NICE National Institute for Health and Care Excellence

Guidance producer:	**National Institute for Health and Care Excellence**
Guidance product:	**Interventional Procedures Guidance**
Date:	**14 December 2015**
Version:	**1.6**

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 renewed accreditation of the process used by the **National Institute for Health and Care Excellence (NICE)** to produce **Interventional Procedures Guidance**. The renewed accreditation is valid until **31 March 2020** and applies to guidance produced using the processes described in the **Interventional Procedures Programme Manual (2015)**. The original accreditation term began on **20 January 2010**.

Background to the guidance producer

NICE is commissioned by the Department of Health to produce guidance on interventional procedures. This guidance aims to assess the safety and efficacy of procedures for diagnosis or treatment, which involve entry into a patient's body with instruments or energy; for example scalpels, cameras, x-rays or acoustic energy.

To be eligible as a topic, the procedure must be relatively new or have sufficient uncertainty around its efficacy or safety to warrant an assessment. Recommendations may be that a procedure can be used with standard arrangements for clinical governance, audit and consent, that special arrangements must be in place, or that the procedure should only be used in a research context. Alternatively it may be recommended that the procedure should not be used at all.

This is a decision on renewal of accreditation, which was originally granted in January 2010. The assessment has been made on the basis of an updated process and recent examples of implementation.

Summary

The Accreditation Advisory Committee considered that the processes used by the NICE Interventional Procedures programme to produce Interventional Procedures Guidance complied with 22 of the 25 accreditation criteria.

The processes for producing Interventional Procedures Guidance are documented in the Interventional Procedures Programme Manual (2015).

The scope and purpose of Interventional Procedures Guidance are clear. Development involves a multidisciplinary committee including lay representatives. Target users provide input as specialist advisers and through public consultation comments.

Development is systematic with published search strategies and minimal exclusion criteria to maximise the evidence identified. The strengths, limitations and areas of uncertainty in the evidence base are considered along with the possible benefits, risks and harms of the recommendations. The committee makes decisions by consensus, with voting in exceptional circumstances. External review is provided by public consultation.

The guidance provides clear, specific and unambiguous recommendations. Details of other treatment options are provided. The publication and search dates are clear. Support tools are provided and audit tools are provided where relevant tools and registers do not already exist. Organisational requirements with implicit resource impacts such as training, facilities, personnel and oversight are considered. This is appropriate for the early stage of development of the procedures examined, as accurate information on costs and financial barriers is often not available.

The funding source is transparent and editorial independence from the funding source is maintained. Interests are declared and managed appropriately and the possibility of bias is accounted for.

There are processes for the regular review of some guidance; however it is not clear how important new evidence is taken account of between planned updates and for guidance without fixed review dates. For some guidance it is not clear to end users what the review date is, or that there is no fixed review date. There is a lack of transparency around any declarations of interest as users cannot easily find them.

Suggestions to improve the process used to develop Interventional Procedures Guidance include:

- Identifying named peer reviewers, who may be non-experts on the topic, to provide external review, as it is possible that few consultation responses may be received
- Improving the process to identify important new evidence, particularly around safety, between planned updates or for guidance without a fixed review date
- Clearly stating in guidance what the proposed date for review is, or if there is no fixed date for review
- Providing declarations of interest in the guidance appendices, or clearly stating in the guidance where users can find the relevant declarations of interest

Professor Martin Underwood

Chair, Accreditation Advisory Committee

November 2015

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 a further 5 years from the expiry of the previous accreditation term. Guidance already produced under the previous accreditation decision continues to be accredited.

