NICE National Institute for Health and Care Excellence

Guidance producer:	**British Association of Chartered Physiotherapists in Amputee Rehabilitation (BACPAR)**
Guidance product:	**Clinical Guidelines**
Date:	**18 January 2017**
Version:	**1.4**

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 **British Association of Chartered Physiotherapists in Amputee Rehabilitation** to produce a specific **Clinical Guideline.** Accreditation is valid for 5 years from **10 January 2017** and is only applicable to the guideline processes described in '**Clinical guidelines for the pre and post-operative physiotherapy management of adults with lower limb amputations'**.

Background to the guidance producer

The British Association of Chartered Physiotherapists in Amputee Rehabilitation (BACPAR) is a professional network recognised by the Chartered Society of Physiotherapy (CSP). It consists of an elected executive committee and a membership of over 200 consisting of Physiotherapists, Physiotherapy Technicians and Rehabilitation Assistants with varying levels of experience across the United Kingdom.

BACPAR aims to promote best practice in the field of amputee and prosthetic rehabilitation, through evidence and education, for the benefit of patients and the profession. The organisation produces clinical guidelines for physiotherapists and associated professions who are involved in the specialist field of amputee and prosthetic rehabilitation. Guidelines are primarily targeted at physiotherapists in the United Kingdom. Although BACPAR produce other guidelines, accreditation only

applies to the example guideline submitted for this assessment and the process to which it has been developed.

The process manual for developing clinical guidelines and the example guideline are contained in one document, ‘Clinical guidelines for the pre and post-operative physiotherapy management of adults with lower limb amputations’, 2016. The guidance producer has separated the recommendations section into a separate document of the same title. For the purposes of the analysis, as both documents have the same title, the phrase ‘guideline document’ was employed when referring to the process and supporting document (appendices), while ‘recommendations document’ was used in reference to the detached recommendations section. This guideline is a final draft version.

Summary

The Accreditation Advisory Committee considered that the processes used by the British Association of Chartered Physiotherapists in Amputee Rehabilitation to produce Clinical guidelines for the pre and post-operative physiotherapy management of adults with lower limb amputations’, 2016 demonstrated compliance with 24 out of the 25 criteria for accreditation.

The scope and purpose of the guideline is clear, and the content and style is suitable for the main target audience of physiotherapists working in the field of amputation management.

The process includes relevant stakeholders and patient groups throughout the guideline development process as members of the GUG and during the public consultation. Patients’ views and preferences are included. Intended users are also represented in the process.

The guidance is produced from systematic, transparent search methods with defined inclusion and exclusion criteria. The strengths and limitations of the evidence are considered, alongside risks and benefits, when developing recommendations. The method for arriving at recommendations is clear. The mechanism for external review is

through invitations for comments from peer reviewers. There are processes for regular and unscheduled review and update of guidelines but no documented process for how any new evidence is identified.

The recommendations are clearly identifiable in the recommendations document and where relevant, the guideline contains options. The guideline and the Information for Public document are suitable for the target audiences. The draft guideline includes publication and review dates as well as the dates the literature searches were carried out.

Organisational and financial barriers are considered and support tools such as the service evaluation form and Good Practice Points (GPPs) achievement form are provided to aid implementation. The patient's note audit form which aids the implementation of the guideline is also available for use on publication.

The guideline development process is editorially independent. Funding mechanisms are transparent, with conflicts of interests declared and managed according to a policy that applies to all those involved in the development of the guideline. The possibility of bias in the process is accounted for.

A suggestion for improving the process used to produce the BACPAR guideline is

- Updating the process manual to include a procedure for ad-hoc updates of guidance in response to the availability of new evidence.

