Producer: **Duodecim Medical Publications**

Product: **Evidence Based Medicine guidelines, Evidence Summaries and Evidence Based Medicine electronic Decision Support (EBMeDS) rules**

Date: **1 February 2012**

Final Accreditation Report

Contents

Introduction

The 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 **National Institute for Health and Clinical Excellence** (NICE) has accredited the process used by **Duodecim Medical Publications** to produce **Evidence Based Medicine Guidelines (EBM Guidelines), Evidence Summaries and Evidence Based Medicine electronic Decision Support (EBMeDS)**. Accreditation is valid for 5 years from **September 2011** and is retrospectively applicable to guidance produced using the process described in 'Käypä hoito – käsikirja työryhmille' (May 2008).

Background to guidance producer

Duodecim is a Finnish medical society that supports public discussion on ethics in medicine, develops links to international medical societies and authors clinical guidelines. Evidence Based Medicine (EBM) Guidelines are targeted at primary care, ambulatory care and community hospitals. The EBM Guidelines are the basis for quality graded summaries of evidence known as Evidence Summaries, which are therefore also part of this accreditation submission.

Recommendations based on the Evidence Summaries, and therefore the EBM Guidelines, have been developed into decision support tools – known as

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

Evidence Based Medicine electronic Decision Support (EBMeDS). EBMeDS provide context-sensitive guidance to the clinician, highlighting relevant evidence in real time and at the point of care. EBMeDS obtain patient data from electronic patient records and returns reminders, therapeutic suggestions and diagnosis-specific links to guidelines.

Summary

The Accreditation Advisory Committee considered that the processes used by Duodecim Medical Publications to produce EBM Guidelines, Evidence summaries and EBMeDS demonstrated compliance with 21 of the 25 accreditation criteria.

The processes used by Duodecim to produce guidance are documented in 'Käypä hoito – käsikirja työryhmille' (May 2008) and an abridged version in English, 'EBM Guidelines Evidence Summaries' (May 2010).

The processes used to search the evidence and to define the parameters for including and excluding evidence are clearly shown and rigorous. The evaluation of the strengths and limitations of the evidence, consideration of health benefits against side effects and risks, the peer review process and updating are all clearly described. The guidance has a transparent funding mechanism and is independent from the funding body, and a robust conflict of interest policy is in place. Guidance documents are hyperlinked together allowing users to easily find related information in other documents.

The method used to derive recommendations needs to be clarified. Although Duodecim explained that consensus is used to derive recommendations it is unclear whether this method is used on all occasions.

Duodecim is currently developing its guidance production processes to increase patient involvement in developing recommendations. Duodecim has also indicated it will update its processes to include likely organisational barriers.

In summary, the process described to produce EBM Guidelines, Evidence summaries and EBMeDS meets 21 of the 25 criteria for accreditation. Criteria 2.1, 3.4. 4.3 and 5.2 are not fully met.

Suggestions for further improvements to strengthen Duodecim's processes for producing EBM Guidelines, Evidence summaries and EBMeDS include:

- ensuring that patient and patient representatives are actively involved in developing recommendations for guidance
- encouraging patients and service users to continue providing feedback on guidance produced
- ensuring that guidance authors are aware that recommendations should be derived via consensus
- ensuring that all process enhancements are clearly integrated into a new policy document and consistently used when updating guidance at scheduled review dates.

David Haslam

Chair, Accreditation Advisory Committee

September 2011

Implementation

Following accreditation, guidance from the accredited producer will be identified by the Accreditation Mark. The accredited guidance producer is also granted a royalty-free, worldwide licence to use the 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 NICE within 30 days if any significant change is made to a process.

Figure 1: The Accreditation Mark

[2] 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.