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	There is evidence of a standard format for guidance that requires the overall objectives of the guidance to be stated. The guidance examined[1,2] contains the section 'About this guidance' that states the overall objective of the guidance.	Criterion met
	1.2 The clinical, healthcare or social questions covered	The process[3] states that the clinical questions are developed during scoping. The questions inform the overview, a document published for the guidance that summarises the key questions and evidence for consideration by the committee. The overviews[4,5] for the guidance examined state that the key questions considered are whether the procedures are safe and efficacious.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	1.3	Population and/or target audience to whom the guidance applies	The process[3] explains that the target population and audience for the guidance are established during scoping. There is evidence of a standard format for guidance. The target audiences and patient populations are clear in the guidance[1,2] examined. They are also detailed in the overview documents[4,5] that summarise the questions addressed by the guidance.	Criterion met
	1.4	Guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	The process[3] defines several categories of recommendations, depending on the supporting evidence. These include recommendations that the procedure be used with 'standard arrangements', 'special arrangements', for 'research only' or should not be used. It can also be recommended that a procedure is only performed in the context of a particular type of clinical team or unit. Together with the clinical indication for the procedure stated in the guidance, these define the circumstances in which the recommendations apply. The guidance[1,2] examined provides clear recommendations in reference to specific clinical circumstances.	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] describes the involvement of the advisory committee, specialist advisers and patient commentators. The advisory committee is multidisciplinary and includes clinicians who carry out interventional procedures, 2 lay members, carers, representatives of trusts, experts in regulation and the evaluation of healthcare provision, and a representative from the medical technologies industry. The committee membership list[6] provides evidence that a range of relevant professional stakeholders are involved in the development of guidance, in addition to 2 lay members.	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[3] requires that the committee has 2 lay members who are recruited and supported by the NICE Public Involvement Programme. The process may also include the views of patient commentators who have experience of the procedure. Relevant patient groups are asked to comment during public consultation on the draft guidance. Members of the public may also comment. Whilst individual guidance does not provide a list of those involved, the committee membership list[6] shows that 2 lay members are involved in the development of guidance.	Criterion met
	2.3	Representative intended users in developing guidance.	The process[3] states that the advisory committee is multidisciplinary and includes clinicians who carry out interventional procedures, although not necessarily the procedure in question. The opinions of at least 2 specialist advisers who are experts in the clinical field in question are sought for each procedure before it is considered by the committee. To minimise bias NICE seeks the views of advisers who have performed the procedure and those who have not. NICE invites relevant professional bodies to comment during consultations on draft guidance. The committee membership list[6] includes clinicians who perform interventional procedures and the overview documents[4,5] show that comments were received from specialist advisers during guidance development.	Criterion met
Rigour of	**Does the guidance producer have a clear policy in place that:**			

