NICE National Institute for Health and Care Excellence

Guidance producer:	**The Renal Association**
Guidance product:	**Clinical Practice Guidelines**
Date:	**11 January 2017**
Version:	**1.4**

Final Accreditation Report

Contents

Introduction 3

Accreditation recommendation 3

Background to the guidance producer 3

Summary 3

Implementation 5

Appendix A: NICE Accreditation analysis 6

Appendix B: Bibliography 18

Appendix C: NICE Accreditation Advisory Committee, external advisers and NICE Accreditation team 19

Introduction

The NICE Accreditation Programme recognises organisations that demonstrate high standards in producing health or social care guidance. Users of the accredited guidance can therefore have high confidence in the quality of the information. Organisations may 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

NICE has renewed accreditation of the process used by the **Renal Association** to produce **clinical practice guidelines**. Accreditation is valid for 5 years from **10 January 2017** and is applicable to guidance produced using the processes described in '**Clinical practice guideline development manual**' (December, 2016). 'The Renal Association were previously accredited from 10 November 2010 to 30 November 2015.

Background to the guidance producer

The Renal Association was founded in 1950. It is the professional body for UK nephrologists (renal physicians) and renal scientists. It is active in the planning and development of renal services and nephrology. It is also involved in the promotion and dissemination of research, education and clinical guidance relating to the field. More recently, it has started to play an active role in developing renal services in the UK. The Renal Association is registered in England and Wales as a Company limited by guarantee and is a charity.

Summary

The Accreditation Advisory Committee considered that the processes used by the Renal Association to produce clinical practice guidelines demonstrated compliance with all 25 of the criteria for accreditation.

The scope and purpose of the guidance is clear. Guideline development involves relevant stakeholders including patients and professional target users of the guidance. Evidence is gathered and appraised systematically and transparently. As a minimum, sources searched include PubMed or Medline using key search terms agreed by the authors. The Introduction section in each example guideline shows the inclusion and exclusion criteria including the search for evidence date parameters. Many of the studies included are observational. A modified GRADE system is used to describe the strengths and limitations of the body of evidence. Consensus is used to derive recommendations via informal discussion. When it is not possible to reach agreement, voting is used. Guidelines are considered for scheduled review after a maximum of 5 years. If significant new evidence emerges prior to a scheduled review of guidelines, they are updated.

The guidance provides clear recommendations including options where applicable, and the content is suitable for the specified target audience. Guideline examples include summaries of the key recommendations and audit measures, to aid implementation. Potential financial and organisational barriers are included in the guideline examples when relevant. Guideline examples show evidence that auditing and monitoring parameters are included at a number of points. Guidelines are not funded by any external organisation, charity or commercial company. The Renal Association website www.renal.org/aboutus/executivecommittee.aspx shows the statutory annual accounts that detail incoming and expended resources. Declarations of interest are reviewed by the Chair of the Clinical Practice Guidelines Committee to ensure that a conflict of interest is not present. The potential for bias is accounted for.

A recommendation for improvement was to clarify the extra review process outlined by the guidance producer at the Committee meeting.

Professor Martin Underwood

Chair, Accreditation Advisory Committee

January 2017

Implementation

Following accreditation, guidance from the accredited producer will be identified on NICE Evidence Search by the Accreditation Mark. The accredited guidance producer is also granted a royalty-free, worldwide licence to use the NICE Accreditation Mark in accordance with the Conditions and Terms of Use. Providing these conditions are met, a guidance producer's accreditation will last for 5 years from the date of the accreditation decision. Guidance already produced under the previous accreditation decision continues to be accredited.

Accredited guidance producers must take reasonable steps to ensure the accredited processes are followed when generating the type of evidence for which they are accredited. Accredited guidance producers should have quality assurance mechanisms in place and must inform NICE accreditation within 30 days if any significant change is made to a process.

Figure 1: The NICE Accreditation Mark

Appendix A: NICE Accreditation analysis

The Accreditation 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.

	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 document[1] states the overall objective of the guidance. The example guidelines[2,3] state their individual objectives in the 'Introduction' section in both instances.	Criterion met
	1.2 The clinical, healthcare or social questions covered	The Process document[1] states the clinical issues (questions) that will be covered by guidance. The guideline examples[2,3] state their clinical questions.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	1.3	Population and/or target audience to whom the guidance applies	The Process document[1] requires that the patient population and the target audience covered by the guidance are stated. The Renal Association's guidelines webpage[4] www.renal.org/Clinical/GuidelinesSection/Guidelines.aspx explains that guidelines are prepared for the UK renal community and that the patient population are those with kidney disease. It is apparent from the 'Introduction' section of each guideline example[2,3] that the target audience is any member of the health care team looking after renal patients.	Criterion met
	1.4	Guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	The Process document[1] provides evidence for this criterion. The format of the Renal Association CPGs is standardised with clear numbering of the guideline recommendations. Each recommendation is clearly stated under a specific heading that defines the patient group, treatment or stage of disease to which the recommendations apply. Guideline examples[2,3] include clear recommendations relating to specific clinical circumstances and patient groups.	Criterion met
	Does the guidance producer have a policy in place and adhered to that means it includes:			