Professor Martin Underwood

Chair, Accreditation Advisory Committee

January 2017

Implementation

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

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 aims and objectives of the updated guideline are contained in the guideline document[1] and are unchanged from the original publication. While there is not a specifically stated requirement for members of the Guideline Update Group (GUG) to consider a revision of the objectives, the guidance producer has stated that this exercise was carried out with the objectives remaining the same.	Criterion met
	1.2 The clinical, healthcare or social questions covered	The guideline document[1] identifies the clinical question addressed by the guidance. This is clearly highlighted to potential users of the guidance.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	1.3 Population and/or target audience to whom the guidance applies	The scope section of the guideline document[1] states the levels of amputations covered by the guidelines, and when in the care pathway the guidelines are applicable. It also identifies subject areas not covered by the guideline. The target audience of physiotherapists working in the field of amputation management and service users are also specified.	Criterion met
	1.4 Guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	The recommendation document[2]is divided into six clear sections indicating the recommendations developed for each along with the evidence utilised in deriving them and some GPPs. The recommendations are specific, indicating what the role of the physiotherapist should be, the required knowledge for the care and assessment of patients as well as information to provide to patients and their carers.	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 document[1] states that the GUG consists predominantly of physiotherapists or professionals working in the field of amputee rehabilitation as well as a patient representative who participated in the guideline development process and the development of the Information for Public document[3]. Stakeholders were also invited to provide comments as part of the external review process.	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 guideline document[1] states that the views of patients and carers were sought as part of the guideline update process. This was carried out through the use of questionnaires for comments on the first edition as well as reviews of the draft recommendations and the Information for Public document[3]. Scanned copies of responses received from the reviews were provided as evidence of implementation.	Criterion met
	2.3 Representative intended users in developing guidance.	As stated in the guideline document[1], the guidelines are intended for use primarily by physiotherapists working in the field of amputee rehabilitation and patients. There is evidence in the appendices of the guideline document that these groups of people were involved in the updating of the guideline.	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 document[1] details the method employed by the GUG in the development of the guideline. It includes information about the date of the search, the databases, the keywords and MeSH terms used as part of the search strategy. The search strategy is provided in detail as part of the appendices.	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 inclusion and exclusion criteria are documented, as described in the guideline document[1]. A list of excluded articles, along with reasons for exclusion are provided as part of the appendices.	Criterion met
	3.3 Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty	The procedure for the appraisal of evidence is detailed in the guideline document[1]. The eligible articles were appraised using the Critical Appraisal Skills Programme (CASP) tools. Each member of the GUG used the CASP tool to appraise the full text articles separately before pairing up to complete an evidence table, classifying the level of evidence using the Scottish Intercollegiate Guidelines Network's (SIGN) methodology. Classification of the levels of evidence and evidence tables are available as part of the appendices.	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 document[1] describes the procedure used by the GUG to arrive at the recommendations. After the level of evidence had been agreed by paired members of the GUG, it was decided by consensus if the new evidence strengthened a previous recommendation or supported the development of a new one. For recommendations supported by evidence, informal consensus is used, while for recommendations based on expert opinion, the Delphi process is employed. The good practice point recommendations were all reached by Delphi consensus, which is described in the document.	Criterion met
	3.5	Requires the guidance producers to consider the health benefits against the side effects and risks in formulating recommendations	The guideline document[1] states that the health benefits of recommendations are detailed under the relevant section in the guideline. For the example guideline, no side effects or risks were identified in the development process. The recommendations document[2] indicates under each section, where supported by evidence, the benefits of the recommendation.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	3.6	Describes the processes of external peer review	The guideline document[1] details the procedure utilized to secure non-specialist physiotherapists or those without experience of pre/post-operative lower limb amputee management as peer reviewers to provide feedback for the draft guideline and the Information for Public document[3]. Once feedback was received, the GUG considered the comments and recommendations and where appropriate, updates were made to the documents, shown as part of the appendices.	Criterion met
	3.7	Describes the process of updating guidance and maintaining and improving guidance quality	The guideline document[1] states that the guideline will be reviewed and updated every 5 years in line with its current process. The BACPAR executive committee will perform a literature search to assess the availability of new evidence and any required updates will then either be commissioned to be carried out by the GUG or postponed to a later date. While it is clear that for the example guideline, new evidence was considered and informed the development of the updated guideline, the procedure, however remains undocumented in the process manual.	Criterion not fully met