	Criterion		Evidence for meeting the criterion	Accreditation decision
development	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 an overview document is produced for each procedure, including a summary of a literature review conducted by the NICE Information Services team. If the evidence base is particularly large an external systematic review may be commissioned. The process[3] states that searches aim to identify background information, reviews, technology appraisals, primary and ongoing research, and details the sources searched in each case. It states that summaries of the findings are provided in the overviews, along with the search strategies. The search strategies are detailed in appendix C of both overviews[4,5] examined.	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] states that exclusion criteria on the basis of methodology, language and date are not normally used, in order to identify as much evidence as possible. The overviews[4,5] provide the search strategies used and state that there were no language restrictions. Table 1 in the overviews[4,5] provides the detailed inclusion criteria used based on publication type and population, intervention, comparator, outcome (PICO) elements.	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 NICE technical analyst is responsible for appraising the quality of the evidence found during the searches and highlighting methodological issues for the attention of the committee. Items that might be considered include study type, issues affecting study quality, statistical analysis, effect size and relevance. The process[3] states that different appraisal checklists are available for different kinds of evidence. The overviews examined[4,5] summarise the appraisal and provide some transparency as to the strength of the evidence. Further consideration of the strengths, weaknesses and areas of uncertainty in the evidence is indicated by the type of recommendation in the guidance[1,2].	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 terms of reference[7] for the committee states that decisions are normally made by consensus, with voting in exceptional circumstances. The Chair has a casting vote in the event of a tie. The guidance[1,2] does not mention if consensus or voting were used, but the terms of reference[7] are publicly available.	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[3] states that the committee considers the nature, magnitude and duration of any benefits, as well as how they may be assessed. The process[3] also considers safety aspects such as the magnitude and frequency of reported adverse events, the quantity and quality of evidence on safety outcomes, the impact of adverse events on quality of life, the influence of clinician's experience on the safety of procedures, long-term safety concerns and safety compared to alternative treatments. A summary of the findings on efficacy and safety is presented in the overviews examined[4,5]. The guidance examined[1,2] include standard sections on efficacy and safety, providing detailed discussion of these issues.	Criterion met
	3.6	Describes the processes of external peer review	The external review process is public consultation[3]. Relevant professional bodies, patient organisations and device manufacturers are identified (where they exist) and invited to review the draft guidance. The consultation documents[8,9] for the gudiance are available online. The comments tables[10,11] show that only 1 response was received in each case, but evidence from internal stakeholder management databases[12] shows that relevant organisations were invited to comment.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	3.7	Describes the process of updating guidance and maintaining and improving guidance quality	The review process[3] and timescales depend on the nature of the recommendations issued. Guidance with recommendations for 'standard arrangements' or 'do not use' do not have a fixed review date but may be reviewed if important new evidence emerges[3]. Recommendations for use under 'special arrangements' or 'research only' are reviewed 3 years after publication[3]. This is a reactive process and there are no processes in place to proactively monitor evidence between planned updates or for guidance without a fixed review date.	Criterion not fully met
Clarity and presentation	**Does the guidance producer ensure that:**			
	4.1	Recommendations are specific, unambiguous and clearly identifiable	The process[3] defines different types of recommendation that may be given, depending on the evidence base. It also states that the recommendations must include information on safety and efficacy. The NICE style guide[13] provides requirements around the wording of recommendations to ensure they are clearly and unambiguously written. The guidance examined[1,2] contains recommendations that are specific, unambiguous and clearly identifiable.	Criterion met
