Guidance producer:	**National Institute for Health and Care Excellence: Medicines and Prescribing Centre**
Guidance product:	**Good Practice Guidance (soon to be known as Medicines Practice Guidelines)**
Date:	**4 November 2013**

Final Accreditation Report

Contents

Introduction

The NICE Accreditation Programme recognises organisations that demonstrate high standards in producing 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 **National Institute for Health and Care Excellence: Medicines and Prescribing Centre** to produce **Good Practice Guidance**. Accreditation is valid for 5 years from **November 2013** and is applicable to guidance produced using the processes described in the **interim process guide (January 2013)**.

Background to the guidance producer

NICE is a non-departmental public body producing evidence-based guidance in health and social care. The Department of Health (DH) commissions NICE to develop Good Practice Guidance (GPG). Within NICE the Medicines and Prescribing Centre is responsible for developing GPG as part of its remit to provide advice and support for delivering safe, efficient and effective use of medicines.

GPG are aimed at those involved in handling, prescribing, commissioning and making decisions about medicines. GPG recommendations focus on organisational processes for managing medicines, as opposed to recommendations for treatment or intervention. Because of this, GPG frequently draw on relevant legislation in addition to other published evidence. They may also utilise expert opinion in the form of written and oral testimony about how medicines management processes work in practice.

Summary

The Accreditation Advisory Committee considered that the processes used by the NICE Medicines and Prescribing Centre to produce GPG demonstrated compliance with 24 of the 25 criteria for accreditation.

GPG are clear in their scope and purpose. The guidance development process includes a variety of professional and lay stakeholders including target users. GPG result from a systematic process that considers the risks and benefits of recommendations.

GPG provide clear recommendations in a language and format appropriate for professionals involved in medicines management. It is clear where recommendations must be followed for reasons of safety or legislation, or if alternative options exist. Organisational and financial barriers are considered, and implementation and audit tools are developed if identified by an implementation needs assessment. The process maintains editorial independence and accounts for the possibility of bias.

Recommendations to improve the process used to produce GPG include:

- Explicitly documenting the process used to arrive at recommendations where informal consensus is not possible and ensuring this process is followed
- Clarifying in the process what happens if target numbers for different types of professional members of the guideline development group cannot be met
- Consolidating additional process information into the main process manual

Professor Martin Underwood

Chair, Accreditation Advisory Committee

November 2013

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 process[1] documents the overall scope and purpose of GPG, and how the scope is determined for individual pieces of guidance. The GPG template[2] requires the scope and purpose of GPG to be clearly stated in a background or introduction section, which can be seen in the GPG examined[3,4].	Criterion met
	1.2 The clinical, healthcare or social questions covered	The process[1] describes the development of key questions from the scope, to inform the search strategy. The key questions covered by the GPG are discernible from the background, purpose and recommendations of the guidance[3,4], which are sections in the standard template format[2].	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	1.3 Population and/or target audience to whom the guidance applies	The target audience for GPG is defined in the process[1] and the NICE website[5]. The target audience is also stated in the background or introduction section of the example GPG assessed[3,4], in accordance with the GPG template[2]. The process requires the target population to be documented during scoping and development of key questions. Given the scope of the guidance the target population may be very broad, but where the guidance focuses on a specific population it is clearly defined[4].	Criterion met
	1.4 Guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	The GPG template[2] requires recommendations and sources of evidence to be clearly stated in specific sections of the guidance. GPG provide recommendations on organisational processes for managing medicines, as opposed to recommendations for treatment or intervention. Consequently the recommendations are not usually provided in the context of individual patients' clinical, healthcare or social circumstances. Examination of the example guidance shows that recommendations are provided in reference to wider organisational and legislative contexts[3,4].	Criterion met
Stakeholder	**Does the guidance producer have a policy in place and adhered to that means it includes:**		

