Guidance producer:	**National Clinical Effectiveness Committee (Ireland)**
Guidance product:	**National Clinical Guideline No 6 Sepsis Management**
Date:	**23 March 2015**
Version:	**1.3**

Final Accreditation Report

Contents

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 accredited the process used by the **National Clinical Effectiveness Committee in Ireland** to produce **National Clinical Guideline No 6 Sepsis Management**. Accreditation is valid for 5 years from **March 2015**.

Background to the guidance producer

The National Clinical Effectiveness Committee (NCEC) is a ministerial committee in Ireland, established as part of the Patient Safety First Initiative. The NCEC develops guidelines based on externally produced high quality guidance, adapted to the local healthcare context.

'National clinical guideline no. 6 sepsis management' (2015) aims to facilitate the early recognition and treatment of sepsis in Ireland, in order to maximise survival and minimise the burden of chronic sequelae.

Summary

The Accreditation Advisory Committee considered that the processes used by the National Clinical Effectiveness Committee to produce National Clinical Guideline No 6 Sepsis Management complied with 23 of the 25 accreditation criteria.

The main document used to provide evidence of compliance with the accreditation criteria was 'National clinical guideline no. 6 sepsis management (2015)', with additional

process information obtained from ‘Framework for endorsement of national clinical guidelines’ (2014), ‘Rapid update national clinical guidelines’ (2014), ‘Supplementary process information 1’ (2015) and ‘Supplementary process information 2’ (2015).

The scope and purpose and the recommendations of the guidelines are clear. Development was systematic, multidisciplinary and included professional target users. The content and format of the guidance is suitable for its target audience and implementation issues in the local context have been carefully considered, with support tools and audit requirements provided. Development is editorially independent from any funding source as all work was performed by volunteers who had to declare any conflicts of interest.

Advice to improve the process used to produce National Clinical Guideline No 6 Sepsis Management includes:

- involving lay people in development of the guideline from an earlier stage
- having more than 1 lay person directly involved in guidance development

Professor Martin Underwood

Chair, Accreditation Advisory Committee

March 2015

Implementation

Following accreditation, guidance from the accredited producer will be identified on NICE Evidence 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 publication of approval on the NICE Evidence website.

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 overall objective of the guideline is to diagnose and manage sepsis. This is clearly stated in the introduction to the guideline[1] and section 3.1 'Aim and scope of this national guideline'[1].	Criterion met
	1.2 The clinical, healthcare or social questions covered	The questions covered by the guideline are clear, in terms of how sepsis should be diagnosed and managed. The user can see the topics covered in the contents list at the start of the guideline[1]. Topics are covered in detail in section 2 'National clinical guideline recommendations' of the guideline[1]. Additional questions covered around implementation and financial impact are also clear in section 3.6 'Implementation of this guideline'[1].	Criterion met
	1.3 Population and/or target audience to whom the guidance applies	The introduction to the guideline[1] states that it is aimed at healthcare staff involved in the diagnosis and management of patients with sepsis.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	1.4 Guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	Section 2 'National Clinical Guideline recommendations' of the guideline[1] includes clear recommendations in reference to the clinical circumstances, such as the presence of indicators for suspected sepsis, or confirmed sepsis.	Criterion met
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 guideline was drafted by a group of relevant healthcare professionals[1]. The national sepsis steering committee reviewed the draft guideline on 4 occasions[2]. The steering committee includes a variety of professional stakeholders and 1 patient representative[1]. The patient representative provided written statements explaining their role in development[2] and explaining the impact of sepsis and the importance of the guideline[1]. Because there was only a single patient representative, this criterion is not fully met, whilst recognising their contribution.	Criterion not fully met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	2.2 Patient and service user representatives and seeks patient views and preferences in developing guidance	The guideline was reviewed by a patient representative who was a member of the national sepsis steering committee. The patient representative provided statements explaining their role in development[2] and about the impact of sepsis and the importance of the guideline[1]. As a result of the accreditation overview the guidance producer has committed to reviewing service user involvement in guidance production, with a view to increasing the number of lay members on the steering committee. Because there was only a single patient representative, which makes it difficult to ensure a range of patient views are included, this criterion is not fully met, whilst recognising their contribution.	Criterion not fully met
	2.3 Representative intended users in developing guidance.	The guideline development group and the national sepsis steering committee who reviewed the draft guidance, included representative target users[1].	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 guideline[1] details the systematic search process used to identify evidence. Search parameters and limits are stated along with a list of databases searched. The document 'Supplementary process information 1'[2] provides additional information about the inclusion of the 'Sepsis 6' package of recommendations.	Criterion met

