Producer: **The National Institute for Health and Clinical Excellence: Diagnostics Assessment Programme**

Product: **Diagnostic Technologies Guidance**

Date: **25 September 2012**

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 on the NHS Evidence website.

Accreditation recommendation

NICE has accredited the process used by the **National Institute for Health and Clinical Excellence Diagnostics Assessment Programme** to produce **Diagnostic Technologies Guidance**. Accreditation is valid for 5 years from **September 2012** and is applicable to guidance produced using the processes described in **the Diagnostics Assessment Programme manual (2011).**

Background to the guidance producer

NICE has 2 programmes that evaluate Diagnostic Technologies Guidance: the Diagnostics Assessment Programme and the Medical Technologies Evaluation Programme. The latter was assessed through the accreditation programme and accredited in December 2011.

The Diagnostics Assessment Programme was established in 2010. It assesses diagnostic technologies that have the potential to improve health outcomes but whose introduction into mainstream clinical practice may be associated with an increase in cost to the NHS.

The Diagnostics Assessment Programme is appropriate for complex evaluations of diagnostic tests and technologies. The programme concentrates on pathology tests, endoscopy, imaging and physiological measurement, because these represent most of

the investigations carried out on patients. The Programme does not cover tests based on 'bedside' clinical examinations that do not involve instruments or devices.

Summary

The Accreditation Advisory Committee considered that the processes used by the National Institute for Health and Clinical Excellence Diagnostics Assessment Programme to produce Diagnostic Technologies Guidance complied with all 25 of the criteria for accreditation.

The Diagnostics Assessment Programme manual (revised in December 2011) is used by NICE to produce the Diagnostic Technologies Guidance.

The process for producing Diagnostic Technologies Guidance uses rigorous external assessment and input from all relevant stakeholders including patient groups. The recommendations made in the Diagnostic Technologies Guidance provide clear and appropriate recommendations for the target audiences. Patients are involved in developing the guidance and further information is available for patients in the form of lay translations. Support tools are available to aid implementation of the recommendations when these are appropriate.

A suggestion to strengthen the processes to produce Diagnostic Technologies Guidance is to cement the process for updating guidance.

Professor David Haslam, CBE

Chair, Accreditation Advisory Committee

September 2012.

Implementation

Following accreditation, guidance from the accredited producer will be identified on NHS Evidence by the Accreditation Mark. The accredited guidance producer is also granted a royalty-free, worldwide licence to use the NICE Accreditation 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 NHS 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 Accreditation Mark