	Criterion	Evidence for meeting the criterion	Accreditation decision
involvement	2.1 Individuals from all relevant stakeholder groups, including patient groups, in developing guidance	The process[1] requires the involvement of relevant professional groups as part of the guideline development group (GDG). Alternatively they may register as stakeholders for public consultation. The process[1] requires the GDG to include public, patient or carer representatives. Examination of the guidance[3,4] confirms the involvement of relevant professional and lay stakeholders.	Criterion met
	2.2 Patient and service user representatives and seeks patient views and preferences in developing guidance	The process[1] describes the inclusion of patient and service user representatives and how to seek their views and preferences in guidance development. At least 2 lay members are on every GDG as confirmed by examination of the guidance[3,4]. Members of the public are encouraged to pass on their views during public consultation to lay, patient or service user groups who are registered as stakeholders.	Criterion met
	2.3 Representative intended users in developing guidance.	The process[1] includes a scoping stage to identify organisations and individuals with expertise or experience in the topic area, who may then be invited to join the GDG. Membership criteria are provided for professional members to ensure they have relevant expertise and experience, with a quota of vacancies for each professional area. It is not clear what happens if the quota cannot be met, however. Target user groups may also comment during public consultation. Examination of the GPG[3,4] confirm the involvement of target users.	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[1] uses systematic methods to search for published evidence from a variety of sources including reviews, studies, guidance and legislation. The process[1] states that the search strategies are published in the guidance. Expert opinion may be used to identify current practice where published evidence is not available, and is gathered in a structured way. Examination of the guidance[3,4] confirms that systematic methods have been used, with published search strategies[3,4].	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[1] excludes evidence based on date, study design or language at the search stage, and these criteria are documented in the published search strategies. Evidence identified by the searches may be excluded based on relevance, with the reasons documented internally. Examination of the search strategies[3,4] and internal reference management database[6] confirms that the reasons for exclusion of evidence are documented.	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 process[1] provides links to tools for assessing the quality of different types of evidence including reviews, trials, quantitative and qualitative studies and economic evaluations. Legislation is not assessed for quality as it is mandatory to follow where it exists. If used, expert opinion is accorded the lowest strength of evidence. Examination of the guidance[3,4] shows that the strengths, weaknesses and areas of uncertainty in the evidence base are stated.	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[1] states that informal consensus is the preferred method to reach recommendations, but that formal methods may be used if this is not possible. The process does not require particular formal consensus methods to be used however, and it is up to each GDG to determine what methods to use. The process does not specify how to solve disagreements if informal consensus is not possible. The GPG examined used informal consensus[3,4].	Criterion not fully met
	3.5	Requires the guidance producers to consider the health benefits against the side effects and risks in formulating recommendations	The process[1] requires consideration of risks and safety issues during scoping and development of the review questions that inform subsequent guidance development. Any risks or patient safety issues identified in the evidence are considered. Discussion of risks and safety issues can be seen in the guidance[3,4] where such issues were identified.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	3.6	Describes the processes of external peer review	Public consultation is the main method of external peer review[1]. Registered stakeholders not involved in developing the draft guidance are invited to comment. This means that the consultation actively solicits a wide range of external opinions. Each GPG has its own public consultation page on which draft guidance is published[7,8]. All comments received are published along with responses[9,10].	Criterion met
	3.7	Describes the process of updating guidance and maintaining and improving guidance quality	The process[1] describes the process of review and updating for both scheduled and unscheduled updates of GPG. Systematic searches are performed for all GPG at 2 and 4 years post-publication, to determine if the evidence base has changed significantly. If a full or partial update is required, the process of guidance production is repeated for the relevant sections. Because GPG are new products, none have required updating yet.	Criterion met
Clarity and presentation	**Does the guidance producer ensure that:**			
	4.1	Recommendations are specific, unambiguous and clearly identifiable	The process[1] provides detailed instructions on the location and wording of recommendations. Examination of the guidance[3,4] shows that recommendations are easily identifiable near the beginning of the guidance and are clearly and unambiguously worded.	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[1] requires different wording for required or optional recommendations. Whilst GPG do not discuss individual conditions, there is some discussion of alternative organisational processes and policies for medicines management. In both pieces of guidance examined[3,4], recommendations clearly indicate if there are no options other than the recommended course of action as in the case of legislative requirements. Where alternatives exist this is reflected in the wording of the recommendations[3,4].	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 GPG template[2] requires the dates of publication and review to be stated, and the process[1] requires the dates of search to be provided. These dates can be seen in the guidance examined[3,4].	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[1] provides detailed requirements on language and format for GPG, particularly the recommendations. The NICE style guide[11] is also used and provides wide ranging advice on language and format of publications. Examination of the guidance[3,4] confirms that the language and format are suitable for the target audience of healthcare professionals involved in medicines management.	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 process[1] requires consideration and production of support tools for GPG. The NICE implementation team works with the GDG and the NICE project team to identify priority areas for support, before developing appropriate tools. Priorities for support are those recommendations requiring a change in practice or having significant resource implications. Support tools are provided for the guidance examined[12,13].	Criterion met
	5.2 Discussion of potential organisational and financial barriers in applying its recommendations	The process[1] requires consideration of cost and resource implications as well as trade-offs between organisational factors such as time, service redesign and policy development. Barriers to implementation are also discussed during consultation. The GPG assessed[3,4] discuss organisational and financial barriers.	Criterion met
	5.3 Review criteria for monitoring and/or audit purposes within each product.	The process[1] states that audit tools for GPG are developed by NICE audit specialists if identified in an implementation needs assessment. These tools are designed to help organisations carry out audits based on some of the measurable recommendations in GPG. Audit tools are currently available for one GPG on the NICE website[14] and will be developed for future guidance as required.	Criterion met
Editorial	**Does the guidance producer:**		