	4.2	Different options for the management of the condition or options for intervention are clearly presented	The process[3] requires overview documents to include a brief summary of the treatment options available for the relevant condition. The standard format for guidance includes this information on treatment options in the section 'Indications and current treatments'. The guidance examined[1,2] outlines current treatment options for the relevant conditions.	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 standard format for guidance includes the date of publication on the front cover of the guidance and a 'last modified' date on the footer of subsequent pages. The process[3] specifies the format for the overview documents, which includes the dates of search. The standard format of the guidance does not include the proposed date for review, although a link to the process guide is provided, where review timeframes can be found. The guidance examined[1,2] show that the publication dates and dates of last update are clearly stated. The dates of search are provided in the accompanying overview documents[4,5]. The guidance[1,2] does not state the proposed date for review, or if there is no fixed date for review.	Criterion not fully 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 standard format ensures the provision of recommendations and supporting evidence in a consistent manner. Recommendations are provided first, as they are likely to be the most important information for target users. The format of recommendations is specified in the process[3] and the NICE style guide[13], to ensure clarity. The process[3] states that information for patients is produced for the guidance. Examination of the guidance[1,2] and the information for patients[14,15] confirms that the content and language is suitable for the specified target audiences.	Criterion met
Applicability	**Does the guidance producer routinely consider:**			
	5.1	Publishing support tools to aid implementation of guidance	The webpages for guidance include the sections 'tools and resources' and 'information for patients'. The recommendations pages can be printed or viewed independently. The guidance examined[1,2] provides information for patients[14,15] to facilitate discussions and shared decision making.	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 purpose of the guidance is to assess safety and efficacy rather than cost effectiveness, which is addressed by other NICE guidance programmes. Because the programme often looks at procedures at an early stage in their development, information around financial barriers may not be available or reliable. Organisational factors with resource implications are considered however, including requirements for training, personnel and oversight. This is evident in the guidance[1,2] examined.	Criterion met
	5.3 Review criteria for monitoring and/or audit purposes within each product.	The process[3] states that NICE will develop audit tools for procedures if the committee recommends that special arrangements are in place for audit and there are no existing tools. One of the guidance examples[2] signposts a national audit. The guidance producer has provided an example of an audit tool[16] that was developed where there was no existing national audit.	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	The process[3] states that the committee is multidisciplinary and that all members are independent of NICE. Specialist advisers are nominated or approved by specialist societies, which are also independent of NICE. The funding source is the Department of Health. It would not be possible to develop guidance without NHS employees, who are ultimately funded by the Department of Health, but the Department is not directly represented in guidance development. The expenses policy[17] states that committee members and specialist advisers are volunteers, but do receive travel and subsistence expenses. Examination of the committee membership list[6] confirms that it is multidisciplinary and does not include direct representatives of the Department of Health.	Criterion met
	6.2	Demonstrate transparency about the funding mechanisms for its guidance	The NICE annual report and accounts[18] clearly state that the development of guidance is funded by money from the Department of Health.	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	All NICE staff, committee members and specialist advisers are required to declare any interests which are managed according to the NICE policy[19] for declaring and managing interests. The policy[19] defines interests in categories including financial, non-financial, personal and non-personal. It distinguishes between interests specific and non-specific to the agenda. The Chair cannot have any interests specific to the topic under consideration. Declarations are provided in committee minutes and the guidance producer provided copies of the relevant minutes[20,21] confirming that interests were declared and managed in accordance with the stated policy[19]. Neither guidance examined[1,2] states where users can find the relevant declarations for that guidance however, meaning any declarations are not sufficiently transparent.	Criterion not fully met
	6.4	Take account of any potential for bias in the conclusions or recommendations of the guidance	The process[3] is systematic in the gathering of evidence and the development of recommendations, which occurs through a multidisciplinary committee with input from expert advisers. There is a process[3] for external review through public consultation. Development of recommendations is editorially independent from the funding source[3,6,18]. All those involved declare any interests[19], with defined actions for managing any interests declared. Whilst transparency around the declarations could be improved, the possibility of bias is accounted for.	Criterion met

