National Institute for Health and Clinical Excellence

Producer:	**National Institute for Health and Clinical Excellence; Medical Technologies Evaluation Programme**
Product:	**Medical technologies guidance**
Date:	**7 December 2011**

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[1].

Accreditation recommendation

The process used by the **National Institute for Health and Clinical Excellence; Medical Technologies Evaluation Programme** to produce **Medical Technologies Guidance** has been accredited. Accreditation is valid for 5 years from **November 2011** and is retrospectively applicable to guidance produced using the processes described in **the Medical Technologies Evaluation Programme Methods Guide (2011) and Process Guide (2011)**.

Background to the guidance producer

The Medical Technologies Evaluation Programme at NICE produces national guidance for the promotion of new or innovative medical technologies that have the potential to offer improved cost effectiveness and that may be adopted more consistently and rapidly if NICE develops guidance on them.

Medical Technologies Guidance (MTG) states whether the case for adoption of a technology is supported by the evidence. This includes consideration of clinical evidence, cost effectiveness data and the wider implications for the NHS.

Summary

[1] http://www.evidence.nhs.uk/Accreditation/Documents/NHSEvidenceAccredManual.pdf

The Accreditation Advisory Committee considered that the processes used by the National Institute for Health and Clinical Excellence; Medical Technologies Evaluation Programme to produce Medical Technologies Guidance complied with 24 of the 25 accreditation criteria.

The processes used to develop MTG are detailed in the MTEP Methods Guide (2011) MTEP Process Guide (2011), document templates and publicly available policies.

The process for producing MTG is robust and accounts for the possibility of bias. All relevant stakeholders including patient groups are involved in developing the guidance which is clear and suitable for the specified target audiences. Further information is available in a lay summary of the guidance and through the documents provided for public consultation. A range of support tools is provided to aid implementation of the recommendations.

The assessment found that the process of reviewing guidance would benefit from a fixed review date as well as the existing process of ad-hoc review. Positive recommendations are only considered for review when important new evidence emerges; a fixed review date would allow changes in the evidence base that may affect the case for adoption to be brought to the attention of the guidance producer. The process for reviewing guidance, including how new evidence comes to the attention of the guidance producer, needs to be better described in the process documentation.

Suggestions for improvement to strengthen the NICE MTEP processes to produce MTG include:

- adding a fixed review date for positive recommendations
- describing the process of reviewing guidance (including both scheduled and unscheduled updates) in more detail
- stating the dates of search in the final guidance
- stating the date of the scoping search

Professor David Haslam, CBE

Chair, Accreditation Advisory Committee

November 2011

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 NHS Evidence Accreditation Mark in accordance with the Conditions and Terms of Use[2]. 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 NHS Evidence within 30 days if any significant change is made to a process.