Appendix A: Accreditation analysis

The Accreditation Advisory Committee considered the following analysis of the guidance producer's compliance with the 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	**1. Does the guidance producer have a policy in place and adhered to that requires them to explicitly detail:**		
	1.1 Overall objective	The overall objective of the guidance is described in the Diagnostics Assessment Programme manual[a] as: to promote the rapid adoption of clinically innovative and cost-effective diagnostic technologies; improve treatment choice; extend the length or quality of life of patients by evaluating diagnostic technologies; and to improve the use of NHS resources by assessing diagnostic technologies. The specific aims can be seen in the guidance examples assessed[b-c].	Criterion met
	1.2 The clinical, healthcare or social questions covered	The Diagnostics Assessment Programme process manual[a] describes how the questions addressed by the guidance are treated and outlines the development of the scope. Questions to be addressed are described before the assessment of the evidence by the External Assessment Group. The PICO (Population, Intervention, Comparator, and Outcome) framework is used. It can be seen from the example guidelines that the questions addressed are summarised using the PICO framework.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	1.3 Population and/or target audience to whom the guidance applies	The Diagnostics Assessment Programme manual[a] outlines a process to define the target audience and the patient population to whom the guidance applies. Both guidance examples[b-c] and their scopes specify the patient population.	Criterion met
	1.4 Guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	The Diagnostics Assessment Programme manual[a] explains the process followed by the Diagnostics Advisory Committee to evaluate the evidence and formulate the recommendations. It is clear from the guidelines[b-c] that recommendations made are specific to clinical or healthcare circumstances, are supported by the evidence base and are appropriate to the target population.	Criterion met
Stakeholder involvement	**2. 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 Diagnostics Assessment Programme manual[a] defines how stakeholders including patients are actively involved in the development of guidance and are relevant to the guidance developed. Stakeholder and lay representatives' names and affiliations are provided within each guideline[b-c].	Criterion met
	2.2 Patient and service user representatives and seeks patient views and preferences in developing guidance	Patient preferences are included in guidance development through the Patient and Public Involvement Programme process, described in the Diagnostics Assessment Programme manual[a]. Lay members are present on the committee and relevant patient and carer organisations are identified and sent questionnaires to obtain their views on technologies before draft recommendations are made.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	2.3 Representative intended users in developing guidance.	Representative intended users are involved as members of the Diagnostics Advisory Committee as both specialist and standing committee members according to the Diagnostics Assessment Programme manual[a].	Criterion met
Rigour of development	**3. 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 processes to search for clinical and cost-effectiveness evidence are documented in the Diagnostics Assessment Programme manual[a]. Studies and systematic reviews are sought by searching specialist databases, Search strategies for both example guidelines[b-c] were provided.	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 Diagnostics Assessment Programme manual[a] describes the methods of identifying and synthesising evidence. A record of excluded studies is maintained. The Diagnostics Assessment Programme manual[a] states that methods for inclusion and exclusion of studies should be detailed in the Diagnostics Assessment Report for each guideline. The criteria for including or excluding evidence is described in the guidance examples[b-c].	Criterion met
	3.3 Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty	The Diagnostics Assessment Programme manual states that the Quality Assessment of Diagnostic Accuracy Studies checklist is recommended to critically appraise the quality of the studies reviewed. Potential uncertainties that can arise should be specified. The example guidelines[b-c] highlight study limitations and where uncertainty exists in the evidence base.	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 Diagnostics Assessment Programme manual[a] describes the method by which the Diagnostics Advisory Committee arrives at recommendations. Recommendations are derived by a consensus of members present at a chaired meeting. The quorum is set at 50% of Committee membership. If consensus cannot be reached, a vote is taken to reach a decision.	Criterion met
	3.5	Requires the guidance producers to consider the health benefits against the side effects and risks in formulating recommendations	The quality of the evidence and the degree of risk should be outlined in guidance according to the Diagnostics Assessment Programme manual[a]. The risks and benefits of the technology as seen from the patient's perspective should also be taken into consideration. It is clear that both guidance examples[b-c] show the health benefits, side effects and risks of the recommendations made.	Criterion met
	3.6	Describes the processes of external peer review	The peer review process is defined in the Diagnostics Assessment Programme manual[a]. Manufacturers, sponsors, professional and specialist groups and patient organisations are invited to take part in the peer review process. The guidance examples[b-c] detail the stakeholders, including patient groups who reviewed the recommendations.	Criterion met
	3.7	Describes the process of updating guidance and maintaining and improving guidance quality	The Diagnostics Assessment Programme manual[a] states that a literature search should be conducted every 3 years to update. If new evidence becomes available before a formal update then guidance can be updated on an ad-hoc basis. As the Diagnostics Assessment Programme and guidance examples[b-c] are so new the process of performing updates has not yet been implemented but the documented process is expected to be followed.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
Clarity and presentation	**4. Does the guidance producer ensure that:**			
	4.1	Recommendations are specific, unambiguous and clearly identifiable	The Diagnostics Assessment Programme manual[a] specifies that the language and style used in the guidance should be clear. The wording of the recommendations is specific and unambiguous. The examples of guidance[b-c] show that recommendations 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 Diagnostics Assessment Programme manual[a] explains that individual technologies are assessed by the Diagnostics Assessment Programme but often assessments are performed alongside similar technologies developed for use in parallel settings. The methods to manage the options of comparison technologies (where they exist) is described. The example guidelines[b-c] detail the alternative technologies.	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 Diagnostics Assessment Programme manual[a] states that a literature search should be conducted every 3 years to update. Dates of searches, issue and last modified dates are shown in guidance[b-c]. As guidance examples are so new the process of performing updates has not yet been demonstrated but the documented process is expected to be followed.	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 guidance examples are consistent in terms of style and use a standardised template. The content and language of guidance is suitable for the target audience of healthcare professionals and lay people. Patient versions of guidance are also produced.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
Applicability	**5. Does the guidance producer routinely consider:**			
	5.1	Publishing support tools to aid implementation of guidance	There is an implementation support plan for each guideline. The Diagnostics Assessment Programme manual[a] explains that implementation support tools are published alongside the guidance and aim to assist the NHS with the implementation of the guidance. Support tools can include audit support, costing tools, slide sets (explaining how the guidance can be put into practice), or other specific products when required.	Criterion met
	5.2	Discussion of potential organisational and financial barriers in applying its recommendations	The Diagnostics Assessment Programme manual[a] includes discussion of costs and organisational barriers that can be incorporated into guidance. The diagnostics programme evaluates technologies that have the potential to improve health outcomes but are likely to be associated with an overall increase in cost. These costs are a potential barrier to the use of recommendations by users. The guidance examples[b-c] state the barriers to implementation when relevant.	Criterion met
	5.3	Review criteria for monitoring and/or audit purposes within each product.	The processes for monitoring and auditing the use of guidance are the role of the NICE Impact and Evaluation Team. The specific implementation support needs of individual Diagnostics Assessment Programme topics, including audit and uptake issues are discussed. The Implementation support team at NICE also assist with the roll-out of guidance when required.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
Editorial independence	**6. Does the guidance producer:**			
	6.1	Ensure editorial independence from the funding body	The funding source is the Department of Health. The Diagnostics Assessment Committee is an independent committee which is autonomous from the funding body and NICE. There is public consultation on the Committee's draft recommendations which increases transparency. Overall, the process of developing recommendations is independent from the funding source.	Criterion met
	6.2	Demonstrate transparency about the funding mechanisms for its guidance	NICE publishes its annual accounts in an annual report on the NICE website, in which the Department of Health is identified as the funding source, and consequently it is also the funding source for the Diagnostics Assessment Programme.	Criterion met
	6.3	Record and state any potential conflicts of interest of individuals involved in developing the recommendations	The Standing Orders for NICE Advisory Bodies requires the members of the Diagnostics Assessment Programme or Committee to declare any conflicts of interest as described in the guidance producer's response. NICE staff, members of the External Assessment Group involved in assessing the diagnostic technology, are specifically required to declare conflicts of interest as set out in the Declarations of Interest document.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	6.4 Take account of any potential for bias in the conclusions or recommendations of the guidance	The processes described in the Diagnostics Assessment Programme manual[a] and the policies governing declarations of interest reduce the likelihood of bias. The recommendations are also subject to public consultation. The Expert advisers and independent External Assessment Group have the expertise in the technology and the care pathway to contribute to the development of the scope and reduce the likelihood of bias further. A policy covering conflicts of interest is in place which also reduces potential bias among those involved in developing recommendations.	Criterion met

