NICE National Institute for Health and Care Excellence

Guidance producer:	**Royal Pharmaceutical Society**
Guidance product:	**Professional guidance and standards**
Date:	**23 February 2017**
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 **Royal Pharmaceutical Society** to produce its **professional guidance and standards**. Accreditation is valid for 5 years from **17 February 2017** and is retrospectively applicable to guidance produced using the processes described in '**Professional standards, guidance and frameworks, process development manual' (2016)**.

Background to the guidance producer

The Royal Pharmaceutical Society (RPS) is the professional membership body for pharmacists and pharmacy in Great Britain and an international publisher of medicines information. The RPS aims to advance pharmaceutical science and pharmacy practice, to improve the safety and efficacy of medicines and the quality of pharmaceutical care. It promotes research and evaluation to inform professional practice, and supports the continuous professional development of its members.

As part of its remit to improve pharmacy practice, the RPS produces professional guidance and standards. These are evidence-based recommendations and competency frameworks covering professional practice and may be applicable in a variety of settings. They are not designed to address the management of particular conditions.

Summary

The Accreditation Advisory Committee considered that the processes used by the Royal Pharmaceutical Society to produce professional guidance and standards demonstrated compliance with 23 of the 25 criteria for accreditation.

The scope and purpose of the guidance is clear. Development involves relevant professionals, target users and lay members. The gathering of evidence is systematic and the benefits and risks of different management options are discussed. It is clear how recommendations are developed and there are processes for external review and updating of the guidance.

The guidance provides clear recommendations including any options where applicable, and the content is suitable for the main target audience of prescribers. A variety of support tools are provided, and there are processes for monitoring the uptake of guidance. Guidance development is funded by subscriptions and publications and is editorially independent. All those involved must declare any interests which are managed according to a transparent policy. Overall the possibility of bias is accounted for.

Whilst the process requires a discussion of the strengths and limitations of the evidence during guidance development, it is not clear how some kinds of evidence are assessed and there is a lack of discussion of the strength of the evidence in the guidance. Information on barriers to implementation is gathered during guidance development but it is not clear how this is reflected in the guidance or supporting tools.

Suggestions for improving the process used to develop professional guidance and standards include:

- making it clear how different kinds of evidence should be appraised
- discussing the strengths and limitations of the evidence in the guidance and making it clear if recommendations are based on expert opinion
- ensuring the guidance or supporting tools discuss barriers to implementation.

Professor Martin Underwood

Chair, Accreditation Advisory Committee

February 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.