	Criterion		Evidence for meeting the criterion	Accreditation decision
Clarity and presentation	**Does the guidance producer ensure that:**			
	4.1	Recommendations are specific, unambiguous and clearly identifiable	While there is no specific requirement for the recommendations to be clearly identifiable, it is apparent from the recommendation document[2] that recommendations have been divided into easily identifiable sections alongside the evidence utilised in reaching the recommendations. It is accompanied by a key indicating new and updated recommendations since the first edition for ease of use. Each section also includes GPPs. The Information for Public document is structured in a Question and Answer (Q&A) format, to address potential questions that patients might have about their condition. These answers are also clearly identifiable to users.	Criterion met
	4.2	Different options for the management of the condition or options for intervention are clearly presented	The recommendation document[2] contains examples of different options for intervention such as exercise therapy and physical assessments of movement in patients. These are intended to be used as templates for local adaptation as the location and extent of amputation will vary by patient.	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 guideline document[1] states the dates of the literature search, the period which the search covered and the publication date (when published). It also states that the guideline will be reviewed after a five year period.	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 guideline document[1] indicates that the target audience for this guideline are physiotherapists working in the field of amputation rehabilitation and service users. Representatives of these stakeholders were part of the guideline updating process, ensuring that the content was suitable. In addition, the Information for Public document[3], developed specifically to answer general questions about amputee rehabilitation was reviewed by patient representatives to ensure suitability.	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 document[1] indicates that the audit tool[4] contained in the first edition of the guideline has been updated in line with the review and will be available on publication. The revised tool has been divided and is now made up of three distinct tools which is hoped to be more user-friendly. The recommendation document[2] provides users with quick access to the recommendations. Finally, the Information for Public document[3] provides supporting information for lay people interested in understanding physiotherapy services available in amputee rehabilitation.	Criterion met
	5.2 Discussion of potential organisational and financial barriers in applying its recommendations	The guideline document[1] states that barriers to implementation of the recommendations in the guideline should be considered. Potential barriers to implementation which are discussed are included in the guideline document[1] and in the GPPs section of the recommendation document[2].	Criterion met
	5.3 Review criteria for monitoring and/or audit purposes within each product.	The process of auditing the use of the first edition of the guideline is described in the guideline document[1]. This is through the use of questionnaires to both clinical and lay users of the guideline to assess the suitability of the content and language. There is also information about the audit tools available with the guideline in the guideline document[1].	Criterion met
	Does the guidance producer:		

	Criterion	Evidence for meeting the criterion	Accreditation decision
Editorial independence	6.1 Ensure editorial independence from the funding body	The guideline document[1] clearly states that the source of funding for BACPAR is through membership subscriptions. It states that BACPAR is responsible for funding the guideline. This funding is limited to travel expenses and printing costs for the guideline and any associated documents. The processes of external peer review and use of Delphi to reach consensus on recommendations, limits the potential for the funding body to have undue influence on the recommendations and ensures that editorial independence from the funding organisations is maintained.	Criterion met
	6.2 Demonstrate transparency about the funding mechanisms for its guidance	The guideline document[1] details the funding required for the development of the guideline, which is provided by BACPAR. No external sources of funding were utilised in the development of the guideline. This information will be publicly available once the guideline is published.	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 updated guideline document[1] contains a requirement for everyone involved in the guideline update process, such as GUG members, physiotherapists, patients and other peer reviewers to declare any interests in accordance with the 'conflicts of interests' policy[5]. The types of interests are broken down into specific and non-specific interests and further into personal and non-personal financial interests. Any conflicts are managed by the GUG lead but can be referred to the BACPAR executive committee in a case of disagreement. There is also a requirement for the chair of the GUG to not have any specific financial or non-financial personal, non-personal or family interests. Interests are declared on appointment to the relevant position, at meetings and annually should it be required. The guidance producer supplied examples of completed declaration of interest forms[6].	Criterion met
	6.4	Take account of any potential for bias in the conclusions or recommendations of the guidance	There is a systematic process for gathering and appraising evidence and developing recommendations. Development is editorially independent from any external funding source and the guideline is subject to external peer review by individuals and organisations. All those involved in development must make transparent declarations of interest which are managed according to a described process. Overall the possibility of bias is accounted for.	Criterion met

