



RB-DEL.6.7

Training tools #2

**Platform for sharing best
practices for management of
rare diseases**

(RARE-Bestpractices)

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AREAS-CCI

Revision date
26 November 2015

Dissemination level
Public

Reference WP(s)
6-Dissemination

Funding Scheme
Coordination and Support Actions
(COORDINATING)

Grant Agreement
FP7-HEALTH-2012-Innovation-1-305690

Coordinator
Istituto Superiore di Sanità (IT)

Time
01 January 2013 – 31 December 2016



The activities leading to these results has received funding from the European Union Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 305690



Tutorial of AGREE II instrument on guidelines for rare disease. Application on a Guideline

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Training tool



November 2015

Objective of this tutorial

- ❖ To provide a practical example on how the Appraisal of Guidelines for REsearch & Evaluation (AGREE) II Instrument for assessing the quality and the rigour of development process of Clinical Practice Guidelines can be applied to a clinical guideline on a rare disease (www.agreetrust.org)

Target users of this tutorial

- ❖ Health care providers who wish to undertake their own assessment of a guideline before adopting its recommendations into their practice
- ❖ Guideline developers who wish to follow a structured and rigorous development methodology, to conduct an internal assessment to ensure that their guidelines are sound, or to evaluate guidelines from other groups for potential adaptation to their own context
- ❖ Policy makers to help them decide which guidelines could be recommended for use in practice or to inform policy decisions
- ❖ Consumer representatives participating in the Advisory Committees of Regulatory Agencies
- ❖ Educators to help enhance critical appraisal skills amongst health professionals and to teach core competencies in guideline development and reporting

AGREE II (www.agreetrust.org)

- ❖ The AGREE II instrument is a tool that assesses the methodological rigour and transparency by which a guideline is developed.
- ❖ The AGREE II Instrument Manual is: [*Brouwers M, Kho ME, Browman GP, Cluzeau F, feder G, Fervers B, Hanna S, Makarski J on behalf of the AGREE Next Steps Consortium. AGREE II: Advancing guideline development, reporting and evaluation in healthcare. Can Med Assoc J. Dec 2010, 182:E839-842; doi: 10.1503/cmaj.090449*](#)
- ❖ The AGREE II consists of 23 key items organized within 6 domains followed by 2 global rating items (“Overall Assessment”). Each domain captures a unique dimension of guideline quality:
 - ☐ Domain 1. Scope and Purpose (items 1-3)
 - ☐ Domain 2. Stakeholder Involvement (items 4-6)
 - ☐ Domain 3. Rigour of Development (items 7-14)
 - ☐ Domain 4. Clarity of Presentation (items 15-17)
 - ☐ Domain 5. Applicability (items 18-21)
 - ☐ Domain 6. Editorial Independence (items 22-23)
- ❖ The Overall Assessment includes the rating of the overall quality of the guideline and whether the guideline would be recommended for use in practice

AGREE II – Domain rating scale

- ❖ The AGREE II items of the 6 domains are rated on the following 7-point scale:

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
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- ❖ **Score of 1 (Strongly Disagree).** A score of 1 should be given when there is no information that is relevant to the AGREE II item or if the concept is very poorly reported.
- ❖ **Score of 7 (Strongly Agree).** A score of 7 should be given if the quality of reporting is exceptional and where the full criteria and considerations articulated in the User's Manual have been met.
- ❖ **Scores between 2 and 6.** A score between 2 and 6 is assigned when the reporting of the AGREE II item does not meet the full criteria or considerations. A score is assigned depending on the completeness and quality of reporting. Scores increase as more criteria are met and considerations addressed. The “How to Rate” section for each item includes details about assessment criteria and considerations specific to the item.

