of the example guidelines, Northern Ireland Guidelines for the Management of Chronic Kidney Disease (CKD), 2015[2] provides information on how evidence was graded while the process utilised for the Guideline for admission to Midwife-Led units in Northern Ireland & Northern Ireland Normal labour & birth care pathway, 2016[3] is unclear.	Criterion not fully met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	3.4 Describes the method used to arrive at recommendations (for example, a voting system or formal consensus techniques like Delphi consensus)	The process manual[1] suggests that agreement can be reached using voting methodologies where consensus cannot be achieved. While the guidance producer indicates that recommendations are derived from systematic reviews, it does not explain how the results of systematic reviews are turned into recommendations. The process manual outlines the steps involved in guidance development. It states that results of searches are organised into evidence tables for each of the key questions. No explanation is provided for how the recommendations are developed from these evidence tables, especially where contrary evidence is present. The example guidelines[2,3] state the procedure to develop recommendations as well as the people involved. However there is some inconsistency as the guidance producer indicated in correspondence that recommendations were reached by consensus for the Guideline for admission to Midwife-Led units in Northern Ireland & Northern Ireland Normal labour & birth care pathway, 2016[3] guideline. This information, however is neither publicly available nor is it stated within the guideline that it is available on request. The method of developing recommendations is not indicated for the Northern Ireland Guidelines for the Management of Chronic Kidney Disease (CKD), 2015[2] guideline.	Criterion not fully met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	3.5 Requires the guidance producers to consider the health benefits against the side effects and risks in formulating recommendations	The process manual[1] reminds guideline developers to communicate any identified risks, benefits and side effects considered during guidance development to the end user. It also states that the guidance producer expects the peer reviewer stage to identify any health benefits and potential risks. The example guidelines[2,3] contain discussions of risks associated with conditions, interventions or lack of intervention in the document.	Criterion met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	3.6 Describes the processes of external peer review	The process manual[1] indicates that GAIN sends draft guidelines to all relevant parties for wider consultation. Stakeholders include all Health & Social Care Trusts; the Public Health Agency; the Health & Social Care Board; and relevant patient and carer representative organisations. After the consultation period, all comments received are collated and sent to the project team (guideline developers) for their consideration. The project team make amendments to the draft guidance if necessary, and it is then forwarded for peer review by a smaller group of pre-selected experts in the subject area. Comments from these reviewers is utilised to develop the final version of the guideline. There are inconsistencies in the implementation of the process in the example guidelines. While the peer review process for Guideline for admission to Midwife-Led units in Northern Ireland & Northern Ireland Normal labour & birth care pathway, 2016[3] is transparent the peer review process for Northern Ireland Guidelines for the Management of Chronic Kidney Disease (CKD), 2015[2] is not publicly available.	Criterion not fully met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	3.7 Describes the process of updating guidance and maintaining and improving guidance quality	The process manual[1] requires the GDGs to develop a procedure for updating the guideline, including stating the publication date on the published guideline. Guidelines are reviewed three years after publication, or when new evidence becomes available that requires a guideline to be updated. They can be reviewed sooner if there are changes in the evidence related to the benefits, harms or outcomes of interventions. There is a documented process for the scheduled review of guidelines. The procedure should the original guideline developers be unavailable and ad-hoc updates have only recently been added to the process, so there is currently no evidence of implementation. The guidance producer has also not addressed the deviations from its process with some guidelines on its website that are past their review dates. Consequently, there is an inconsistency in the implementation of the documented process.	Criterion not fully met
Clarity and presentation	**Does the guidance producer ensure that:**		
	4.1 Recommendations are specific, unambiguous and clearly identifiable	The process manual[1] requires guideline developers to highlight the key recommendations in the guideline. It also requires the quality of evidence of each recommendation to be included in the main body of the document. The recommendations in the example guidelines[2,3] are clear and unambiguous.	Criterion met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	4.2 Different options for the management of the condition or options for intervention are clearly presented	The process manual[1] requires guideline developers to include an explanation of available treatment or management options for interventions listed in guidelines as part of the main body of the document. It also states that options for which no evidence exists should still be briefly mentioned. Where appropriate, the different treatment or management options have been included in the example guidelines[2,3].	Criterion met