Documents referenced above:

1 IPG510 Hysteroscopic metroplasty of a uterine septum for recurrent miscarriage (2015)

2 IPG527 Implantation of a sphenopalatine ganglion stimulation device for chronic cluster headache (2015)

3 Interventional procedures programme manual (2015)

4 IPG510 Overview (2015)

5 IPG527 Overview (2015)

6 Interventional procedures advisory committee membership list (2015)

7 Interventional procedures advisory committee terms of reference and standing orders (2014)

8 IPG510 consultation documents (2014)

9 IPG527 consultation documents (2015)

10 IPG510 comments table (2015)

11 IPG527 comments table (2015)

12 Interventional procedures stakeholder management database screenshots (unpublished)

13 NICE style guide (unpublished)

14 IPG510 Information for the public (2015)

15 IPG527 Information for the public (2015)

16 Transcranial direct current stimulation (tDCS) for depression – audit tool (2015)

17 Non-Staff Travel Subsistence and General Expenses Policy and Procedure (2015)

18 NICE annual report and accounts 2014 to 2015 (2015)

19 Policy for declaring and managing conflicts of interest (2014)

20 IPG510 committee minutes: 13 March 2014, 11 June 2014, 13 November 2014

21 IPG527 committee minutes: 12 September 2014, 11 December 2014, 12 March 2015

Appendix B: Bibliography

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

Document name	Description	Location
Accreditation-application-form - NICE IP response Mar 2015 Submitted 310315	Accreditation application form	Supplied
Committee minutes list	List of advisory committee minutes where the guidance examples were discussed	Supplied
Interventional-procedures-programme-process-guide	Process document	http://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-interventional-procedures/Interventional-procedures-programme-process-guide.pdf
IPACDecisionMakingProcessApril2010V1.0	List of questions for committee to consider when assessing a procedure	Supplied
IPAC-ToRSoP-FinalForWebsite	Terms of reference for committee	http://www.nice.org.uk/Media/Default/Get-involved/Meetings-In-Public/Interventional-procedures-advisory-committe/2014/InterventionalProceduresAdvisoryCommittee-ToRSoP-FinalForWebsite.pdf
IPG510 Hysteroscopic metroplasty - evidence overview	Overview of evidence for procedure	http://www.nice.org.uk/guidance/IPG510/documents/hysteroscopic-metroplasty-of-a-uterine-septum-for-recurrent-miscarriage-overview2
IPG510 Hysteroscopic metroplasty	Guidance example	http://www.nice.org.uk/guidance/ipg510
IPG510 specialist advisers	List of external advisers for guidance	Supplied

Document name	Description	Location
ipg510consultation	Table of consultation responses	http://www.nice.org.uk/guidance/IPG510/documents/ip1177-hysteroscopic-metroplasty-of-a-uterine-septum-for-recurrent-miscarriage-consultation-comments-table2
IPG527 Cluster headache implant - evidence overview	Overview of evidence for procedure	http://www.nice.org.uk/guidance/IPG527/documents/implantation-of-a-sphenopalatine-ganglion-stimulation-device-for-chronic-cluster-headache-overview2
IPG527 Cluster headache implant	Guidance example	http://www.nice.org.uk/guidance/ipg527
IPG527 specialist advisers	List of external advisers for guidance	Supplied
IPG527_consultation-comments-table2	Table of consultation responses	http://www.nice.org.uk/guidance/IPG527/documents/consultation-comments-table2
IP Programme Manual V3.4 Post-consultation	Process document	Supplied
NICE-annual-report-2014-2015-v27	NICE annual report and accounts	Supplied
Non-Staff Travel Subsistence and General Expenses Policy and Procedure	Policy for expenses	Supplied
Patient and Public Involvement Policy November 2013	Policy for lay involvement	Supplied
Policy on COI	Policy for declaring and managing conflicts of interest	http://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/code-of-practice-for-declaring-and-managing-conflicts-of-interest.pdf
The-interventional-procedures-programme-methods-guide	Process document	http://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-interventional-procedures/The-interventional-procedures-programme-methods-guide.pdf
wg1-style-guide	NICE style guide for	Supplied

Document name	Description	Location
	documents	

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	N/A
Mr	Richard	Brownhill	Quality and Performance Lead (interim)	Royal Bolton Hospitals Trust
Professor	Ann	Caress	Professor of Nursing	University of Manchester

				and UHSM NHSFT
Ms	Lynda	Cox	Knowledge and Information Lead	NHS England
Ms	Ailsa	Donnelly	Lay member	N/A
Ms	Joyce	Epstein	Lay member	N/A
Dr	Elvira	Garcia	Consultant in Public Health Medicine	Locum
Ms	Diana	Gordon	Company Director	DRG Consultants
Ms	Barbara	Graham	Information Consultant/Senior Health Economist, Public Health and Intelligence	NHS Scotland
Ms	Angela	Green	Lead Clinical Research Therapist	Hull and East Yorkshire Hospitals NHS Trust
Dr	Anthony	Larkin	General Practitioner	The Alexandra Practice
Dr	Mahendra	Patel	Principal Enterprise Fellow in Pharmacy	University of Huddersfield
Ms	Mandy	Sainty	Social Care Practitioner	Research and Development Manager, College of Occupational Therapists
Dr	Sara	Twaddle	Director of Evidence	Healthcare Improvement Scotland
Professor	Martin	Underwood	Director, Warwick Clinical Trials Unit	The University of Warwick

External Advisers for this accreditation application

Dr Hans de Beer, Guideline Methodologist, Independent Consultant, Utrecht, Netherlands

Ms Cheryl Harding-Trestrail, Senior Commissioning Manager: Planned Care (Acute), West Hampshire Clinical Commissioning Group, Hampshire, UK

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