NICE National Institute for Health and Care Excellence

Guidance producer:	**National Osteoporosis Guideline Group**
Guidance product:	**Clinical guideline for the prevention and treatment of osteoporosis**
Date:	**9 March 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 the **National Osteoporosis Guideline Group** to produce **Clinical guideline for the prevention and treatment of osteoporosis**. Accreditation is valid for 5 years from **7 March 2017** and is retrospectively applicable to guidance produced using the processes described in **NOGG protocol document (2017)**.

Background to the guidance producer

The National Osteoporosis Guideline Group (NOGG) is a multidisciplinary group that includes patient representation and professionals involved in the care of people with osteoporosis. NOGG was established in 2007 to update earlier guidelines developed by the Royal College of Physicians (RCP) for the prevention and treatment of osteoporosis. The resulting 'Clinical guideline for the prevention and treatment of osteoporosis' is the sole output of the process considered here. It focuses on the assessment of fracture risk and the prevention of fracture in postmenopausal women, and in men aged 50 years and over.

Summary

The Accreditation Advisory Committee considered that the processes used by the National Osteoporosis Guideline Group to produce the clinical guideline for the prevention and treatment of osteoporosis 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, lay members and patient charity representatives. The guideline is based on systematic reviews and meta-analyses, and the strengths and limitations of the evidence are described. The benefits and risks of different management options are discussed. It is clear how recommendations are developed and there are processes for consultation, external review and updating of the guidance.

The guidance provides clear recommendations including any options where applicable, and the content is suitable for the multidisciplinary target audience. The guideline can be used in conjunction with a 10-year fracture risk assessment tool. Barriers to implementation are considered and audit points are provided. No external funding source was involved in development and editorial independence was maintained.

All those involved declared any interests, however the individual peer reviewers declared interests retrospectively and the process is not explicit about how those declarations should be managed. Accordingly there is some possibility for bias in the process.

Suggestions for improving the process used to produce ‘Clinical guideline for the prevention and treatment of osteoporosis’ include:

- Ensuring peer reviewers declare any interests before their comments are taken into account, and that any declarations are managed according to an appropriate process
- Considering the use of clinicians other than osteoporosis specialists as individual peer reviewers.