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[1] states that the scope and purpose of the guidance is decided by the steering group and included in the final guidance. The guidance[2] describes its overall objectives, to help healthcare professionals to be safe, effective prescribers who are able to support patients to get the best outcomes from their medicines.	Criterion met
	1.2 The clinical, healthcare or social questions covered	The process[1] states that the questions to be addressed by the guidance are decided at an initial meeting of the steering group and should be included in the guidance. In the guidance[2] the key questions addressed and the individual topics covered are clear.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	1.3	Population and/or target audience to whom the guidance applies	The process[1] states that the intended audience of the guidance is agreed by the steering group and should be stated in the guidance. There is no requirement to state the target population for the guidance, because it is not for specific interventions or conditions. The guidance[2] states that the target audience is all prescribers. It provides examples of how it can be used in different professional areas[2]. The guidance is not about treating specific patient groups and therefore a target population is not described[2].	Criterion met
	1.4	Guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	The process[1] states that the guidelines should be clear, with specific examples of how the recommendations can be implemented. The guidance[2] provides clear recommendations and it is clear in which circumstances they apply, for example during assessment of a patient, reaching a shared decision, or prescribing. The circumstances are not patient or condition-specific as the framework covers all prescribing[2].	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 process[1] states that the steering group should include at least 2 lay people and a variety of relevant professionals. The group agrees the scope, develops the guidance with the lead author and project team, and considers its wider impact[1]. The guidance[2] provides details of the steering group including 2 lay representatives and a variety of relevant professionals. The guidance[2] was also checked by a validation group including another lay representative and healthcare professionals.	Criterion 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 process[1] states that the steering group should include at least 2 lay people, who help to agree the scope and develop the guidance. The guidance[2] provides details of the steering group including 2 lay representatives. It was also checked by an internal validation group including a lay representative[2].	Criterion met
	2.3	Representative intended users in developing guidance.	The process[1] states that the steering group should include target users, who help to agree the scope, develop the guidance and considers its wider impact. The guidance[2] provides details of the steering group including target users. The guidance[2] was also checked by a validation group including target users.	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[1] requires systematic search methods to be used, with search terms based on key questions. It states that the search criteria and dates should be provided in the guidance or supporting documentation[1]. The guidance[2] states that a literature review was performed and provides details of the dates, search terms, databases and exclusion criteria in a separate document[3] on the hosting website.	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 process[1] states that the systematic searches are informed by inclusion and exclusion criteria, which should be stated in the guidance or supporting documentation. The inclusion and exclusion criteria for evidence are stated in a supporting document[3] on the hosting website.	Criterion met
	3.3	Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty	The process[1] states that the strength of the evidence is discussed by the steering group. The Scottish Intercollegiate Guidelines Network (SIGN) levels of evidence are provided, but the process[1] does not require their use in the guidance. There is no explicit requirement to discuss the strengths, weaknesses and areas of uncertainty of the evidence in the guidance[1]. The guidance[2] considers evidence including frameworks and standards for which the SIGN levels of evidence may not be applicable. The guidance[2] does not clearly discuss the strengths and limitations of the evidence.	Criterion not fully 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[1] states that standards are developed through a consensus of the steering group. Where consensus cannot be reached prior to review it is highlighted to the reviewers[1]. If consensus cannot be reached following review, the issues are voted on with the Chair having the casting vote[1]. The guidance[2] states that the steering group used consensus to agree the content of the framework.	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[1] states that the steering group should discuss the impact, benefits and risks of the standards, including from the patients' perspective. It states that a summary of benefits and risks should be included in the guidance[1]. The guidance[2] discusses ensuring prescribing risks are considered and discussed with patients, and also discusses risks around handling of sensitive information.	Criterion met
	3.6	Describes the processes of external peer review	The process[1] states draft guidance is published on the RPS website for 4-6 weeks for public consultation, during which any interested party can provide comments. Key stakeholder organisations are invited to provide comments[1]. The guidance[2] states that it was released for public consultation for 6 weeks, with 95 responses received.	Criterion met
	3.7	Describes the process of updating guidance and maintaining and improving guidance quality	The process[1] states that guidance is reviewed 4 years after publication. It also states that new or updated content may be triggered by changes to regulation or policy, safety incidents, feedback or policy priorities[1]. There is then a scoping stage and a review of existing content with the potential for a new literature review, after which changes are made and consulted on[1]. The guidance[2] provides the date for review and an overview of the updating process.	Criterion met
	Does the guidance producer ensure that:			

	Criterion	Evidence for meeting the criterion	Accreditation decision
Clarity and presentation	4.1 Recommendations are specific, unambiguous and clearly identifiable	The process[1] states that a summary of professional standards should be included in the guidance, which would make them clearly identifiable. It states that the standards, guidance or framework should be clear and unambiguous[1]. The guidance[2] provides recommendations that are clearly identifiable, specific and unambiguous, whilst accepting the need to be high-level in some cases to address the breadth of prescribing practice.	Criterion met
	4.2 Different options for the management of the condition or options for intervention are clearly presented	The process[1] states that different options should be considered. The guidance[2] includes a section on considering the options, in which users are directed to consider the full range of pharmacological and also non-pharmacological options, taking into account the evidence and patient preferences. This is supported by a section on shared decision making[2].	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[1] states that the publication date, review date and date of evidence search should be included in specific sections of the guidance. The guidance[2] provides the date of publication, the intended date of review and the date the literature search was conducted. The date range covered by the searches is provided in supplementary documentation[3].	Criterion met