Figure 1: The NHS Evidence Accreditation Mark

[2] http://www.evidence.nhs.uk/Accreditation/Documents/NHSEvidenceConditions.doc

Appendix A: Accreditation analysis

The Accreditation Advisory Committee considered the following analysis of the guidance producer's compliance with the accreditation criteria, which covers six 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 provided by the MTG template[a]. This includes standard wording for the beginning of the document, explaining the overall objective of the programme and the basis on which a recommendation is reached. This can be seen in the guidance examples assessed[b,c,d].	Criterion met
	1.2 The clinical, healthcare or social questions covered	Section five, 'The Scope', of the MTEP methods guide[e] requires that the clinical, healthcare and social questions addressed by the guidance are stated. The scope document for each MTG is publicly available as part of the consultation documents provided for each MTG. In the scope examples assessed[f,g,h] the questions to be addressed by the MTG are summarised in the section 'statement of decision problem' at the end.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	1.3 Population and/or target audience to whom the guidance applies	The template for the final MTG guidance[a] requires that the population to whom the guidance applies is stated. In the guidance examples assessed the patient population is defined in either the 'Recommendations' or 'The Technology' sections. The MTEP process[i] guide specifies the target audience, which includes a range of people, from commissioners and clinicians to managers and patients and carers.	Criterion met
	1.4 Guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	The MTEP methods guide[e] and MTG template[a] require that recommendations refer to specific clinical or healthcare circumstances, as supported by the evidence base. This was seen in the examples of MTG assessed[b,c,d], which defined the technology under assessment and the condition it is intended to help with.	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 MTEP process guide[i] specifies that membership of the MTAC should include healthcare professionals from a variety of disciplines, lay members and individuals from the medical technology industry. Membership lists are publicly available. The MTEP process guide[i] describes the processes used to identify and engage with expert advisers and the scope of information they may be asked to provide. Patient and carer organisations are asked to provide information and share their views before draft recommendations are made.	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	Patient views and preferences are included in guidance development as required by the MTEP process guide[i]. The MTAC includes lay members and relevant patient and carer organisations are identified and sent questionnaires to obtain their views on technologies before draft recommendations are made. Any interested party may comment on draft recommendations during the public consultation stage.	Criterion met
	2.3 Representative intended users in developing guidance.	The MTEP process guide[i] specifies that representative intended users are involved as expert advisers. A wide range of healthcare professionals is also represented on the MTAC. Interested organisations may comment on the draft scope and the draft recommendations.	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 MTEP methods guide[e] requires sponsors to undertake a systematic evidence search and states that searches typically include medical literature databases and clinical and health economics studies. The EAC reproduces the sponsor's search to validate that all relevant evidence has been identified. Systematic methods are used to search for evidence of clinical and cost effectiveness and details of the search strategy are published.	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 manufacturer's submission template[m] requires manufacturers to detail the search strategy and inclusion and exclusion criteria with the rationale for these criteria, for both clinical and economic evidence. The EAC assessment report template requires EACs to comment on the reasons for inclusion and exclusion of evidence. This can be seen in the examples of EAC assessment reports examined which are publicly available[j,k,l].	Criterion met
	3.3 Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty	There are process requirements to describe the strengths and limitations of the body of evidence in the manufacturer's submission and the EAC assessment report, both of which follow a template format and are published online as part of the public consultation documents. There is also some discussion of these issues in the final MTGs examined[b,c,d].	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 of arriving at recommendations, including topic selection, scoping, assessment of the manufacturer's submission, making draft recommendations, public consultation and making final recommendations is described in the MTEP process guide[i]. The specific method of arriving at recommendations at the MTAC is provided by the 'Standing orders for NICE advisory bodies' document[p], which specifies consensus, if possible, or voting if not, including a casting vote by the MTAC Chair.	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 MTEP process guide[i], methods guide[e] and document templates[a,m,n] outline a process for considering the health benefits, side effects and risks of technologies when formulating recommendations. This happens at the manufacturer's submission, EAC assessment, MTAC and public consultation stages. These issues are discussed in the MTG examined[b,c,d].	Criterion met
	3.6	Describes the processes of external peer review	The process of external peer review for MTG is public consultation and is described in the MTEP process guide[i]. The consultation period is 4 weeks and all preceding documents are published online. The guidance producer also makes an executable version of the cost model available to those who register an interest in the topic, on request, and subject to certain conditions. Feedback from public consultation can change the draft recommendations made by the MTAC.	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 MTEP methods guide[e] and the MTEP process guide[i] are reviewed by the NICE Board 3 years after publication. Any substantial changes that meet defined criteria require a period of public consultation of 3 months before being implemented. Unsuccessful applications are reviewed 2 years after a final decision, to see if the device is eligible for reassessment on the basis of new evidence supplied by the manufacturer. The assessment found that the process would benefit from the addition of a fixed review date to ensure the case for adoption can be systematically reviewed to take changes to the evidence base into account. It was also found that the process for reviewing guidance, in both scheduled and unscheduled updates, needs to be better described.	Not fully met
Clarity and presentation	**4. Does the guidance producer ensure that:**		
	4.1 Recommendations are specific, unambiguous and clearly identifiable	The location, style and wording of the recommendations are provided by the MTG template[a]. The MTEP methods guide[e] specifies the type of recommendation that may be made depending on the extent to which the case for adoption is supported, and the potential patient and healthcare system benefits. The recommendations are specific, unambiguous and clearly identifiable[b,c,d].	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	4.2	Different options for the management of the condition or options for intervention are clearly presented	The MTG template[a] requires that current options for management of the condition are described. Therefore, although each MTG focuses on one specific technology, users can find information on other treatment options within the guidance.	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 manufacturer's submission template[m] requires the date range of the literature search to be displayed. The EAC replicates the manufacturer's search according to the details provided, so there is no requirement for the EAC assessment report[n] to state the date range again. The MTG template[a] requires that the date of publication is shown. There is no process requirement to display the date of review for the guidance, as the MTEP process guide[i] specifies that guidance does not have a fixed review date.	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 producer ensures that the content and language of MTG is suitable for a diverse audience of healthcare professionals and lay people by providing a lay summary of the as well as the full versions for practitioners, clinicians, managers and those involved in purchasing or procurement. The 'Understanding NICE guidance' pages on the website clearly describe the technology and key recommendations for each MTG. They are very short and contain much less technical language than the full guidance.	Criterion met
Applicability	**5. Does the guidance producer routinely consider:**			