Professor Martin Underwood

Chair, Accreditation Advisory Committee

March 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 style guide[1] states that the overall aim of the guideline should be described. The guideline[2] states that it aims to provide guidance on the prevention and treatment of osteoporosis.	Criterion met
	1.2 The clinical, healthcare or social questions covered	The style guide[1] states that the scope of the guideline should be described. The guideline[2] scope covers key questions around the assessment and diagnosis of osteoporosis, the therapeutic interventions available and how these can be used to prevent osteoporotic fracture in postmenopausal women and in men age 50 years or over.	Criterion met
	1.3 Population and/or target audience to whom the guidance applies	The style guide[1] states that the target audience and the target population should both be stated in the guideline. The guideline[2] states that it is aimed at healthcare professionals involved in the management of osteoporosis. The target populations are defined as postmenopausal women, and men aged 50 years or over[2].	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	The style guide[1] states that clear recommendations for specific populations should be provided. Examination of the guideline[2] confirms that the recommendations are clear and provided in reference to specific circumstances; for example in specific demographic groups, fracture risk groups, or if different pharmacological options have been tried.	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[3] is multidisciplinary including 2 lay representatives. The guideline[2] provides the composition of the core guideline group and the expert advisory group, detailing the involvement of relevant professionals and lay representatives.	Criterion met
	2.2 Patient and service user representatives and seeks patient views and preferences in developing guidance	The process[3] includes 2 lay representatives as members of the core guideline development group, along with 2 representatives of a patient charity. The guideline was sent to 2 named patient groups for review[3]. The acknowledgements in the guideline[2] confirm that lay and patient charity representatives were involved in development, although 1 lay representative had to drop out during the process.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	2.3 Representative intended users in developing guidance.	The process[3] states that a range of specialities involved in the management of osteoporosis are included in development, through the core group and the expert advisory group. A variety of professional groups were also invited to review the draft guideline[2,3]. The guideline[2] details the names and affiliations of the core group and the expert advisory group, confirming the involvement of a variety of 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[3] states that searches are conducted to identify any relevant systematic reviews and meta-analyses, which are then appraised using the 'assessment of multiple systematic reviews' (AMSTAR) tool. The process[3] states the databases and date ranges used. The guideline[2] provides details of this process and the reviews and meta-analyses identified.	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[3] provides details of the date ranges, language limits and limits on study type used. The guideline[2] provides partial details of these inclusion and exclusion criteria, but the process[3] will be made available alongside the guideline to provide transparency.	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[3] states that the quality of systematic reviews and meta-analyses is assessed using the AMSTAR tool. The style guide[1] states that the method used to grade evidence should be stated in the guideline. The guideline[2] explains that the quality of systematic reviews and meta-analyses was assessed using AMSTAR and that individual studies were graded from I to IV. Recommendations are also graded from A to C and this system is explained in the guideline[2].	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[3] states that consensus is used to arrive at recommendations, with decision making restricted to members of the core guideline group. The guideline[2] states that recommendations were developed by a consensus of the core guideline group.	Criterion met
	3.5	Requires the guidance producers to consider the health benefits against the side effects and risks in formulating recommendations	The process[3] states that contraindications, precautions and side-effects of interventions are considered, along with potential long-term benefits and risks for long-term treatments. The guideline[2] discusses the benefits, risks and side effects of different interventions. The guideline[2] also discusses risk factors for fractures such as age, falls, diet and lifestyle. The use of the 10-year fracture risk assessment tool (FRAX) is also discussed.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	3.6	Describes the processes of external peer review	The process[3] states that the guideline is externally reviewed by individuals and organisations. The guideline[2] provides details of 17 organisations who participated in a consultation and 4 individuals who provided an external review of the guideline.	Criterion met
	3.7	Describes the process of updating guidance and maintaining and improving guidance quality	The process[3] states that the guideline will be reviewed no more than 5 years after publication. It states that an earlier revision may be triggered by the approval of new drugs, or a significant change to the evidence base[3]. The style guide[1] states that the proposed date for review should be clearly stated in the guideline. The guideline[2] explains the process of review and is also clear that it is an update of an earlier version.	Criterion met
Clarity and presentation	**Does the guidance producer ensure that:**			
	4.1	Recommendations are specific, unambiguous and clearly identifiable	The style guide[1] states that the recommendations should be clear, specific and explicitly linked to the evidence. The process[3] states that a summary of recommendations is provided at the beginning of the document and that tables and algorithms are used where applicable, to add clarity. The guideline[3] provides recommendations that are clearly identifiable, specific and unambiguous.	Criterion met
	4.2	Different options for the management of the condition or options for intervention are clearly presented	The style guide[1] states that the guideline should clearly present all options for management or intervention for the condition. The process[3] states that tables and algorithms are used for clarity. Within the guideline[2] any options for intervention are clearly presented, using tables or algorithms where applicable.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	4.3	The date of search, the date of publication or last update and the proposed date for review are clearly stated	The style guide[1] states that the dates of literature searches, publication and the proposed date for review should be clearly stated. The guideline[2] provides the date of last update, the date ranges of searches and the proposed 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 style guide[1] states that the content and style of the guideline should be appropriate for the target audience. The process[3] defines the target audience as specialists caring for those with osteoporosis. It states[3] that a list of frequently asked questions for professionals and a patient information leaflet are available on the hosting website[4]. Examination of the guideline[2] confirms that the content is suitable for the specified audience of healthcare professionals.	Criterion met
Applicability	**Does the guidance producer routinely consider:**			
	5.1	Publishing support tools to aid implementation of guidance	The process[3] states that the guideline provides graphs with intervention thresholds designed to link to the FRAX tool, showing how the guideline can be used within existing assessment frameworks. A patient information leaflet is also available[4] to assist patient consultations. The guideline[2] provides graphs of intervention thresholds and explains how it can be used with the FRAX tool.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	5.2	Discussion of potential organisational and financial barriers in applying its recommendations	The process[3] states that the recommendations are supported by analysis of cost-effectiveness, and that barriers to implementation are discussed in specific sections of the guideline. The guideline[2] discusses how fracture liaison services can improve care in a cost-effective way. It discusses the barrier that care is split across different specialties and a multidisciplinary approach with greater recognition of the public health problem posed by fractures[2].	Criterion met
	5.3	Review criteria for monitoring and/or audit purposes within each product.	The process[3] states that suggestions for audit are provided in the guidance. Examination of the guideline[2] confirms that audit points are provided.	Criterion met
Editorial independence	**Does the guidance producer:**			
	6.1	Ensure editorial independence from the funding body	The process[3] states that no funding source was involved in development of the revised guideline. It explains that the expert advisory group did not take part in developing recommendations, to help mitigate any potential bias from conflicts of interest[3]. The conflicts of interest policy[5] states that members of the guideline group are not paid and do not receive expenses. The guideline[2] states that no external funding was used and explains the functions of the core and expert advisory groups.	Criterion met
	6.2	Demonstrate transparency about the funding mechanisms for its guidance	The process[3] states that no funding body or source of funding was involved in development of the guideline, and this is reiterated in the guideline[2].	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 conflicts of interest policy[5] defines different kinds of interests and describes how they are declared and managed. Guideline development is undertaken by a core group without any conflicts of interest, and an expert advisory group who may have conflicts but do not decide the guideline recommendations[5]. The declarations show that the Chair did not have any conflicts[6]. External reviewers were asked to declare any interests after they had already provided comments. Some reviewers declared interests[6] but the process[5] is not clear about how they are managed.	Criterion not fully met
	6.4	Take account of any potential for bias in the conclusions or recommendations of the guidance	The process[3] states that no external funding source is used to develop the guidance. Guidance developers, expert advisors and individual peer reviewers are required to declare any interests[5]. This was done retrospectively for individual reviewers however and it is not clear how their declarations were managed. For this reason the process allows some possibility of bias.	Criterion not fully met