	Criterion	Evidence for meeting the criterion	Accreditation decision
Stakeholder involvement	2.1 Individuals from all relevant stakeholder groups, including patient groups, in developing guidance	The Process document[1] and the Renal Association website[4] contain the names of the delegates that comprise the CPG Committee includes two patient representatives. The membership of the CPG Committee is shown on the Renal Association website at http://www.renal.org/guidelines/clinical-practice-guidelines-committee. Guidance examples[2,3] show named lead authors and provide details of job roles. It is clear different professional groups and individuals possessing specialist knowledge are consulted including patients.	Criterion met
	2.2 Patient and service user representatives and seeks patient views and preferences in developing guidance	The Process document[1] confirms that the intended users of the guidance should be represented by the roles of the authors who write the guidelines. The guidance examples[2,3] confirm that the intended users have been involved in the preparation of guidelines as the various job roles of the authors show that authors are a multidisciplinary group.	Criterion met
	2.3 Representative intended users in developing guidance.	The Process document[1] confirms that the intended users of the guidance should be represented by the roles of the authors who write the guidelines. It is clear from the guidance examples[2,3] that the intended users have been involved in the preparation of guidelines as the various job roles of the authors indicate that authors are a multidisciplinary group.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
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 document[1] shows that the Co-authors for each new or updated guideline conduct systematic searches of the literature immediately prior to starting work on the guideline. As a minimum, sources searched should include PubMed or Medline using key search terms agreed by the authors. Each example guideline[2,3] shows the databases searched. The example PubMed search for the forthcoming 'Selection of Dialysate Bicarbonate for Haemodialysis guideline'[5] provides the search keywords, date restrictions and number of hits retrieved.	Criterion met
	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 document[1] states that studies not available in English or with significant methodological flaws or bias, case reports or small case series are excluded. Renal medicine is an evolving field, the evidence base is variable and therefore observational studies often need to be included. Each example guideline[2,3] shows the inclusion and exclusion criteria including the search for evidence date parameters.	Criterion met

	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 modified GRADE tool is detailed in the Process document[1] and is used to describe the strengths and limitations of the body of evidence and areas of uncertainty in the evidence base. The guideline examples[2,3] demonstrate that the modified GRADE system has been used to assess the quality of the evidence and the strength of recommendations. A quality or level of evidence is selected as high (Grade A), moderate (Grade B), low (Grade C) or very low (Grade D) based on factors such as study design, directness of evidence and consistency of results. Grades of recommendation and quality of evidence can range from 1A to 2D.	Criterion met
	3.4	Describes the method used to arrive at recommendations (for example, a voting system or formal consensus techniques like Delphi consensus)	The Process document states that consensus via informal discussion is the method used to set recommendations and when agreement is not possible to grade a recommendation, majority voting is used instead. Both example guidelines[2,3] state that the recommendations for the first draft are reached by informal discussion of the authors. If no agreement is reached on grading a recommendation, a vote is held and the majority opinion carried forward.	Criterion met

	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 document[1] discusses the balancing of benefits, side effects and risks through use of the GRADE system. Both guideline examples[2,3] show that the benefits, side effects and risks are considered when this is required.	Criterion met
	3.6	Describes the processes of external peer review	The process document[1] states that a draft version of guidelines are uploaded onto the Renal Association website for a minimum period of 4 weeks. Feedback is invited from Renal Association members, non-members, patients and any other relevant stakeholders. The Clinical Practice Guidelines (CPG) Committee oversees the process of external review and ensures that the comments are addressed by the guideline authors, and will approve the final version. Both example guidelines[2,3] state that they have been externally reviewed by key stakeholders.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	3.7 Describes the process of updating guidance and maintaining and improving guidance quality	The process document[1] shows that guidelines are considered for scheduled review after a maximum of 5 years. If significant new evidence emerges prior to a scheduled review of the guideline, it is updated. Authors may become aware of new evidence that can prompt an ad-hoc review of a guideline, through their own knowledge of current research or by communication from other colleagues and/or Renal Association members. The Renal Association Clinical practice guidelines committee will decide if an update to the guideline is necessary, and this will be considered and ratified by the Renal Association Clinical Affairs Board. The example guidelines[2,3] specify a scheduled review date five years after the publication of the current version.	Criterion met
Clarity and presentation	**Does the guidance producer ensure that:**		
	4.1 Recommendations are specific, unambiguous and clearly identifiable	The Process document[1] states that the guidance recommendations should be written using standard and up-to-date-vocabulary to avoid ambiguity. Guidance examples[2,3] show that recommendations are specific, unambiguous and clearly identifiable.	Criterion met