	Criterion		Evidence for meeting the criterion	Accreditation decision
independence	6.1	Ensure editorial independence from the funding body	All recommendations are made by the independent GDG, which the DH is not represented on. In addition all comments and responses are published[9,10] which ensures transparency.	Criterion met
	6.2	Demonstrate transparency about the funding mechanisms for its guidance	The funding source is the DH, as identified in the process[1] and in the NICE annual review[15].	Criterion met
	6.3	Record and state any potential conflicts of interest of individuals involved in developing the recommendations	The GDG members and NICE staff are required to declare any conflicts of interest according to the NICE policy for declaring and managing conflicts of interest[16], including categories for personal, non-personal, financial and non-financial interests. The policy[16] requires declarations of interest to be published. Declarations of interest[17,18] are available for the guidance examined.	Criterion met
	6.4	Take account of any potential for bias in the conclusions or recommendations of the guidance	Overall the possibility of bias is accounted for by the process[1]. Methods are systematic, the funding source is transparent and editorial independence from the funding source is maintained. There is a comprehensive policy for declaring conflicts of interest and both the policy[16] and declarations[17,18] are published on the guidance producer's website.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
1	Interim methods guide (2013)		
2	GPG template (2013)		
3	GPG1 Developing and updating local formularies (2012)		
4	GPG2 Patient group directions (2013)		
5	GPG target audience		
6	Reference management database		
7	Public consultation for GPG1		
8	Public consultation for GPG2		
9	Public consultation comments table for GPG1		
10	Public consultation comments table for GPG2		
11	NICE style guide		
12	NICE website – support tools GPG1		
13	NICE website – support tools GPG2		
14	NICE website – audit tools GPG2		
15	NICE annual review 2011-2012		
16	NICE policy for declaring and managing conflicts of interest		
17	Declarations of interest GPG1		
18	Declarations of interest GPG2		

Appendix B: Bibliography

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

Document name	Description	Location
A Code of practice for Declaring and Dealing with Conflicts of Interest	Process for declaring conflicts of interest	Supplied
Accreditation Application Form V 0.2	Accreditation application form	Supplied
Appendix E – Interview form template	Recruitment information	Supplied
Become a lay member of the NICE Patient Group Directions (PGD) good practice guidance development group	Recruitment information	Supplied
Chair JD	Recruitment information	Supplied
combined comments	Implementation feedback	Supplied
Consort diagram MMinCH		Supplied
Evaluations	Feedback	Supplied
Correspondence with guidance producer	Email answering some questions on process and implementation after application received.	Supplied
Delegate packs	Information pack explaining how local formularies guidance was developed	Supplied
Fac packs	Workshop information packs on development of local formularies guidance	Supplied
Formulary development &	Reference list	Supplied