Methods

- ❖ The Guideline «NICE clinical guideline 105 Motor neurone disease: the use of non-invasive ventilation in the management of motor neurone disease» has been chosen as an example for evaluation
 - Link to the Guideline is: <http://www.nice.org.uk/guidance/cg105>
 - Link to the Appendix:
<http://www.nice.org.uk/guidance/cg105/evidence/appendices-134707502>
 - Link to the tools and resources: <http://www.nice.org.uk/guidance/cg105/resources>
 - Link to the «Developing NICE guidelines: the manual»:
<http://www.nice.org.uk/article/pmg20>
- ❖ Three authors (GF, SM, CDG) independently assessed the guideline using the AGREE II instrument, scored each item and justified the score.
- ❖ Because the scope of this tutorial is to show the best way to apply to AGREE II instrument, the results of the independent assessment were discussed among the authors and an unique final score and comment was reported for each item in the next slides.

Motor neurone disease (MND)

- ❖ MND is a neurodegenerative condition affecting primarily motor neurones in the brain and spinal cord
- ❖ There are several forms of MND:
 - Amyotrophic lateral sclerosis (ALS) which affects about 66% of people with MND
 - Progressive bulbar palsy which occurs in about 25% of people with MND
 - Progressive muscular atrophy, which affects about 10% of people with MND
 - Primary lateral sclerosis, which is very rare
- ❖ MND first manifests itself as one of these forms, but as the disease progresses the clinical condition becomes similar, with increasing muscle weakness in the arms and legs, swallowing, communicating and breathing difficulties

A critical appraisal of:

“NICE clinical guideline 105 Motor neurone disease: the use of non-invasive ventilation in the management of motor neurone disease”

using AGREE II Instrument

Instructions for reading the next slides

- ❖ A slide introducing each AGREE II domain and relative items is present
- ❖ For each item a slide is present and it is reported:
 - Item title
 - Item content and criteria for judgment as suggested in AGREE II (text on the left side of the slide)
 - In the [User's manual instruction for using the AGREE II](#) further details are reported for item judgment (i.e. Where to look, Additional considerations etc.)
 - Collective analysis of the guideline for the specific item performed by the authors: score and justification (text on the right side of the slide in the yellow box)
- ❖ The overall guideline assessment is reported as:
 - Overall quality score of this guideline (range 1=Lowest possible quality to 7=Highest possible quality)
 - Recommendation for using the guideline recommended (Yes, Yes with modifications, No)
- ❖ Total domain scores (expressed as percentage) calculated as suggested in the [User's manual instruction for using the AGREE II](#)

DOMAIN 1: Scope and purpose

Items:

1.1 The overall objective(s) of the guideline is (are) specifically described

1.2 The health question(s) covered by the guideline is (are) specifically described

1.3 The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described

1.1 The overall objective(s) of the guideline is (are) specifically described

SCORE: 6

Item content and criteria by AGREE II

The overall objective(s) of the guideline should be described in detail and the expected health benefits from the guideline should be specific to the clinical problem or health topic.

Criteria:

- ❖ health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.)
- ❖ expected benefit or outcome
- ❖ target(s) (e.g., patient population, society)

Comment

In the introduction of the guideline it is reported:
“This guideline considers the signs and symptoms that can be used for predicting respiratory impairment in patients with MND, the diagnostic accuracy of investigations for detecting and monitoring respiratory impairment, the clinical and cost effectiveness of non-invasive ventilation for treating respiratory impairment and the information and support needs of patients and their families and carers relating to the use of non-invasive ventilation.” (page4)

In the patient-centred care paragraph it is reported:
“This guideline offers best practice advice on the use of non-invasive ventilation in the care of adults (aged 18 and over) with a diagnosis of motor neurone disease (MND).” (pagee. 5)

Further explanation is reported in the [Appendix 9.1](#) of the guideline describing the scope of this guideline.

1.2 The health question(s) covered by the guideline is (are) specifically described

SCORE: 7

Item content and criteria by AGREE II

A detailed description of the health questions covered by the guideline should be provided, particularly for the key recommendations.