Criterion	Evidence for meeting the criterion	Accreditation decision
Documents referenced above: 1 Clinical guidelines for the pre and post-operative physiotherapy management of adults with lower limb amputations, 2016 (Guideline document) 2 Clinical guidelines for the pre and post-operative physiotherapy management of adults with lower limb amputations, 2016 (Recommendation document) 3 Information for the public about physiotherapy following amputation of a lower limb 4 Audit and Implementation Guide: Clinical guidelines for the pre and post-operative physiotherapy management of adults with lower limb amputations 5 BACPAR Conflicts of Interest Policy 6 Signed declaration of Interests		

Appendix B: Bibliography

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

Document name	Description	Location
Clinical guidelines for the pre and post-operative physiotherapy management of adults with lower limb amputations	Process document and appendix	Supplied
Clinical guidelines for the pre and post-operative physiotherapy management of adults with lower limb amputations	Guideline documentation	Supplied
Audit and Implementation Guide: Clinical guidelines for the pre and post-operative physiotherapy management of adults with lower limb amputations	Audit and Implementation guide	Supplied
Information for the public about physiotherapy following amputation of a lower limb	Patient information leaflet	Supplied
BACPAR Conflicts of Interest Policy	COI documentation	Supplied
Supplementary files (6)	Signed declaration of interests	Supplied

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

NICE Accreditation Advisory Committee

The NICE Accreditation Advisory Committee operates as a standing advisory committee of the Board of the National Institute for Health and Care Excellence (NICE). The Committee provides advice to NICE on a framework for accrediting sources of evidence that should be recognised as trusted sources of information for the NHS. The Chair of the Committee is appointed by the NICE Board and the meetings are conducted by the chair or in his/her absence the vice chair. The current Chair is Martin Underwood. A full list of the Accreditation Advisory Committee membership is available on the NICE website. Members are appointed for a period of 3 years. This may be extended by mutual agreement for a further 3 years, up to a maximum term of office of 10 years.

The decisions of the Committee are arrived at by a consensus of the members present. The quorum is set at 50% of committee membership. The Committee submits its recommendations to the NICE Publications executive which acts under delegated powers of the NICE Board in considering and approving its recommendations.

Committee members are asked to declare any interests in the guidance producer to be accredited. If it is considered that there is a conflict of interest, the member(s) is excluded from participating further in the discussions. Committee members who took part in the discussions for this accreditation decision are listed below.

Title	Name	Surname	Role	Organisation
Dr	Adrian	Brown	Principal Screening Advisor (formerly)	Public Health England (formerly)
Mrs	Susan	Cervetto	Senior Appraisal Pharmacist	All Wales Therapeutics & Toxicology Centre
Mrs	Lynda	Cox	Knowledge and Implementation Lead (formerly)	NHS England (formerly)
Ms	Ailsa	Donnelly	Lay member	N/A

Ms	Joyce	Epstein	Lay Member	N/A
Dr	Steve	Hajioff	Director of Public Health	Hillingdon Borough Council
Dr	Anthony	Larkin	General Practitioner	The Alexandra Practice
Mr	Duncan	Service	Evidence Manager	Scottish Intercollegiate Guidelines Network
Dr	Sara	Twaddle	Director of Evidence	Healthcare Improvement Scotland
Prof.	Martin	Underwood	Professor of Primary Care Research, Director of Warwick Clinical Trials Unit	The University of Warwick
Ms	Ruth	Wakeman	Assistant Director of Professional Development and Support	Royal Pharmaceutical Society
Dr	Charles	Young	Emergency Physician Chief Medical Officer	Guys and St Thomas' NHS Foundation Trust Capita Healthcare Decisions

External Advisers for this accreditation application

John Blenkinsopp, Deputy Clinical Effectiveness Manager/Clinical Effectiveness Advisor North Tees and Hartlepool NHS Foundation Trust

Safia Qureshi, PhD, Project Director, Scottish National Blood Transfusion Service

NICE Accreditation team for this accreditation application

Olufunke Usikalu, 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