Document name	Description	Location
NICE		
Good practice guidance – PGDs consultation comments	Consultation comments	Supplied
Good practice guidance (GPG)	Supporting slides for patient group direction guidance	Supplied
Good practice guidance Managing medicines in care homes Guidance development group (GDG) meeting 1 June 25th 2013, London	Meeting minutes	Supplied
Good practice guidance Project plan Patient Group Directions	Project plan	Supplied
Good practice guidance topic selection consultation 29 October – 24 December 2012	Topic selection comments	Supplied
Good Practice Guide for the development and updating of Local Formularies Evidence contribution	Request for written evidence	Supplied
Good Practice Guide for the development and updating of local formularies Notes from the Project Development Group (PDG) meeting 30th May 2012, 10.00 am, London	Meeting minutes	Supplied
Implementation Briefing	Guidance appendix	Supplied

Document name	Description	Location
Appendix to Guidance Sign Off report for good practice guidance on Patient group directions		
Interim methods guide for developing good practice guidance CONFIDENTIAL DRAFT NOT FOR CIRCULATION	Process manual	Supplied
Invitation to apply for the position of: Chair of the guidance development group for the production of Managing medicines in care homes - NICE good practice guidance	Recruitment information	Supplied
Invitation to apply for the position of: Chair of the Guidance Development Group for the production of Patient Group Directions - NICE Good Practice Guidance	Recruitment information	Supplied
Invitation to apply for the position of: Chair of the Project Development Group for the production of a Good Practice Guide for the development and updating of Local Formularies	Recruitment information	Supplied
Invitation to apply for the position of: Member of the	Recruitment information	Supplied

Document name	Description	Location
guidance development group for the production of Managing medicines in care homes - NICE good practice guidance		
Invitation to apply for the position of: Member of the Guidance Development Group for the production of Patient Group Directions - NICE Good Practice Guidance	Recruitment information	Supplied
Invitation to apply for the position of: Member of the Project Development Group for the production of a Good Practice Guide for the development and updating of Local Formularies	Recruitment information	Supplied
Literature search request for 'Managing Medicines in Care Homes'	Literature search request	Supplied
Local Formularies GDG – 23rd October 2012	Meeting minutes	Supplied
Local Formularies Role Description and Person Specification draft 0.2	Recruitment information	Supplied
Local Formularies Role Description and Person Specification draft 0.2	Recruitment information	Supplied
Local formularies stakeholder list	Stakeholder list	Supplied

Document name	Description	Location
Long list of potential topics for NICE Good Practice Guidance (GPG): 2012–14	List of potential guidance topics	Supplied
Managing medicines in care homes – good practice guidance Scoping workshop	Scoping workshop information	Supplied
Managing medicines in care homes - NICE good practice guidance. Guidance development group (GDG) meeting 1	Meeting minutes	Supplied
Managing medicines in care homes Good practice guidance Gap Analysis	Gap analysis for GPG	Supplied
Managing medicines in care homes Good practice guidance Reference List	Reference List	Supplied
Managing medicines in care homes Good practice guidance Rejected Reference List	Reference list (rejected references)	Supplied
Member job description	Recruitment information	Supplied
MMCH Summary of responses to draft scope	Comments on scope	Supplied
Needs Assessment and Implementation Plan framework	Needs assessment for GPG	Supplied
NICE clinical guidelines stakeholder registration	Stakeholder registration information	Supplied
NICE good practice	Guidance template	Supplied

Document name	Description	Location
guidance, draft		
NICE Local Formularies Guidance Development Group 29th August 2012	Meeting minutes	Supplied
NICE Project Development Group for the production of a Good Practice Guide for the development and updating of Local Formularies Criteria for selection - member	Recruitment information	Supplied
Oral evidence list	List of oral evidence for developing local formularies GPG	Supplied
Patient group direction template	Support tool template	Supplied
Patient Group Directions – new NICE good practice guidance published	Journal article	Supplied
Patient group directions - NICE good practice guidance	Guidance example	http://www.nice.org.uk/mpc/goodpracticeguidance/GPG1.jsp
Patient group directions - NICE good practice guidance Guidance development group (GDG) meeting 1 11am, 13th December 2012, Liverpool	Meeting minutes	Supplied
Patient group directions - NICE good practice guidance, Guidance	Meeting minutes	Supplied