Criteria:

- ❖ target population
- ❖ intervention(s) or exposure(s)
- ❖ comparisons (if appropriate)
- ❖ outcome(s)
- ❖ health care setting or context

Comment

In [Appendix 9.1](#) five key clinical questions that the guideline intends to answer are reported.

In [Appendix 9.2](#) for each clinical question a table is provided with information about: review question, objectives, language, study design, status, population and healthcare setting, interventions, comparisons, outcomes, other criteria for inclusion/ exclusion of studies, search and review strategy.

All criteria are met.

1.3 The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described

SCORE: 7

Item content and criteria by AGREE II

A clear description of the population (i.e., patients, public, etc.) covered by a guideline should be provided. The age range, sex, clinical description, and comorbidity may be provided.

Criteria:

- ❖ target population, gender and age
- ❖ clinical condition (if relevant)
- ❖ severity/stage of disease (if relevant)
- ❖ comorbidities (if relevant)
- ❖ excluded populations (if relevant)

Comment

In [Appendix 9.1](#) the target population is described: “a) Adults (aged 18 and over) with a diagnosis of MND, b) The guideline will specifically consider the assessment of respiratory function and response to NIV in people with MND who have moderate or severe bulbar impairment, c) The guideline will also specifically consider assessment of respiratory impairment in people with MND who have severe cognitive impairment or dementia.” (pagee. 6)

The groups of patients that will not be covered by the guideline are also reported.

The healthcare setting to which guideline’s recommendation apply are: primary care and community settings, secondary care and tertiary care.

The epidemiology and the current practice of the MND are reported in [Appendix 9.1](#).

All criteria are met.



DOMAIN 2: Stakeholder involvement

Items:

2.1 The guideline development group includes individuals from all relevant professional groups

2.2 The views and preferences of the target population (patients, public, etc.) have been sought

2.3 The target users of the guideline are clearly defined

2.1 The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described

SCORE: 5

Item content and criteria by AGREE II

The guideline development group includes individuals from all relevant professional groups.

Criteria:

For each member of the guideline development group, the following information is included:

- ❖ name
- ❖ discipline/content expertise (e.g. internal medicine, methodologist)
- ❖ institution (e.g., St. Peter's hospital)
- ❖ geographical location (e.g., Seattle, WA)
- ❖ a description of the member's role in the guideline development group

Comment

The list of authors is included with name, discipline, institution and geographical location. Sixteen persons form the guideline development group.

The description of the role in the guideline production, the institution and geographical location is not explicit for any member.

2.2 The views and preferences of the target population (patients, public, etc.) have been sought

SCORE: 4

Item content and criteria by AGREE II

Information about target population experiences and expectations of health care should inform the development of guidelines.

Criteria:

- ❖ statement of type of strategy used to capture patients'/public's' views and preferences (e.g., participation in the guideline development group, literature review of values and preferences)
- ❖ methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups)
- ❖ outcomes/information gathered on patient/public information
- ❖ description of how the information gathered was used to inform the guideline development process and/or formation of the recommendations

Comment

In the guideline development group there are four patients or carer members.

Nothing is reported about the specific contribution of patients and carer members in the GDG and how the information gathered from them were used to inform the guideline development process and/or formulation of the recommendations.

2.3 The target users of the guideline are clearly defined

SCORE: 7

Item content and criteria by AGREE II

The target users should be clearly defined in the guideline, so the reader can immediately determine if the guideline is relevant to them.

Criteria:

- ❖ clear description of intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators)
- ❖ description of how the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)

Comment

In the guideline it is reported that *“the document is intended to be relevant to healthcare professionals who care for people with MND.”* (page. 22)

How the guideline may be used by the target audience is reported in the following sentence: *“The guideline considers the signs and symptoms that can be used for predicting respiratory impairment in patients with MND, the diagnostic accuracy of investigations for detecting and monitoring respiratory impairment, the clinical and cost effectiveness of non-invasive ventilation for treating respiratory impairment and the information and support needs of patients and their families and carers relating to the use of non-invasive ventilation.”* (page. 4)

All criteria are met.