Domain	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 abridged process document[1] states that guidelines '... cover clinically important evidence on diagnosis, screening, treatment and follow-up of all conditions encountered in primary and ambulatory care'. Specific objectives are stated in the titles of the EBM Guideline[8–16], Evidence Summary[17–21] and EBMeDS[28–30] examples.	Criterion met
	1.2. The clinical, healthcare or social questions covered	The abridged process document[1] explains that questions on diagnosis, screening, treatment and follow-up encountered in primary and ambulatory care are covered. Detailed clinical questions are specified throughout the body of the EBM Guideline[8–16] and Evidence Summary[17–21] examples.	Criterion met
	1.3. Population and/or target audience to whom the guidance applies	The abridged process document[1] states that EBM Guidelines and Evidence Summaries are intended for use by doctors working in specific clinical settings such as primary care. It is clear that the guidance examples[8–21] have been prepared for healthcare professionals and define patient demographics.	Criterion met
	1.4. Guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	Process documentation[1,3] shows that EBM Guidelines and Evidence Summaries are structured into a logical 'template' and that clear and specific recommendations are provided to manage each condition. EBM Guidelines[8–16] are linked to relevant Evidence Summaries[17–21], which are linked in turn to EBMeDS[28–30] rules via hyperlinks.	Criterion met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
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	Editorial team information is on the guidance producer's website. The editorial team is multidisciplinary but there appears to be a lack of patient involvement in developing guidance. Confirmation of how the guidance producer aims to take 'patient involvement under special scrutiny via the editorial process in the future' is required.	Not fully met
	2.2. Patient and service user representatives, and seeks patient views and preferences in developing guidance	The view of patients in guidance development is supported by the Finnish version of the process document[2].	Criterion met
	2.3. Representative intended users in developing guidance	The abridged process document[1] explains that guidelines are used mainly in primary care by healthcare professionals. It is clear that the intended users of the guidance are represented by the membership of the authoring group.	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 criterion is supported by the abridged process document[1]. A search protocol[3], along with a sample search[4], shows the search terms, number of hits and articles identified. All search information is accessible to editors of EBM Guidelines. Hyperlinks in the EBM Guidelines allow the user to 'click through' to the included evidence base and Evidence Summaries.	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	Process documentation[1,3] confirms that search filters ensure only relevant studies are identified and that Cochrane reviews are prioritised for inclusion. Studies excluded include those conducted in settings irrelevant to the EBM Guidelines target audience or patient population. A sample search strategy[4] specifies date ranges. EBM Guidelines[8–16] do not show inclusion and exclusion criteria because of space limitations.	Criterion met

Domain	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 abridged process document[1] states that evidence uses the GRADE system. All EBM Guideline examples use the GRADE system.	Criterion met
	3.4. Describes the method used to arrive at recommendations (for example, a voting system or formal consensus techniques like Delphi consensus)	Consensus is reached by iterative amendments in the recommendation until all members of the editorial team agree. If consensus cannot be reached, a recommendation is not given. Voting is rarely used. It is unclear whether the extra detail recently added to the process documentation[2] is a new part of the process or has been in use informally for some time.	Not fully met
	3.5. Requires the guidance producers to consider the health benefits against the side effects and risks in formulating recommendations	The criterion is supported by the process documentation[1,6]. The EBM Guidelines[8–16] , Evidence Summaries[17–21] and EBMeDS[28–30] show that the balances of health benefits are considered against the likely side effects or safety concerns for recommendations.	Criterion met
	3.6. Describes the processes of external peer review	The full process document[2] explains that staff from university, regional and local hospitals (in Finland), along with physicians in health centres are asked to act as stakeholders. Because of the succinct nature of all guidance, no information in the example guidance includes reference to peer review.	Criterion met
	3.7. Describes the process of updating guidance and maintaining and improving guidance quality	The abridged process document[1] explains that there are major and minor updates to EBM Guidelines[8–16] and Evidence Summaries[17–21]. All example guidance shows that the documents have been updated.	Criterion met

Domain	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 abridged process document[1] explains that evidence should be summarised succinctly and shows all guidance is structured into a logical 'template' format that gives prominence to the key research finding. EBM Guidelines[8–16], Evidence Summaries[17–21] and EBMeDS[28–30] present recommendations for a treatment, or delivery of a procedure or drug in a clear and concise manner. Stock phrases are provided[6] to standardise expressions, which reduces ambiguity.	Criterion met
	4.2. Different options for the management of the condition or options for intervention are clearly presented	Evidence Summaries[17–21] recommend a single treatment, which is explained by the abridged process[1]. EBM Guideline[8–16] examples show that a number of options for the management of a condition are usually suggested. EBMeDS[28–30] show different options are presented interactively depending on a patient's symptoms or blood results.	Criterion met
	4.3. The date of search, the date of publication or last update and the proposed date for review are clearly stated	Guidance is updated every 3 years according to the full process document[2]. The date that the latest search was conducted has not yet been added to all Evidence Summaries. The date that EBMeDS were last updated has already been added, according to the guidance producer. EBM Guidelines have always been reviewed but the date of the last update and the expected review date for each article will be displayed from 2011. Therefore not all date information currently appears in guidance and the criterion is not fully met.	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.	Process documentation[1,6,7] provides key phrases for use in Evidence Summaries. Stock phrases are used to formulate evidence statements to aid clarity. Guidance examples are suitable for the target audience.	Criterion met