	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 guideline[1] provides the inclusion and exclusion criteria for evidence. These aimed to identify national or international, evidence based, peer reviewed guidelines. Guidelines without multidisciplinary input and clear references were excluded, as were guidelines that were deemed too narrow in scope. During the search process the 'Sepsis 6' package of recommendations was identified through references in other guidelines, as explained in 'Supplementary process information 2'[3] and its inclusion is clearly stated in the guideline[1].	Criterion met
	3.3 Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty	The guideline[1] states that the Appraisal of Guidelines for Research & Evaluation (AGREE II) tool was used to assess the quality of guidelines identified. Details of the AGREE II domain scores and comments from the individual reviewers are also provided in the guidance. Recommendations were graded using the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) tool, which was also applied to the recommendations of Sepsis 6, to indicate the strength of the evidence underpinning its recommendations. The grading of recommendations can be seen in the guideline[1].	Criterion met

	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 guideline[1] explains how recommendations were arrived at. Recommendations identified by the evidence review were individually considered by the guideline development group and assessed for acceptability and applicability in the local healthcare context. The draft recommendations were then reviewed and revised 4 times by the wider steering committee, before external peer review.	Criterion met
	3.5 Requires the guidance producers to consider the health benefits against the side effects and risks in formulating recommendations	The guideline[1] states that the identified recommendations were individually assessed for acceptability before inclusion. It is not explicitly stated how benefits, risks and side effects were weighed up, but the final recommendations carefully consider these issues. Additional evidence of consideration of risks is provided by sections devoted to the risks of antibiotic prescribing such as antimicrobial resistance.	Criterion met
	3.6 Describes the processes of external peer review	The guideline[1] states that it was sent to 2 external peer reviewers and their details are provided.	Criterion met
	3.7 Describes the process of updating guidance and maintaining and improving guidance quality	The guideline[1] states that it will be reviewed and updated every 3 years. The process document 'Framework for Establishment of National Clinical Guidelines'[4] states that NCEC guidelines are reviewed every 3 years or sooner if important new evidence emerges between these points. The supplementary process document 'Rapid update national clinical guidelines'[5] explains that the guideline development group assess any new evidence and determine if changes are required.	Criterion met
Clarity and	**Does the guidance producer ensure that:**		

	Criterion		Evidence for meeting the criterion	Accreditation decision
presentation	4.1	Recommendations are specific, unambiguous and clearly identifiable	The recommendations are specific, unambiguous and clearly identifiable, both in the guideline[1] and in the support tools provided as appendices[1].	Criterion met
	4.2	Different options for the management of the condition or options for intervention are clearly presented	For the most part, the guideline is directive; it is clear what needs to be done at each stage depending on the results of diagnostic tests or observations[1]. The number of options is limited but this is appropriate where time is of the essence and the evidence supports only a single course of action. Where different options are available, or discretionary, this is indicated in the text[1], for example whether to provide certain drugs in a single bolus or continuous infusion. Algorithms are used to make the course of action clear at each stage, including any options.	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 guideline[1] provides the dates of publication, search and 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 content and format of the guideline[1] is suitable for the specified target audience of healthcare professionals caring for people with suspected or confirmed sepsis.	Criterion met
Applicability	**Does the guidance producer routinely consider:**			