DOMAIN 3: Rigour of development

Items:

- 3.1 Systematic methods were used to search for evidence
- 3.2 The criteria for selecting the evidence are clearly described
- 3.3 The strengths and limitations of the body of evidence are clearly described
- 3.4 The methods for formulating the recommendations are clearly described
- 3.5 The health benefits, side effects, and risks have been considered in formulating the recommendations
- 3.6 There is an explicit link between the recommendations and the supporting evidence
- 3.7 The guideline has been externally reviewed by experts prior to its publication
- 3.8 A procedure for updating the guideline is provided

3.1 Systematic methods were used to search for evidence

SCORE: 7

Item content and criteria by AGREE II

Details of the strategy used to search for evidence should be provided including search terms used, sources consulted, and dates of the literature covered.

Criteria:

- ❖ named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL)
- ❖ time periods searched (e.g., January 1, 2004 to March 31, 2008)
- ❖ search terms used (e.g., text words, indexing terms, subheadings)
- ❖ full search strategy included (e.g., possibly located in appendix)

Comment

Literature searches were undertaken in June 2009.

Detailed description of databases searches, search terms used, full search strategies are provided in [Appendix 9.5](#).

All criteria are met.

3.2 The criteria for selecting the evidence are clearly described

SCORE: 7

Item content and criteria by AGREE II

Criteria for including/excluding evidence identified by the search should be provided.

Criteria:

- ❖ description of the inclusion criteria, including
 - target population (patient, public, etc.) characteristics
 - study design
 - comparisons (if relevant)
 - outcomes
 - language (if relevant)
 - context (if relevant)
- ❖ description of the exclusion criteria (if relevant)

Comment

For each clinical question inclusion and exclusion criteria (including patients, intervention, comparators, outcomes, study design, language and publication status) are clearly reported in the [Appendix 9.2](#).

All criteria are met.

3.3 The strengths and limitations of the body of evidence are clearly described

SCORE: 7

Item content and criteria by AGREE II

Statements highlighting the strengths and limitations of the evidence should be provided.

Criteria:

- ❖ descriptions of how the body of evidence was evaluated for bias and how it was interpreted by members of the guideline development group
- ❖ aspects upon which to frame descriptions include:
 - study design(s) included in body of evidence
 - study methodology limitations
 - appropriateness/relevance of primary and secondary , outcomes considered
 - consistency of results across studies
 - direction of results across studies
 - magnitude of benefit versus magnitude of harm applicability to practice context

Comment

For each clinical question GRADE* profiles are provided for relevant outcomes.

All criteria are met.

**The GRADE approach is a systematic and explicit approach to grading the quality of evidence and the strength of recommendations.
(<http://www.gradeworkinggroup.org/>)*

3.4 The methods for formulating the recommendations are clearly described

SCORE: 4

Item content and criteria by AGREE II

A description of the methods used to formulate the recommendations and how final decisions were arrived at should be provided.

Criteria:

- ❖ description of the recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered)
- ❖ outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures)
- ❖ description of how the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)

Comment

In the guideline it is reported that: *“For a full explanation of how this type of guideline is developed, see ‘The guidelines manual’ (2009) at www.nice.org.uk/GuidelinesManual.”* (pagee. 22)

In the "Developing NICE guidelines: the manual" it is stated that the GRADE approach was used.

Only generic statement that the GRADE approach was used is reported; no clear description of the recommendation development process and of its results.

3.5 The health benefits, side effects, and risks have been considered in formulating the recommendations

SCORE: 5

Item content and criteria by AGREE II

The guideline should consider health benefits, side effects, and risks when formulating the recommendations.

Criteria:

- ❖ supporting data and report of benefits
- ❖ supporting data and report of harms/side effects/risks
- ❖ reporting of the balance/trade-off between benefits and harms/side effects/risks
- ❖ recommendations reflect considerations of both benefits and harms/side effects/risks

Comment

Harm/risks/side effects of treatment and diagnostic procedures have not been fully considered.