	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[1] requires that the language used is suitable for the intended audience, and that the steering group should include target users. This helps to ensure the content and language is appropriate. The guidance[2] is clear and the language use is appropriate for the professional audience.	Criterion met
Applicability	**Does the guidance producer routinely consider:**		
	5.1 Publishing support tools to aid implementation of guidance	The process[1] states that support tools are developed to aid implementation, which may include handbooks, templates, presentations, FAQs, case studies, webinars and checklists. The hosting webpage[4] provides links to a variety of support tools.	Criterion met
	5.2 Discussion of potential organisational and financial barriers in applying its recommendations	The process[1] states that the steering group should discuss organisational and financial barriers to implementation and that information on barriers should be included in the guidance. External reviewers are asked to consider any barriers to implementation[1]. There is no clear discussion of barriers in the guidance[2] or support tools[4] however.	Criterion not fully met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	5.3 Review criteria for monitoring and/or audit purposes within each product.	The process[1] describes how analytics are used to monitor downloads of guidance and how organisations testing the professional standards are approached for feedback. There are also processes[1] for reactive consideration of feedback and contact details are provided in the guidance[2] to facilitate this. Analytics reports[5] for the guidance and the supporting tools have been provided.	Criterion met
Editorial independence	**Does the guidance producer:**		
	6.1 Ensure editorial independence from the funding body	The process[1] states that the RPS is funded by membership subscriptions and the publication activities of the Pharmaceutical Press. A link to the annual review and accounts is provided[6]. It is necessary to include RPS members in guidance development as they are the target users, however the process[1] ensures that the steering group is multidisciplinary, including members of other organisations relevant to the topic. The guidance[2] states that guidance development was funded wholly by the RPS with no external funding, and provides details of the multidisciplinary development group.	Criterion met
	6.2 Demonstrate transparency about the funding mechanisms for its guidance	The process[1], which is available online, states that the RPS is funded by membership subscriptions and the publication activities of the Pharmaceutical Press. A link to the annual review[6] with further funding details is provided. The guidance[2] states that development was funded wholly by the RPS with no external funding.	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[1] states that all members of the steering group are required to submit completed declarations of interest, which are made available upon request. The process[1] states how different kinds of interest are managed and that the Chair cannot have any conflicts of interest. The guidance[2] states that all members of the steering group were required to declare any interests which are available upon request. The declarations[7] were provided in the application, confirming that the process has been adhered to.	Criterion met
	6.4	Take account of any potential for bias in the conclusions or recommendations of the guidance	The process[1] is systematic and includes external review. Development includes a variety of stakeholders and all those involved declare any conflicts of interest, which are managed according to a transparent policy[1]. The funding source is clear[6] and editorial independence is maintained[1]. The guidance[2] and its associated declarations of interest[7] demonstrate that these processes are followed.	Criterion met

Documents referenced above:
1 Professional standards, guidance and frameworks, process development manual (2016)
2 A Competency Framework for all Prescribers (2016)
3 A Competency Framework for all Prescribers - literature review (2015)
4 Hosting webpage showing support tools
5 Analytics reports for the guidance and the supporting tools
6 Annual review and accounts (2015)
7 Declarations of interest

Appendix B: Bibliography

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

Document name	Description	Location
1. NICE Accreditation Application form RPS September 2016 Final	Accreditation application form	Supplied
2. RPS professional standards guidance and frameworks development manual	Process manual	Supplied
3. RPS prescribing competency framework for all prescribers	Guidance example	Supplied
4. Consultation draft and consultation questions	Consultation document	Supplied
5. Implementation tool prescribing framework template	Support tool	Supplied
6. Implementation tool prescribing framework presentation	Support tool	Supplied
7. Framework webpage usage analytics	Monitoring example	Supplied
8. Framework PDF and implementation tool downloads	Monitoring example	Supplied

Document name	Description	Location
9. Register of interests Competency Framework for Prescribers steering group	Declarations of interest	Supplied
10. Register of interests Competency for Prescribers validation group	Declarations of interest	Supplied
11. Pre work for validation group Jan 2016	Stakeholder engagement example	Supplied
12. Project Board meeting notes from 20.11.15	Stakeholder engagement example	Supplied
A. Guidance producer feedback_RPS_6.1.2017	Guidance producer feedback	Supplied
B (13) Summary notes Prescribing framework Steering group 3 11 15	Meeting minutes	Supplied
C. Process manual (amended)	Process document	Supplied
D. Prescribing-competency-framework (amended)	Guidance example	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)
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
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

External Advisers for this accreditation application

Mr Aung Soe, Consultant Neonatologist, Medway NHS Foundation Trust, Kent, UK

Dr Timothy Edward Bates, Chief Scientific Officer, Drugs With A Difference Limited

NICE Accreditation team for this accreditation application

James Stone, Accreditation Technical Analyst, National Institute for Health and Care Excellence, Manchester, UK

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