Domain	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	Links on the guidance producer's website and user guide[5] state that appropriate EBM Guidelines[8,16] should contain implementation assistance tools such as audio samples, pictures, audio links, videos, program files, calculators and disease-specific patient questionnaires. EBMeDS are effectively tools for implementing the guidelines. EBMeDS and related products contain tools for handling user feedback and software that can assist with clinical decision making.	Criterion met
	5.2. Discussion of potential organisational and financial barriers in applying its recommendations	The process manual is to be updated to include direction about how to approach barriers to implementation. This is a positive development but the criterion is not fully met because this process is not yet embedded.	Not fully met
	5.3. Review criteria for monitoring and/or audit purposes within each product.	The development of quality indicators and audit started in 2010. A list of the first indicators to be implemented is provided in a table format[26]. The indicators are implemented via EBMeDS decision rules that record quality measures. Further process evidence shows how quality measures can be implemented[27] and details the raw output data from a virtual health check, along with an example that details triggered reminders[24]. The tools can be used to develop and implement national and local quality measures, including audit. A flowchart shows the full development process[25].	Criterion met
Editorial independence	**6. Does the guidance producer:**		
	6.1. Ensure editorial independence from the funding body	Guideline panel members are selected by the current care guidelines editorial team. No members of the funding body take part in authoring the guidelines or participate in any guidance development meetings. Referee comments are not requested or obtained from the funding body.	Criterion met

Domain	Criterion	Evidence for meeting the criterion	Accreditation decision
	6.2. Demonstrate transparency about the funding mechanisms for its guidance	A translated section of the full process document[2] explains that the current care guidelines unit supports and manages the production and distribution of EBM Guidelines. Their work is financed via the Finnish National Institute for Health and Welfare[23].	Criterion met
	6.3. Record and state any potential conflicts of interest of individuals involved in developing the recommendations	A translation from the full process document[2] confirms that conflicts of interest are requested from the guideline authoring group. The guidance producer also supplied a full translation of its conflict of interest policy[22]. EBM Guideline examples do not show that conflict of interest declarations are sought from authors – it is suggested that to be fully transparent any conflict of interests are stated.	Criterion met
	6.4. Take account of any potential for bias in the conclusions or recommendations of the guidance	The editorial team is multidisciplinary and there is transparency with regards to funding. A robust conflict of interests policy is also in place, minimising the potential for bias influencing the recommendations made in EBM Guidelines.	Criterion met

Documents submitted:

[1] EBM Guidelines Evidence Summaries, 2010

[2] Handbook for Guideline Authors ('Käypä hoito – käsikirja työryhmille', 2008, in Finnish)

[3] Search strategy for current care and EBM guidelines, 2006

[4] Sample search (for atrial fibrillation)

[5] EBM Guidelines user guide http://onlinelibrary.wiley.com/book/10.1002/0470057203

[6] Grading the strength of recommendations

[7] Wording of effects document

[8] Benign prostatic hyperplasia, 2010

[9] Brief interventions for heavy use of alcohol, 2009

[10] Risk of suicide in adolescence, 2010

[11] Cancers of the urinary system and testes, 2009

[12] Insulin therapy in type 2 diabetes, 2010
[13] Examining a patient with a thyroid complaint, 2010
[14] Coronary heart disease, 2010
[15] Prostate Cancer, 2010
[16] Conservative and plastic treatment of leg ulcers, 2010
[17] Brief interventions and alcohol use, 2009
[18] Intravesical bacillus Calmette-Guerin versus mitomycin C for bladder cancer, 2009
[19] Homocysteine lowering interventions for preventing cardiovascular events, 2009
[20] Short acting insulin analogues versus regular human insulin in patients with diabetes mellitus, 2008
[21] Long acting insulin analogues versus NPH insulin (human isohane insulin) for type 2 diabetes mellitus, (no date provided)
[22] Conflict of interest (translation) handbook of guideline authors (2007)
[23] www.thl.fi/enUS/web/en/Home
[24] www.ebmeds.org/sipoo.htm
[25] Current Care process for indicator development (flowchart)
[26] Planned Current Care indicators to be implemented via EBMeDS
[27] Example of implementation of the Quality and Outcomes Framework [QOF] Coronary Heart Disease [CHD 6] rule by EBMeDS
[28] Aspirin for nitrate users (no date provided)
[29] Follow-up of high PSA concentration (no date provided)
[30] Metformin is the first choice oral hypoglycaemic agent in type 2 diabetes

Appendix B: Bibliography

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

Document name	Description	Location
'EBM Guidelines Evidence Summaries' May 2010.	Summarised version of the full Finnish process manual 'Käypä hoito – käsikirja työryhmille', May 2008 (shown below) – supplied by the guidance producer	Supplied as evidence
'Handbook for Guideline Authors' ('Käypä hoito – käsikirja työryhmille') May 2008. In Finnish	Finnish language version of the full process manual. Parts of the full manual were translated into English by the guidance producer. A full English translation of this manual is expected in 2011	Supplied as evidence
'Search strategy for Current Care and EBM Guidelines' February 2006	Search strategy – supplied by the guidance producer	Supplied as evidence
'EBM Guidelines – guidance at the point of care' January 2011	Congress presentation based on a questionnaire – supplied by guidance producer	Supplied as evidence
'Grading the strength of recommendations' paper	Advice on wording and symbols to highlight the strength of recommendations – supplied by the guidance producer	Supplied as evidence
'Wording of effects' paper	Results of questionnaire findings – supplied by the guidance producer	Supplied as evidence
Link to Duodecim's online database	EBM Guidelines, Evidence summaries, EBMeDS and evidence pictures, audio links, videos and program files available for downloading and searchable by keyword	Supplied as evidence
'Benign prostatic hyperplasia' October 2010	EBM Guideline – example selected arbitrarily	Supplied as evidence