	4.3 The date of search, the date of publication or last update and the proposed date for review are clearly stated	The process manual[1] requires guideline developers to provide a publication date on the final documents to be published. It asks guideline developers to consider reviewing publications on a three year basis in addition to considerations for ad-hoc updates. Both example guidelines[2,3] contain publication and review dates. However, there is some inconsistency in the evidence of implementation for the example guidelines[2,3] as only the Northern Ireland Guidelines for the Management of Chronic Kidney Disease (CKD), 2015[2] provides information of the dates of searches.	Criterion not fully met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	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.	The process manual[1] contains a list of segments required to be included in guidelines. These segments such as 'who is the guideline intended for' would aid guideline developers to tailor the content of their guidance to their target audience using suitable language. The example guidelines[2,3] state who the guideline is intended for and it is clear that the guidelines are fit for the intended audience of healthcare professionals and people involved in clinical governance.	Criterion met
Applicability	**Does the guidance producer routinely consider:**		
	5.1 Publishing support tools to aid implementation of guidance	The process manual[1] requires the publication of support tools in the appendices of guidelines by developers. The application process includes questions on how developers plan to support guideline implementation ensuring that this has been considered prior to the start of the development process. Support tools were provided for the example guidelines[2,3].	Criterion met
	5.2 Discussion of potential organisational and financial barriers in applying its recommendations	The process manual[1] requires guideline producers to document any barriers to applying recommendations that users may encounter. The example guidelines[2,3] contain information to indicate that organisational and financial barriers to applying recommendations have been considered in the development of guidelines.	Criterion met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	5.3 That their guidance is current, with review criteria for monitoring and/or audit purposes within each product.	The process manual[1] requires developers to consider the inclusion of clinical audit requirements, along with suggested clinical audit tools. The project team in collaboration with the GAIN regional clinical facilitator identify key areas that are auditable along with tools to carry out the audits. Examples of monitoring tools have been provided in the examined guidelines[2,3].	Criterion met
Editorial independence	**Does the guidance producer:**		
	6.1 Ensure editorial independence from the funding body	The process manual[1] states the funding source is the Department of Health Northern Ireland (DOHNI), which provides finance to GAIN for guidance development. The manual makes no reference to any roles or representation for the DOHNI in the guideline development process. There is no indication that the funding source could exert any influence over the development of recommendations in the guidance.	Criterion met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	6.2 Demonstrate transparency about the funding mechanisms for its guidance	The process manual[1] requires guideline developers to apply once a year for funding to aid in the development of guidelines. A link to the RQIA website is provided in the manual, where information about funding can be found including annual reports and business plans. These documents state the funding source as the Department of Health Northern Ireland (DOHNI). It is a requirement for GAIN applicants to detail how the money will be spent and report on this on a quarterly basis. The example guidelines[2,3] both contain funding details.	Criterion met
	6.3 Record and state any potential conflicts of interest of individuals involved in developing the recommendations	The process manual[1] contains information about the guidance producer's declaration of interest's policy and describes examples of different types of interests including pecuniary and non-pecuniary interests as well as actions to be taken in the event of a conflict. It defines the procedure for proceeding with a meeting, should the chair of the GDG be conflicted. Finally, it requires that a register of interests be maintained annually and is available on request. No evidence of implementation was provided for the example guidelines[2,3] to indicate the declaration of interest's policy and how any conflicts, if applicable were managed and this information is not currently available within the guidelines or stated that it is available on request. Additionally, there is currently no requirement for peer reviewers to complete a declaration of interests form.	Criterion not fully met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	6.4 Take account of any potential for bias in the conclusions or recommendations of the guidance	The process[1] is systematic, multidisciplinary and takes account of the potential for bias, but there is some uncertainty as to if the process is consistently followed. The inconsistency of evidence of implementation of the documented processes, around systematic search, inclusion and exclusion of evidence, external peer review and declaring conflicts of interest within the example guidelines [2,3] allows some possibility of bias to remain.	Criterion not fully met