	Criterion	Evidence for meeting the criterion	Accreditation decision
	5.1 Publishing support tools to aid implementation of guidance	A range of support tools, including costing templates, podcasts and slide sets, is provided as standard for each MTG to aid implementation of the guidance. Further support is provided by visits from NICE Implementation Consultants who visit NHS organisations to explain how to put NICE guidance into practice.	Criterion met
	5.2 Discussion of potential organisational and financial barriers in applying its recommendations	The EAC assessment report template[n] requires the EACs to evaluate all cost effectiveness evidence supplied by the manufacturer and critique the methods used. The MTG template[a] includes sections devoted to cost considerations and organisational barriers. Financial and organisational barriers are discussed in the examples of MTG assessed[b,c,d].	Criterion met
	5.3 Review criteria for monitoring and/or audit purposes within each product.	The NICE Impact and Evaluation team monitors the uptake of NICE guidance, working with the NHS and manufacturers to identify, access and review uptake information. An implementation report[o] includes routine healthcare activity data such as hospital episode statistics, published implementation studies, feedback from the field team and any implementation issues that have been reported to NICE.	Criterion met
Editorial	**6. Does the guidance producer:**		

	Criterion		Evidence for meeting the criterion	Accreditation decision
independence	6.1	Ensure editorial independence from the funding body	The funding source identified in criterion 6.2 is the Department of Health. Manufacturers make submissions independent of the funding source. Submissions are then assessed by EACs which are independent of the manufacturer and the Department of Health, although they are contracted by NICE. The MTAC, whose members are independent of NICE, makes the final recommendations which are then subject to public consultation. The process of developing recommendations is as independent from the funding source as is possible, given the necessity of paying certain expenses.	Criterion met
	6.2	Demonstrate transparency about the funding mechanisms for its guidance	NICE publishes its annual accounts in a report on the NICE website each year, in which the Department of Health is identified as the funding source, and therefore the funding source for MTG.	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'[p] document requires the members of MTAC to declare any conflicts of interest. NICE staff, members of the EAC involved in assessing the manufacturer's submission, and expert advisers are required to declare conflicts of interest as set out in the 'Guidance on declarations of interest' document[q], which is publicly available.	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 MTEP process guide[i], MTEP methods guide[e] and the policies governing declarations of interest[q] for committee members, advisers and the EACs significantly reduce the possibility of bias. An important potential source of bias is the selection and assessment of evidence by the manufacturer. This is accounted for by a defined, systematic search strategy with published inclusion and exclusion criteria, as required by the template form for the manufacturer's submission[m]; and an independent, published assessment of the search strategy and the evidence by the EACs. Expert advisers and NICE technical analysts also assess the submissions before the MTAC. All recommendations are subject to public consultation, for which all key documents are available.	Criterion met