Document name	Description	Location
'Brief interventions for heavy use of alcohol' December 2009	EBM Guideline – example selected arbitrarily	Supplied as evidence
'Risk of suicide in adolescence' July 2010	EBM Guideline – example selected arbitrarily	Supplied as evidence
'Cancers of the urinary system and testes' March 2009	EBM Guideline – example selected arbitrarily	Supplied as evidence
'Insulin therapy in type 2 diabetes' October 2010	EBM Guideline – example selected arbitrarily	Supplied as evidence
'Examining a patient with a thyroid complaint' November 2010	EBM Guideline – example selected arbitrarily	Supplied as evidence
'Coronary heart disease' April 2010	EBM Guideline – example selected arbitrarily	Supplied as evidence
'Prostate cancer' December 2010	EBM guideline – example selected arbitrarily	Supplied as evidence
'Conservative and plastic treatment of leg ulcers' March 2010	Sample - supplied by guidance producer	Supplied as evidence
'Brief interventions and alcohol use' February 2009	Evidence summary – example selected arbitrarily	Supplied as evidence
'Intravesical bacillus *Calmette-Guerin* versus mitomycin C for bladder cancer' February 2009	Evidence summary – example selected arbitrarily	Supplied as evidence
'Homocysteine lowering interventions for preventing cardiovascular events' November 2009	Evidence summary – example selected arbitrarily	Supplied as evidence

Document name	Description	Location
'Short acting insulin analogues versus regular human insulin in patients with diabetes mellitus' Sepember 2008	Evidence summary – example selected arbitrarily	Supplied as evidence
'Long acting insulin analogues versus NPH insulin (human isohane insulin) for type 2 diabetes mellitus' date unavailable	Evidence summary – sample supplied by guidance producer	Supplied as evidence
'Aspirin for nitrate users'	EBMeDS – example selected arbitrarily	Supplied as evidence
'Follow-up of high PSA concentration'	EBMeDS rule – example selected arbitrarily	Supplied as evidence
'Metformin is the first choice oral hypoglycaemic agent in type 2 diabetes'	EBMeDS rule – sample supplied by guidance producer	Supplied as evidence
The EBM Guidelines user guide		http://onlinelibrary.wiley.com/book/10.1002/0470057203

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.

Title	Name	Surname	Role	Organisation
Ms	Judy	Birch	Lay member	
Mr	Jim	Blair	Consultant Nurse Learning Disabilities	St. George's Healthcare NHS Trust

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

Mr	Richard	Brownhill	Unscheduled Care Lead	Stepping Hill Hospital Stockport Foundation Trust
Ms	Joyce	Epstein	Lay member	
Ms	Lynda	Cox	Head of Transformation	NHS North East
Ms	Amanda	Edwards	Deputy Chief Executive	Social Care Institute for Excellence (SCIE)
Professor	David	Haslam	President	British Medical Association
Dr	Bobbie	Jacobson	Director of London Health Observatory, Vice Chair of Association of PH Observatories	London Health Observatory
Dr	Monica	Lakhanpaul	Senior Lecturer / Consultant Paediatrician	Leicester Children's Community Health Service
Miss	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	Donal	O'Donoghue	National Clinical Director for Kidney Care and Consultant Renal Physician	Salford Royal NHS Foundation Trust
Professor	Sandy	Oliver	Professor of Public Policy, Deputy Director	Cochrane Consumers and Communication Review Group, University of London
Dr	Carl	Parker	Primary Care Medical Advisor	North Tees and Hartlepool Foundation Trust
Dr	Karen	Ritchie	Head of Knowledge Management	Healthcare Improvement Scotland
Ms	Sasha	Shepperd	University Research Lecturer	University of Oxford
Ms	Ann	Slee	Director of Pharmacy and Medicines Management	University Hospitals Birmingham NHS Foundation Trust
Dr	Peter	Smith	Vice President	National Association of Primary Care
Ms	Gill	Swash	Head of knowledge and Library Services	NHS Western Cheshire

External advisers for the Duodecim EBM Guidelines, Evidence summaries and EBMeDS accreditation application

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Accreditation team for the Duodecim EBM Guidelines, Evidence summaries and EBMeDS application

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