a Diagnostics Assessment Programme manual (Dec 2011)
b DG1: The EOS 2D/3D imaging system (Oct 2011)
c DG3: Computed tomography (CT) scanners for cardiac imaging - Somatom Definition Flash, Aquilion One, Brilliance iCT and Discovery CT750 (Jan 2012).

Appendix B: Bibliography

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

Document name	Description	Location
Diagnostics Assessment Programme manual (Dec 2011)	Process documentation	http://www.nice.org.uk/aboutnice/howwework/developingnnicediagnostictechnologiesguidance/developingnicediagnostictechnologiesguidance.jsp?domedia=1&mid=8A32125A-19B9-E0B5-D46C9C0F25A558DD
Item 2b-EOS 2D/3D X-ray Imaging System	Final scope	http://guidance.nice.org.uk/DT/1/Scope/pdf/English
Item 2d-Computed tomography (CT) scanners for cardiac imaging	Final scope	http://guidance.nice.org.uk/DT/3/Scope/pdf/English
Item 3a-EOS 2D/3D X-ray Imaging System	Protocol	http://guidance.nice.org.uk/DT/1/FinalProtocol/pdf/English
Item 3c-Computed tomography (CT) scanners for cardiac imaging	Protocol	http://guidance.nice.org.uk/DT/3/FinalProtocol/pdf/English
Item4c-Computed tomography (CT) scanners for cardiac imaging	Diagnostic Assessment Report	http://guidance.nice.org.uk/DT/3/DiagnosticAssessmentReport/pdf/English
Item4a-EOS 2D/3D X-ray Imaging System	Diagnostic Assessment Report	http://guidance.nice.org.uk/DT/1/AssessmentReport/pdf/E