Documents referenced above:

1 Advice for developing guidance in Northern Ireland (2016)

2 Northern Ireland Guidelines for the Management of Chronic Kidney Disease (CKD), 2015

3 Guideline for admission to Midwife-Led units in Northern Ireland & Northern Ireland Normal labour & birth care pathway (2016)

Appendix B: Bibliography

Appendix B lists the additional information taken into account in the analysis and considered by the committee.

Document name	Description	Location
Advice for developing guidance in Northern Ireland (2016)	Process manual for developing guidelines	Supplied
Northern Ireland Guidelines for the Management of Chronic Kidney Disease (CKD), 2015	Guidance example	Supplied
Guideline for admission to Midwife-Led units in Northern Ireland & Northern Ireland Normal labour & birth care pathway (2016)	Guidance example	Supplied

Appendix C: NICE Accreditation Advisory Committee, external advisers and NICE Accreditation team

NICE Accreditation Advisory Committee

The Accreditation Advisory Committee operates as a standing advisory committee of the Board of the National Institute for Health and Care Excellence (NICE). The Committee provides advice to NICE 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 NICE Board and the meetings are conducted by the chair, or in his/her absence the vice chair. The current Chair is Martin Underwood. A full list of the Advisory Committee membership is available on the NICE website. Members are appointed for a period of 3 years. This may be extended by mutual agreement for a further 3 years, up to a maximum term of office of 10 years.

The decisions of the Committee are arrived at by a consensus of the members present. The quorum is set at 50% of committee membership. The Committee submits its recommendations to the NICE Publications Executive which acts under delegated powers of the NICE Board in considering and approving its recommendations.

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 is excluded from participating further in the discussions. Committee members who took part in the discussions for this accreditation decision are listed below.

Title	Name	Surname	Role	Organisation
Dr	Adrian	Brown	Principal Screening Advisor (formerly)	Public Health England (formerly)
Mr	Richard	Brownhill	Independent health care improvement manager	Royal Bolton Hospitals Trust
Ms	Ailsa	Donnelly	Lay member	N/A

Ms	Joyce	Epstein	Lay Member	N/A
Dr	Elvira	Garcia	Consultant in Public Health Medicine - Health Protection Lead	NHS Ayrshire & Arran
Mrs	Diana	Gordon	Company Director	DRG Consultants
Ms	Barbara	Graham	Service Manager	Health Improvement Team, NHS National Services Scotland
Ms	Angela	Green	Lead clinical research therapist	Hull and East Yorkshire Hospitals NHS Trust
Dr	Steve	Hajioff	Director of Public Health	Hillingdon Borough Council
Dr	Anthony	Larkin	General Practitioner	The Alexandra Practice
Prof	Donal	O'Donoghue	Consultant Renal Physician	Salford Royal NHS Foundation Trust
Dr	Mahendra	Patel	Principal Enterprise Fellow (Senior Academic Pharmacist)	University of Huddersfield
Ms	Mandy	Sainty	Research and Development Manager	College of Occupational Therapists
Mr	Duncan	Service	Evidence Manager	Scottish Intercollegiate Guidelines Network

Dr	Sara	Twaddle	Director of Evidence	Healthcare Improvement Scotland
Prof	Martin	Underwood	Professor of Primary Care Research, Director of Warwick Clinical Trials Unit	The University of Warwick
Ms	Ruth	Wakeman	Assistant Director of Professional Development and Support	Royal Pharmaceutical Society

External Advisers for this accreditation application

Catherine Marshall, Independent Guideline Adviser, New Zealand
Adrian Palfreeman, FRCP Consultant Physician, University Hospitals Leicester

NICE Accreditation team for this accreditation application

Olufunke Usikalu, Accreditation Technical Analyst, National Institute for Health and Care Excellence, Manchester, UK

Victoria Carter, Senior Accreditation Technical Analyst, National Institute for Health and Care Excellence, Manchester, UK