	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 document[1] states that guidelines should consider all treatment options, including conservative management. The benefits of treatment should be evaluated against the risk/side effects, and against the risks of not treating. The example guidelines[2,3] confirm that options for the management of the conditions are included when they are relevant.	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 document[1] states that the date of search, the date of publication or last update and the proposed date for review should be provided in guidelines. The example guidelines[2,3] state the date searches where performed, draft version dates and their scheduled date of review.	Criterion met
	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 document[1] states that guidelines should be suitable for their target audiences. Section 6 provides a standardised format that should be followed for all guidelines produced. Final versions of approved guidelines include a lay summary. It is clear from the guidance examples[2,3] that they are suitable for the target audience: nephrologists, renal nurses and other professionals. Section 5 of each guideline example is a lay summary.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
Applicability	**Does the guidance producer routinely consider:**			
	5.1	Publishing support tools to aid implementation of guidance	The Process document[1] states that authors should include a summary list of recommendations, audit measures, research recommendations and lay summary after the guideline introduction section so users can see the most important information quickly. The guideline examples[2,3] include summaries of the key recommendations and audit measures. Audit measures are used as performance indicators in national audit that helps to ensure the implementation of recommendations is high.	Criterion met
	5.2	Discussion of potential organisational and financial barriers in applying its recommendations	The Process document[1] details the resource and cost implications that should be considered. Examples of potential financial and organisational barriers are included in the guideline examples[2,3] when relevant.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	5.3 Review criteria for monitoring and/or audit purposes within each product.	The Process document[1] states that the guideline recommendations and audit measures help define the dataset collected by the UK Renal Registry as well as for local and regional audit. All guidelines should contain a number of audit measures to help with the implementation of guidelines, promote an improvement in the quality of care and allow comparative audit. A summary of all of the audit measures in each module is included before the rationale section of all of the recommendations. Guideline examples[2,3] show evidence that auditing but also monitoring parameters are included at a number of points.	Criterion met
Editorial independence	**Does the guidance producer:**		
	6.1 Ensure editorial independence from the funding body	The Process document[1] and the website confirms that the Renal Association is a registered charity and funds guidance production on an 'in-house' basis. The Process document[1] confirms that the guidelines are editorially independent from the Renal Association.	Criterion met
	6.2 Demonstrate transparency about the funding mechanisms for its guidance	The Process document[1] explains that guidelines are not funded by any external organisation, charity or commercial company. The Renal Association website[4] (www.renal.org/aboutus/executivecommittee.aspx) shows the statutory annual accounts that detail incoming resources and resources expended.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	6.3 Record and state any potential conflicts of interest of individuals involved in developing the recommendations	The Process document[1] states that all authors should provide declarations of interest. The Chair of the CPG Committee should ensure all members have declared any conflicts of interest they may have. Authors should declare all commercial interests and remuneration from the biomedical industry to be on the committee. The time period to declare relevant interests is 12 months before starting work on a guideline, and covers the duration of the guideline development. Declarations of interest are reviewed by the Chair of the CPG Committee to ensure that a conflict of interest is not present. Copies of completed Declaration of Interest forms are kept on file by the Renal Association for the duration of the work of the Guideline Group (and usually for 5 years after the guideline is archived). The Chair of guideline groups should not have shares in a biomedical company or remain as a consultant with a company. A blank Conflict of Interest Declaration form (Appendix D of Process document[1]) is completed by authors. Information such as name, guideline committee, interests to be declared, signature and date are collected. Both example guidelines[2,3] include a section entitled 'Conflict of interest statement' where any conflicts of interest are stated. Full details are available on request.	Criterion met

	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 potential of bias affecting the conclusions or recommendations has been accounted for by the cross section of stakeholders including patients, the rigorous search and inclusion criteria, external peer review and the comprehensive conflict of interest policy.	Criterion met
Documents referenced above: 1 Clinical Practice Guideline development manual, Sept 2016 2 Clinical Practice Guideline Peritoneal Dialysis in Adults and Children, Sept 2016 3 Clinical Practice Guideline Post-Operative Care in the Kidney Transplant Recipient, Sept 2016 4 Renal website: www.renal.org/Clinical/GuidelinesSection/Guidelines.aspx 5 Selection of Dialysate Bicarbonate for Haemodialysis guideline				

Appendix B: Bibliography

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

Document name	Description	Location
Clinical Practice Guideline development manual, Sept 2016	Process document	Supplied
Renal website: www.renal.org	Process documentation	www.renal.org
Renal Association sample literature search	Process evidence	Supplied
Clinical Practice Guideline Peritoneal Dialysis in Adults and Children, Sept 2016	Guideline example	Supplied
Clinical Practice Guideline Post-Operative Care in the Kidney Transplant Recipient, Sept 2016	Guideline sample	Supplied
Selection of Dialysate Bicarbonate for Haemodialysis guideline	Search information for forthcoming guideline	Supplied

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

NICE Accreditation Advisory Committee

The NICE 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 Accreditation 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(s) 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)
Mrs	Susan	Cervetto	Senior Appraisal Pharmacist	All Wales Therapeutics & Toxicology Centre
Mrs	Lynda	Cox	Knowledge and Implementation Lead (formerly)	NHS England (formerly)
Ms	Ailsa	Donnelly	Lay member	N/A

Ms	Joyce	Epstein	Lay Member	N/A
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
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
Dr	Charles	Young	Emergency Physician Chief Medical Officer	Guys and St Thomas' NHS Foundation Trust; Capita Healthcare Decisions

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