Document name	Description	Location
development group (GDG) meeting 4		
Patient Group Directions (PGD) good practice guidance Project Development Group – Information for applicants	Recruitment information	Supplied
Patient Group Directions Good Practice Guidance Guidance Development Group (GDG) Terms of Reference	Terms of reference	Supplied
Patient group directions good practice guidance Registered stakeholders	Stakeholder list	Supplied
Patient group directions Good practice guidance stakeholder consultation	Consultation comments form	Supplied
Patient group directions GPG2 – Full evidence list	List of evidence identified by search	Supplied
Patient group directions: draft good practice guidance consultation	Consultation comments web page text	Supplied
PGD GPG Role Description and Person Specification	Recruitment information	Supplied
PGD GPG Role Description and Person Specification	Recruitment information	Supplied
PGD review questions	Review questions for patient group directions GPG	Supplied
Project Plan Good	Project plan	Supplied

Document name	Description	Location
practice guide for the development and update of local formularies (for use in the NHS)		
Project plan Managing medicines in care homes	Project plan	Supplied
Proposed structure for good practice guidance on Managing Medicines in Care Homes	Proposed topic questions	Supplied
Scoping workshop Managing medicines in care homes	Scoping workshop information	Supplied
Search request NICE good practice guidance Patient Group Directions	Literature search request	Supplied
Search results from Patient Group Directions Search	Lists of evidence identified by searches	Supplied
Shortlist of potential topics for NICE Good Practice Guidance: 2012–14	List of potential guidance topics	Supplied
The appointment of members to the guidance development group (GDG) Managing medicines in care homes - NICE good practice guidance Information pack for applicants (Chair)	Recruitment information	Supplied
The appointment of members to the guidance development group	Recruitment information	Supplied

Document name	Description	Location
(GDG) Managing medicines in care homes - NICE good practice guidance Information pack for applicants (Members)		
The appointment of Members to the Guidance Development Group (GDG) Patient Group Directions - NICE Good Practice Guidance Information Pack for Applicants (Chair)	Recruitment information	Supplied
The appointment of Members to the Guidance Development Group (GDG) Patient Group Directions - NICE Good Practice Guidance Information Pack for Applicants (Members)	Recruitment information	Supplied
The appointment of Members to the Project Development Group (PDG) Good Practice Guide for the development and updating of local formularies	Recruitment information	Supplied
The appointment of Members to the Project Development Group (PDG) Good Practice	Recruitment information	Supplied

Document name	Description	Location
Guide for the development and updating of local formularies Information Pack for Applicants (Members)		

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
Ms	Judy	Birch	Lay Member	
Mr	Richard	Brownhill	Deputy General Manager for Emergency Care	Sheffield Teaching Hospitals NHS Trust

Professor	Ann	Caress	Professor of Nursing	University of Manchester and University Hospital of South Manchester NHS Foundation Trust
Ms	Ailsa	Donnelly	Lay member	
Ms	Gail	Fortes Mayer	Lead Commissioner	Sandwell and West Birmingham clinical commissioning group
Dr	Bobbie	Jacobson	Public Health Consultant	Institute of Health Equity
Dr	Lel	Meleyal	Social work Lecturer	University of Sussex
Dr	Edward	Ng	General Practitioner	Ley Hill Surgery, Sutton Coldfield
Dr	Donal	O'Donoghue	Consultant Renal Physician	Salford Royal NHS Foundation Trust
Professor	Sandy	Oliver	Professor of Public Policy	University of London
Ms	Rita	Ranmal	Clinical Standards Manager	Royal College of Paediatrics and Child Health
Ms	Mandy	Sainty	Research and Development Manager	College of Occupational Therapists
Professor	Sasha	Shepperd	Professor of Health Services Research	University of Oxford
Dr	Sara	Twaddle	Head of Evidence and Technologies / Director of Scottish Intercollegiate Guidelines Network	Healthcare Improvement Scotland

Professor	Martin	Underwood	Head of Division of Health Sciences, Professor of Primary Care Research	The University of Warwick
Dr	Stephen	Webb	Consultant in Anaesthesia & Intensive Care, Lead Clinician for Clinical Governance	Papworth Hospital NHS Foundation Trust
Dr	Charles	Young	Emergency Physician	St Thomas' Hospital, London

External Advisers for this accreditation application

Dr Aung Soe, Consultant Neonatal Paediatrician, Medway NHS Trust, Kent, UK
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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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