	Criterion	Evidence for meeting the criterion	Accreditation decision
	5.1 Publishing support tools to aid implementation of guidance	The guideline[1] contains several support tools such as diagnostic and management algorithms, guidance on antibiotic use and a budget impact analysis.	Criterion met
	5.2 Discussion of potential organisational and financial barriers in applying its recommendations	The guideline[1] states that recommendations were individually assessed by the guideline development group for applicability and practicality in the local healthcare context. A budget impact analysis is provided, detailing the cost implications of the recommendations. Various organisational barriers are also discussed, such as staff training, the availability of equipment, how equipment will be maintained, and the need for additional staff to help coordinate implementation and audit.	Criterion met
	5.3 Review criteria for monitoring and/or audit purposes within each product.	The guideline[1] provides audit requirements for measuring the primary outcome of mortality among patients with severe sepsis or septic shock, secondary outcomes such as reduced length of stay, and other items such as record keeping.	Criterion met
Editorial independence	**Does the guidance producer:**		
	6.1 Ensure editorial independence from the funding body	As stated in the guideline[1], development was entirely voluntary, including the work of external peer reviewers. The steering group and guideline development group were multidisciplinary, with individuals from multiple organisations and also a lay member. Development of the recommendations was therefore independent from any funding body.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	6.2 Demonstrate transparency about the funding mechanisms for its guidance	The guideline[1] states that membership of the steering group and the guideline development group was voluntary and development was not funded by any public or private agency. Peer reviewers were also not paid for their work.	Criterion met
	6.3 Record and state any potential conflicts of interest of individuals involved in developing the recommendations	The document 'Supplementary process information 1'[2] provides details of the policy for declaring and managing conflicts of interest. It provides a requirement to declare financial interests, and non-financial interests such as academic interests or membership of professional groups with a specific interest in running a particular service. The guideline[1] states declarations of interest for those involved in development, for which only 1 person declared an interest. 'Supplementary process information 1'[2] explains how this conflict was managed; it was not specific to the agenda so transparent declaration was sufficient.	Criterion met
	6.4 Take account of any potential for bias in the conclusions or recommendations of the guidance	The process was systematic. Development was multidisciplinary and independent from any funding source. All those involved in development were required to declare conflicts of interest and these are stated in the guideline. The process accounts for the possibility of bias.	Criterion met

Criterion	Evidence for meeting the criterion	Accreditation decision
Documents used: 1 National clinical guideline no. 6 sepsis management (2015) [February 2015 update to November 2014 guideline] 2 Supplementary process information 1 (2015) – supplied by guidance producer during the initial assessment 3 Supplementary process information 2 (2015) – supplied by guidance producer during the guidance producer feedback stage 4 Framework for endorsement of national clinical guidelines (2014) 5 Rapid update national clinical guidelines (2014) – supplied by guidance producer in response to specific queries from NICE		

Appendix B: 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
Ms	Judy	Birch	Lay member	Lay Member
Dr	Adrian	Brown	Public Health Specialist	Principal Screening Advisor, Public Health England and NHS England (London)
Ms	Susan	Cervetto	Nursing and Allied Health Professional	Senior Appraisal Pharmacist , All Wales Therapeutics & Toxicology Centre

Ms	Ailsa	Donnelly	Lay member	Lay member
Ms	Joyce	Epstein	Lay member	Lay member
Ms	Diana	Gordon	Social Care Practitioner	Company Director
Ms	Barbara	Graham	Health Economist	Information Consultant/Senior Health Economist, PHI NHS Scotland
Ms	Angela	Green	Nursing and Allied Health Professional	Lead clinical research therapist, Hull and East Yorkshire Hospitals NHS Trust
Dr	Steve	Hajioff	Public Health Specialist	General Practitioner and Public Health Consultant
Dr	Anthony	Larkin	General Practitioner	General Practitioner
Professor	Donal	O'Donoghue	Senior Medical Professional	Consultant Renal Physician, Salford Royal NHS Foundation Trust and Honorary Professor of Renal Medicine, University of Manchester
Dr	Mahendra	Patel	Academic & Consultant Pharmacist	Principal Enterprise Fellow in Pharmacy University of Huddersfield Pharmacy Research Champion CRN (NIHR)
Ms	Mandy	Sainty	Social Care Practitioner	Research and Development Manager, College of Occupational Therapists
Professor	Sasha	Shepperd	Methodological Expert	Professor of Health Services Research, Nuffield Department of Population Health, University of Oxford
Professor	Martin	Underwood	Chair	Director , Warwick Clinical Trials Unit, University of Warwick
Dr	Charles	Young	Methodological Expert	VP and Publishing director, Global clinical solutions; Editor-in-Chief Clinical Case Reports; Emergency Physician, Guys and St Thomas' NHS Trust

External Advisers for this accreditation application

Cheryl Harding-Trestrail, nurse and clinical commissioner, West Hampshire Clinical Commissioning Group, UK

Professor António Vaz Carneiro, Professor of Medicine, University of Lisbon School of Medicine, Portugal

NICE Accreditation team for this accreditation application

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