Document name	Description	Location
		nglish
Item5b-EOS 2D/3D X-ray Imaging System	Diagnostics Consultation Document	http://guidance.nice.org.uk/DT/1/Consultation/Latest
Item5d-Computed tomography (CT) scanners for cardiac imaging	Diagnostics Consultation Document	http://guidance.nice.org.uk/DT/3/Consultation/Latest
Item 6a-EOS	Diagnostics Guidance Document	Supplied
Item 6c-CT	Diagnostics Guidance Document	Supplied
Item7-MTEP notification template	Notification form	Supplied
Item8a-DAR letter to manufacturers	DAR	Supplied
Item8b-DAR letter to stakeholders	DAR	Supplied
Item8c-DAR comments table	DAR	Supplied
Item9-Technology Selection Questionnaire	Questionnaire	Supplied
Item10a-PPIP advert	Advert	Supplied
Item 10b-PPIP advert	Advert	Supplied
Item11a-Template	Scoping workshop invite	Supplied
Item 11b-Template	Scoping workshop invite	Supplied
Item 12a-EOS search strategy	Search info	Supplied

Document name	Description	Location
Item 12b-EOS references	Search info	Supplied
Item 12g-Dual source search strategies revised	Search info	Supplied
Item 12k-Lipochip Refs 14 Sept 2010	Search info	Supplied
Item 13a-Appendix to EOS DAR	Part of DAR	Supplied
Item 14a- Final EOS overview	Overview	http://guidance.nice.org.uk/DT/1/Overview/pdf/English
Item 14c-NGCCT-Evidence Overview	Overview	Supplied
Item15-DA generic microtimeline V14 12 01 12	MS Excel Spreadsheet	Supplied
EOS 2D/3D imaging system (DG1), Oct 2011	Guidance example	http://guidance.nice.org.uk/DG1
Computed tomography (CT) scanners for cardiac imaging - Somatom Definition Flash, Aquilion One, Brilliance iCT and Discovery CT750 (DG3), Jan 2012.	Guidance example	http://guidance.nice.org.uk/DG3

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

NICE Accreditation Advisory Committee

The Accreditation Advisory Committee operates as a standing advisory committee of the Board of the National Institute for Health and Clinical 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 NICE Board and the meetings are conducted by the chair or in his/her absence the vice chair. The current Chair is David Haslam. 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	
Dr	Adrian	Brown	Consultant in Public Health Medicine	Inner North West London PCTs
Ms	Ailsa	Donnelly	Lay member	
Ms	Amanda	Edwards	Deputy Chief Executive	Social Care Institute for Excellence

	Joyce	Epstein	Lay member	
Professor	David	Haslam	National Clinical Adviser	Care Quality Commission
Dr	Bobbie	Jacobson	Director	London Health Observatory
Professor	Monica	Lakhanpaul	Professor of Integrated Community Child Health	University College London (Institute of Child Health)
	Ruth	Liley	Assistant Director of Quality Improvement	Marie Curie Cancer Care
Professor	Stuart	Logan	Professor of Paediatric Epidemiology	Peninsula College of Medicine and Dentistry
Dr	Edward	Ng	General Practitioner	Ley Hill Surgery
Professor	Sandy	Oliver	Prof of Public Policy, Deputy Director	University of London
Dr	Mahendra	Patel	Senior Lecturer and Consultant Pharmacist	Universities of Huddersfield and Bradford
Dr	Karen	Ritchie	Head of Knowledge Management	Healthcare Improvement Scotland
Professor	Sasha	Shepperd	Professor of Health Services Research	University of Oxford
Dr	Peter	Smith	Vice President	National Association of Primary Care
Dr	Mark	Strong	MRC Fellow	School of Health and Related Research (ScHARR) University of Sheffield
Ms	Gill	Swash	Head of Knowledge and Library Services	NHS Western Cheshire
Dr	Sara	Twaddle	Director	Scottish Intercollegiate Guidelines Network

External Advisers for the National Institute for Health and Clinical Excellence Diagnostics Assessment Programme – Diagnostic Technologies Guidance accreditation application

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NICE Accreditation team for the National Institute for Health and Clinical Excellence Diagnostics Assessment Programme – Diagnostic Technologies Guidance accreditation application

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