Criterion	Evidence for meeting the criterion	Accreditation decision
a MTG template (2010) b MTG1: SeQuent Please balloon catheter for in-stent coronary restenosis (2010) c MTG2: moorLDI2-BI laser doppler blood flow imager for burn wound assessment (2011) d MTG3: CardioQ-ODM oesophageal doppler monitor (2011) e MTEP methods guide (2011) f Scope for MTG1: SeQuent Please balloon catheter for in-stent coronary restenosis g MTG2 Scope for MTG2: moorLDI2-BI laser doppler blood flow imager for burn wound assessment h MTG3 Scope MTG 3: CardioQ-ODM oesophageal doppler monitor i MTEP process guide (2011) j EAC Assessment Report for MTG1: SeQuent Please balloon catheter for in-stent coronary restenosis (2010) k EAC Assessment Report for MTG2: moorLDI2-BI laser doppler blood flow imager for burn wound assessment (2011) l EAC Assessment Report for MTG 3: CardioQ-ODM oesophageal doppler monitor (2011) m Manufacturer's submission template (2011) n EAC Assessment Report template (2011) o Implementation report (2011) p Standing Orders for NICE Advisory Bodies (2011) q Guidance on Declarations of Interest (2008)		

Appendix B: Bibliography

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

Document name	Description	Location
FW NICE - resolution on Moor LDI2 Burns imager	Email to stakeholder advising on resolution dates	Supplied
Guidanceondeclarationsofinterest.pdf	NICE policy on declaring conflicts of interest	http://www.nice.org.uk/aboutnice/whoweare/policiesandprocedures/policiesandprocedures.jsp
Item1-MTEP methods guide FINAL 14Apr11.pdf	Process document	http://www.nice.org.uk/aboutnice/whatwedo/aboutmedicaltechnologies/MTEPProcessGuideAndMethodsGuide.jsp
Item2-Med Tech process guide FINAL 15Apr11.pdf	Process document	http://www.nice.org.uk/aboutnice/whatwedo/aboutmedicaltechnologies/MTEPProcessGuideAndMethodsGuide.jsp
Item3-Standing_Orders_for_NICE_Advisory_Bodies.pdf	Standing orders for NICE advisory bodies including MTAC	http://www.nice.org.uk/aboutnice/whoweare/policiesandprocedures/policiesandprocedures.jsp
Item4-BoardMarch11-7BoardCoverPaper.pdf	Board Cover Paper 16 March 2011 Summarising the outcome of the public consultation on the Process Guide and the Methods Guide	Supplied
Item4a-BoardMeetingMarch2011Item7ProcessGuideAppendix.pdf	Appendix 1 to Board Cover Paper summarising the changes to the MTEP Process Guide arising from comments received during public consultation. Relating to improvements to the	Supplied

Document name	Description	Location
	descriptions of the process.	
Item4b-BoardMeetingMarch2011Item7MethodsGuideAppendix.pdf	Appendix 2 to Board Cover Paper summarising the changes to the MTEP Methods Guide arising from comments received during public consultation: relates to improvements to the descriptions of the methods.	Supplied
Item5-MTEP assessment report v5.pdf	MTEP assessment report v5, showing the case-by-case Declaration of Interest requirements for staff of External Assessment Centres	http://www.nice.org.uk/aboutnice/whatwedo/aboutmedicaltechnologies/ProgrammeInformationAndDocumentation.jsp
Manufacturers Submission TemplateV8.doc	Manufacturer's submission template	http://www.nice.org.uk/aboutnice/whatwedo/aboutmedicaltechnologies/ProgrammeInformationAndDocumentation.jsp
Item7-DecisionProblem-EP094 Scope_MIST_6.doc	Example of scope document	Supplied
Item8-Final guidance template.doc	Template for MTGs	Supplied
Item9a-HowToPutNICEGuidanceIntoPractice.pdf	Implementation support document	http://www.nice.org.uk/usingguidance/implementationtools/howtoguide/
Item9b-Howtochangepractice1.pdf	Implementation support document	http://www.nice.org.uk/usingguidance/implementationtools/howtoguide/
Item9c-NICEGuidanceLocalCommunities.pdf	Implementation support document	http://www.nice.org.uk/usingguidance/implementationtools/howtoguide/
Item9d-NICEGuidanceLocalCom	Implementation support document	http://www.nice.org.uk/usingguidance/implementationtools/howt