The balance /trade –off between benefits and harms/side effects/risk have not been reported as a basis for formulating recommendations.

3.6 There is an explicit link between the recommendations and the supporting evidence

SCORE: 5

Item content and criteria by AGREE II

An explicit link between the recommendations and the evidence on which they are based should be included in the guideline.

Criteria:

- ❖ the guideline describes how the guideline development group linked and used the evidence to inform recommendations
- ❖ each recommendation is linked to a key evidence description/paragraph and/or reference list
- ❖ recommendations linked to evidence summaries, evidence tables in the results section of the guideline

Comment

The GRADE profile is provided for each recommendation in the guideline, evidence tables are provided in [Appendix 9.6](#).

In the "Developing NICE guidelines: the manual" it is reported that: "*NICE uses 'offer' (or similar wording such as 'measure', 'advise', 'commission' or 'refer') to reflect a strong recommendation, usually where there is clear evidence of benefit. NICE uses 'consider' to reflect a recommendation for which the evidence of benefit is less certain.*" (page 177)

The guideline does not describe how the guideline development group linked and used the evidence to inform recommendations.

3.7 The guideline has been externally reviewed by experts prior to its publication

SCORE: 6

Item content and criteria by AGREE II

A guideline should be reviewed externally before it is published.

Criteria:

- ❖ purpose and intent of the external review (e.g., to improve quality, disseminate evidence)
- ❖ methods taken to undertake the external review (e.g., rating scale, open-ended questions)
- ❖ description of the external reviewers (e.g., number, type of reviewers, affiliations)
- ❖ outcomes/information gathered from the external review (e.g., summary of key findings)
- ❖ description of how the information gathered was used to inform the guideline development process and/or formation of the recommendations

Comment

In the "Developing NICE guidelines: the manual" it is reported that: *"The draft version of the guideline is posted on the NICE website for consultation with registered stakeholders. Stakeholders can register at any point during guideline development. NICE informs registered stakeholders that the draft is available and invites them to comment by the deadline. Consultation usually lasts for 6 weeks."* (page 192)

In the guideline it is reported that: *"The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry."* (page 126)

3.8 A procedure for updating the guideline is provided

SCORE: 7

Item content and criteria by AGREE II

Guidelines need to reflect current research. A clear statement about the procedure for updating the guideline should be provided.

Criteria:

- ❖ a statement that the guideline will be updated
- ❖ explicit time interval or explicit criteria to guide decisions about when an update will occur
- ❖ methodology for the updating procedure is reported

Comment

In the guideline it is reported that: “*NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations*”. (page 99)

All the criteria are met.

DOMAIN 4: Clarity of presentation

Items:

4.1 The recommendations are specific and unambiguous

4.2 The different options for management of the condition or health issue are clearly presented

4.3 Key recommendations are easily identifiable

4.1 The recommendations are specific and unambiguous

SCORE: 6

Item content and criteria by AGREE II

A recommendation should provide a concrete and precise description of which option is appropriate in which situation and in what population group, as informed by the body of evidence.

If evidence is not clear cut in the and there is uncertainty about the best care option(s), this should be stated in the guideline.

Criteria:

- ❖ statement of the recommended action
- ❖ identification of the intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects)
- ❖ identification of the relevant population (e.g., patients, public)
- ❖ caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply)

Comment

The guideline includes a list of recommendations that are specific and clearly described. Example: *“As part of the initial assessment to diagnose MND, or soon after diagnosis, a healthcare professional from the multidisciplinary team who has appropriate competencies should perform the following tests (or arrange for them to be performed) to establish the patient’s baseline respiratory function:*

- *oxygen saturation measured by pulse oximetry (SpO₂):*
 - *this should be a single measurement of SpO₂ with the patient at rest and breathing room air,*
 - *if it is not possible to perform pulse oximetry locally, refer the patient to a specialist respiratory service*

then one or both of the following:

- *forced vital capacity (FVC) or vital capacity (VC)*
- *sniff nasal inspiratory pressure (SNIP) and/or maximal inspiratory pressure (MIP).” (page 10)*

Statement of the recommendation action, its intent or purpose, caveats or qualifying statements, specific modality to implement the recommendation are clearly provided.