Documents referenced above:
1 NOGG style guide (2016)
2 Clinical guideline for the prevention and treatment of osteoporosis (2017)
3 NOGG protocol document (2017)
4 NOGG hosting website
5 NOGG Conflicts of interest policy (2016)
6 Declarations of interest (2017)

Appendix B: Bibliography

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

Document name	Description	Location
Conflict of interests policy- NOGG-final	Policy for declaring and managing interests	Supplied
Declarations for external reviewers	Declarations of interest	Supplied
DoIs NOGG	Declarations of interest	Supplied
Guidance producer feedback form_NOGG	Guidance producer feedback form	Supplied
NOGG guideline 30-11-2016	Guideline	Supplied
NOGG protocol document 16-1-2017	Process document	Supplied
NOGG style guide	Writing guide	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
Mr	Richard	Brownhill	Independent health care improvement manager	Royal Bolton Hospitals Trust
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
Dr	Elvira	Garcia	Consultant in Public Health Medicine - Health Protection Lead	NHS Ayrshire & Arran
Mrs	Diana	Gordon	Company Director	DRG Consultants
Dr	Steve	Hajioff	Director of Public Health	Hillingdon Borough Council
Dr	Anthony	Larkin	General Practitioner	The Alexandra Practice
Dr	Mahendra	Patel	Principal Enterprise Fellow (Senior Academic Pharmacist)	University of Huddersfield
Ms	Mandy	Sainty	Research and Development Manager	College of Occupational Therapists
Mr	Duncan	Service	Evidence Manager	SIGN
Dr	Sara	Twaddle	Director of Evidence	Healthcare Improvement Scotland
Prof.	Martin	Underwood	Professor of Primary Care Research,	The University of Warwick

			Director of Warwick Clinical Trials Unit	
Ms	Ruth	Wakeman	Assistant Director of Professional Development and Support	Royal Pharmaceutical Society

External Advisers for this accreditation application

Professor Adrian Palfreeman, Hon. Associate Professor, University of Leicester, UK

Judith Hargreaves, Director, Health economics and reimbursement, Acelity UK, UK

NICE Accreditation team for this accreditation application

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

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