Document name	Description	Location
munities		oguide/
Item10-Medical Technologies Notification Form.doc	Medical Technologies Notification Form	Supplied
Item 11-Moor LDI2 BI Resolution CA&U.doc	Confidentiality form	Supplied
Item12-WkPkg-Stage-2-Instruction-To-Proceed-2011.doc	Containing Conflict of Interest declaration for completion in respect of each individual work package.	Supplied
Item 11-NICE Resolution letter - Moor LDI2 BI.doc	Stakeholder engagement email	Supplied
MedTechPatientAndCarerOrganisationQuestionnaire.doc	Questionnaire for public consultation at scoping stage	Supplied
MT submission template 111011	Manufacturer's submission template	Supplied at feedback
MTEP Uptake and Implementation Feedback - template Oct 2011.doc	Report for monitoring guidance from the NICE Impact and Evaluation team	Supplied at feedback
MTG1.pdf	Guidance example	http://guidance.nice.org.uk/MTG1/Guidance/pdf/English
MTG2.pdf	Guidance example	http://guidance.nice.org.uk/MTG2/Guidance/pdf/English
MTG3.pdf	Guidance example	http://guidance.nice.org.uk/MTG3/Guidance/pdf/English
MTG1 – EAC report.pdf	Example of EAC report	http://guidance.nice.org.uk/MT/72/Consultation/AssessmentReport/pdf/English
MTG2 – EAC report.pdf	Example of EAC report	http://guidance.nice.org.uk/MT/104/Consultation/AssessmentReport/pdf/English
MTG3 – EAC report.pdf	Example of EAC report	http://guidance.nice.org.uk/MT/8

Document name	Description	Location
		0/Consultation/AssessmentReport/pdf/English
MTG1 – Scope.pdf	Example of scope document	http://guidance.nice.org.uk/MT/72/Consultation/Scope/pdf/English
MTG2 – Scope.pdf	Example of scope document	http://guidance.nice.org.uk/MT/104/Consultation/Scope/pdf/English
MTG3 – Scope.pdf	Example of scope document	http://guidance.nice.org.uk/MT/80/Consultation/Scope/pdf/English

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

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[3]. 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.

[3] http://www.nice.org.uk/nhsevidence/nhseac.jsp

Title	Name	Surname	Role	Organisation
Ms	Judy	Birch	Lay member	
Mr	Jim	Blair	Consultant Nurse Learning Disabilities	St. George's Healthcare NHS Trust
Dr	Adrian	Brown	Consultant in Public Health Medicine	Inner North West London PCTs
Professor	Ann	Caress	Professor of Nursing/Director of postgraduate research programmes	University of Manchester
Ms	Lynda	Cox	Head of Transformation	NHS North East
Ms	Ailsa	Donnelly	Lay member	
Ms	Amanda	Edwards	Deputy Chief Executive	Social Care Institute for Excellence
Professor	David	Haslam	National Clinical Adviser	Care Quality Commission
Dr	Leonard	Jacob	GPSI and Hospital Practitioner - Cardiology	CVD GP Lead NHS Rotherham
Dr	Monica	Lakhanpaul	Consultant Community Paediatrician/Senior Lecturer in Child Health	Leicester City Community Children's Health Services/University of Leicester
Dr	Donal	O'Donoghue	National Clinical Director for Kidney Care and Consultant Renal Physician	Salford Royal NHS Foundation Trust

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, Elliott House

Advisory Committee deputies

Title	Name	Surname	Role	Organisation	Deputising for
Ms	Rebecca	Rees	RCUK Academic Fellow	Social Science Research unit, University of London	Sandy Oliver

External Advisers for the National Institute for Health and Clinical Excellence; Medical Technologies Evaluation Programme – Medical Technologies Guidance accreditation application

Dr Matthew Westmore, Director, National Institute of Health Research; Evaluation, Trials and Studies Coordinating Centre, UK.

Mr Nigel Beasley, Consultant in Otolaryngology, Deputy Medical Director, Nottingham University Hospital, UK.

Dr Timothy Bates, Senior Lecturer in Biomedical Sciences, University of Lincoln, UK.

NHS Evidence accreditation team for the National Institute for Health and Clinical Excellence; Medical Technologies Evaluation Programme – Medical Technologies Guidance accreditation application

James Stone, Accreditation Technical Analyst, NHS Evidence, National Institute for Health and Clinical Excellence, Manchester, UK.

Stephanie Birtles, Accreditation Technical Analyst, NHS Evidence, National Institute for Health and Clinical Excellence, Manchester, UK.