4.2 The different options for management of the condition or health issue are clearly presented

SCORE: 5

Item content and criteria by AGREE II

A guideline that targets the management of a disease should consider the different possible options for screening, prevention, diagnosis or treatment of the condition it covers. These possible options should be clearly presented in the guideline.

Criteria:

- ❖ description of options
- ❖ description of population or clinical situation most appropriate to each option

Comment

The guideline focuses on non-invasive ventilation as a treatment option for patients with motor neuron disease and respiratory impairment. Palliative strategies are an alternative to non-invasive ventilation and the guideline refers to this alternative.

Palliative strategies are not detailed in the guideline but link to the specific guideline is provided (see 'Improving supportive and palliative care for adults with cancer'. NICE guidance on cancer services (2004); available from www.nice.org.uk/csgsp)

4.3 Key recommendations are easily identifiable

SCORE: 7

Item content and criteria by AGREE II

Users should be able to find the most relevant recommendations easily.

Criteria:

- ❖ description of recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms
- ❖ specific recommendations are grouped together in one section

Comment

Recommendations are summarized in one section at the beginning of the guideline.

Care pathways for the assessment of respiratory function and for non-invasive ventilation are reproduced as flow charts from the quick reference guide for the guideline.

All the criteria are met.

DOMAIN 5: Applicability

Items:

5.1 The guideline describes facilitators and barriers to its application

5.2 The guideline provides advice and/or tools on how the recommendations can be put into practice

5.3 The potential resource implications of applying the recommendations have been considered

5.4 The guideline presents monitoring and/or auditing criteria

5.1 The guideline describes facilitators and barriers to its application

SCORE: 4

Item content and criteria by AGREE II

There may be existing facilitators and barriers that will impact the application of guideline recommendations.

Criteria:

- ❖ identification of the types of facilitators and barriers that were considered
- ❖ methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation)
- ❖ information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography)
- ❖ description of how the information influenced the guideline development process and/or formation of the recommendations

Comment

Guideline recommends that care should be coordinated through a multidisciplinary team that provides ongoing management and treatment for a patient with MND, including regular respiratory assessment and provision of non-invasive ventilation.

Strategies for dissemination and local implementation are reported in the tools that accompany the guideline ([Tools and resources](#)).

Specific types of facilitators and barriers are not detailed in the guidelines or tools.

5.2 The guideline provides advice and/or tools on how the recommendations can be put into practice

SCORE: 6

Item content and criteria by AGREE II

For a guideline to be effective it needs to be disseminated and implemented with additional materials.

Criteria:

- ❖ an implementation section in the guideline
- ❖ tools and resources to facilitate application:
 - guideline summary documents
 - links to check lists, algorithms
 - links to how-to manuals
 - solutions linked to barrier analysis
 - tools to capitalize on guideline facilitators
 - outcome of pilot test and lessons learned
- ❖ directions on how users can access tools and resources

Comment

Several tools and resources ([Tools and resources](#)) accompany the guideline including a summary document, a quick reference guide, and educational tools and resources (baseline assessment, audit support, shared learning, slide set).

Implementation of the recommendations into practice is limited by the fact that barriers and facilitators are not detailed.

5.3 The potential resource implications of applying the recommendations have been considered

SCORE: 7

Item content and criteria by AGREE II

The recommendations may require additional resources in order to be applied. There should be a discussion in the guideline of the potential impact of the recommendations on resources.

Criteria:

- ❖ identification of the types of cost information that were considered (e.g., economic evaluations, drug acquisition costs)
- ❖ methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.)
- ❖ information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course)
- ❖ description of how the information gathered was used to inform the guideline development process and/or formation of the recommendations resources

Comment

A cost effectiveness analysis has been performed and results clearly reported. A costing report and a costing template accompany the guideline ([Tools and resources](#)).

All the criteria are met.

5.4 The guideline presents monitoring and/or auditing criteria

SCORE: 6

Item content and criteria by AGREE II

Measuring the application of guideline recommendations can facilitate their ongoing use. This requires clearly defined criteria that are derived from the key recommendations in the guideline.

Criteria:

- ❖ identification of criteria to assess guideline implementation or adherence to recommendations
- ❖ criteria for assessing impact of implementing the recommendations
- ❖ advice on the frequency and interval of measurement
- ❖ descriptions or operational definitions of how the criteria should be measured.

Comment

Frequency and interval of measurement, operational definitions and clinical/health outcomes to be measured, are reported as a measure of the correct application of the recommendation. An audit support accompany the guideline ([Tools and resources](#)).

Most of the criteria are met but criteria needed to assess guideline implementation or adherence to recommendations are not detailed.

DOMAIN 6: Editorial Independence

Items:

6.1 The views of the funding body have not influenced the content of the guideline

6.2 Competing interests of guideline development group members have been recorded and addressed

6.1 The views of the funding body have not influenced the content of the guideline

SCORE: 6

Item content and criteria by AGREE II

Many guidelines are developed with external funding (e.g., government, professional associations, charity organizations, pharmaceutical companies).

Criteria:

- ❖ the name of the funding body or source of funding (or explicit statement of no funding)
- ❖ a statement that the funding body did not influence the content of the guideline

Comment

In the "Developing NICE guidelines: the manual" it is reported that: *"The National Institute for Health and Care Excellence (NICE) is an independent public body that provides national guidance and advice to improve health and social care in England."* (page 11)

This guideline was produced by NICE for the National Health System (NHS). We think that probably the NHS has not influenced the content of the guideline.

6.2 Competing interests of guideline development group members have been recorded and addressed

SCORE: 5

Item content and criteria by AGREE II

There are circumstances when members of the development group may have competing interests.

Criteria:

- ❖ description of the types of competing interests considered
- ❖ methods by which potential competing interests were sought
- ❖ description of the competing interests
- ❖ description of how the competing interests influenced the guideline process and development of recommendations

Comment

In the guideline it is reported that: “A full list of all declarations of interest made by this Guideline Development Group is available on the NICE website (www.nice.org.uk)” (page 127) however we were not able to find that list in the website.

Overall guideline assessment

Items:

1. Rate the overall quality of this guideline (range 1=Lowest possible quality to 7=Highest possible quality)
2. I would recommend this guideline for use (Yes, Yes with modifications, No)

Overall Assessment

- ❖ Overall quality rate of this guideline: **6/7**
- ❖ Guideline recommended for use? **Yes**

Total domain scores

- ❖ Total domain scores are calculated as suggested in the [User's manual instruction for using the AGREE II](#)
- ❖ For each domain the total score is expressed as a percentage of the maximum possible:

DOMAIN	Total %
1. Scope and Purpose	94%
2. Stakeholder Involvement	72%
3. Rigour of Development	83%
4. Clarity of Presentation	83%
5. Applicability	79%
6. Editorial Independence	75%

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Acknowledgement

The tutorial was developed in the framework of the task 6.4 training tools preparation and dissemination (leader Graziella Filippini, Associazione sulla Efficacia della Assistenza Sanitaria-Centro Cochrane Italiano) in the framework of the work package 6 dissemination (leader Cristina Morciano, Istituto Superiore di Sanità) of the RARE-Bestpractices project (leader Domenica Taruscio, Istituto Superiore di Sanità) (www.rarebestpractices.eu)

The training tool has been uploaded in the “Training tools” webpages of the RARE-Bestpractices website (<http://www.rarebestpractices.eu/tutorials>).

The research leading to these results has received funding from the European Union Seventh Framework Programme (FP7/2007-2011) under grant agreement n° 305690

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