APPRAISAL OF GUIDELINES FOR RESEARCH & EVALUATION II

AGREE II

INSTRUMENT

The AGREE Next Steps Consortium

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FOR FURTHER INFORMATION ABOUT THE AGREE II, PLEASE CONTACT
AGREE Project Office, agree@mcmaster.ca
AGREE Website, www.agreetrust.org

AGREE NEXT STEPS CONSORTIUM MEMBERSHIP

Dr. Melissa C. Brouwers
Principal Investigator, AGREE Next Steps Consortium
McMaster University, Hamilton, Ontario, Canada

Consortium Members:
Dr. G.P. Browman, Victoria, British Columbia, Canada
Dr. J.S. Burgers, Dutch College of General Practitioners, Utrecht, The Netherlands
Dr. F. Cluzeau, Global Health and Development Group, Imperial College London, UK
Dr. D. Davis, Association of American Medical Colleges, Washington DC, USA
Dr. G. Feder, University of Bristol, UK
Dr. B. Fervers, Cancer et Environement, Centre Léon Bérard, France
Dr. I. Graham, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada
Dr. J. Grimshaw, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada
Dr. S.E. Hanna, McMaster University, Hamilton, Ontario, Canada
Ms. M.E. Kho, McMaster University, Hamilton, Ontario Canada
Dr. P. Littlejohns, Kings College London, UK
Ms. J. Makarski, Hamilton, Ontario, Canada
Dr. L. Zitzelsberger, Quebec, Canada

AGREE II VERSIONS & UPDATES

AGREE II Original Public Release and Publication Date: 2009/2010
AGREE II Update: September 2013
AGREE II Update: December 2017

What's new in the December 2017 update?

The August 2017 update includes revisions to the following sections of the Introduction: 'AGREE Website: Resources and References', '10 Years of AGREE', and 'Scoring the AGREE II'. Guidance has been added regarding the use of AGREE II score thresholds to distinguish between higher and lower quality guidelines. In addition, minor editorial changes have been made throughout the Introduction and User's Manual. The content of the AGREE II Instrument itself has not been modified since 2009 and all versions of the AGREE II remain valid for use.

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I. INTRODUCTION

I. OVERVIEW

i) Purpose of the AGREE II Instrument

Clinical practice guidelines ('guidelines') are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances (1). In addition, guidelines can play an important role in health policy formation (2,3) and have evolved to cover topics across the health care continuum (e.g., health promotion, screening, diagnosis).

The potential benefits of guidelines are only as good as the quality of the guidelines themselves. Appropriate methodologies and rigorous strategies in the guideline development process are important for the successful implementation of the resulting recommendations (4-6). The quality of guidelines can be extremely variable and some often fall short of basic standards (7-9).

The ***A****ppraisal of* ***G****uidelines for* ***RE****search &* ***E****valuation (AGREE) Instrument* (10) was developed to address the issue of variability in guideline quality. To that end, the AGREE instrument is a tool that assesses the methodological rigour and transparency in which a guideline is developed. The original AGREE instrument was refined, which resulted in the AGREE II, and a User's Manual was developed (11-13).

The purpose of the AGREE II, is to provide a framework to:

1. Assess the quality of guidelines;
2. Provide a methodological strategy for the development of guidelines; and
3. Inform what information and how information ought to be reported in guidelines.

The AGREE II replaces the original instrument as the preferred tool and can be used as part of an overall quality mandate aimed to improve health care.

ii) History of the AGREE Project

The original AGREE Instrument was published in 2003 by a group of international guideline developers and researchers, the AGREE Collaboration (10). The objective of the Collaboration was to develop a tool to assess the quality of guidelines. The AGREE Collaboration defined quality of guidelines *as the confidence that the potential biases of guideline development have been addressed adequately and that the recommendations are both internally and externally valid, and are feasible for practice* (10). The assessment includes judgments about the methods used for developing the guidelines, the components of the final recommendations, and the factors that are linked to their uptake. The result of the Collaboration's effort was the original AGREE Instrument, a 23-item tool comprising 6 quality domains. The AGREE Instrument has been translated into many languages, has been cited in over 600 publications, and is endorsed by several health care organizations. More details about the original instrument and related publications are available on the AGREE Website (http://www.agreetrust.org/).

As with any new assessment tool, it was recognized that ongoing development was required to strengthen the measurement properties of the instrument and to ensure its usability and feasibility among intended users. This led several members of the original team to form the

AGREE Next Steps Consortium (Consortium). The objectives of the Consortium were to further improve the measurement properties of the instrument, including its reliability and validity; to refine the instrument's items to better meet the needs of the intended users; and to improve the supporting documentation (i.e., original training manual and user's guide) to facilitate the ability of users to implement the instrument with confidence.

The result of these efforts is the AGREE II, which is comprised of the new User's Manual and 23 item tool organized into the same six domains, described here. The User's Manual is a significant modification of the original training manual and user's guide and provides explicit information for each of the 23 items. Table 1 compares the items of the original AGREE to the items in the AGREE II.

Table 1. Comparison of the original AGREE and AGREE II items.

Original AGREE Item	AGREE II Item
Domain 1. Scope and Purpose	
1. The overall objective(s) of the guideline is (are) specifically described.	No change
2. The clinical question(s) covered by the guideline is (are) specifically described.	The health question(s) covered by the guideline is (are) specifically described.
3. The patients to whom the guideline is meant to apply are specifically described.	The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.
Domain 2. Stakeholder Involvement	
4. The guideline development group includes individuals from all the relevant professional groups.	No change
5. The patients' views and preferences have been sought.	The views and preferences of the target population (patients, public, etc.) have been sought.
6. The target users of the guideline are clearly defined.	No change
7. The guideline has been piloted among end users.	Delete item. Incorporated into user guide description of item 19.
Domain 3. Rigour of Development	
8. Systematic methods were used to search for evidence.	No change in item. Renumbered to 7.
9. The criteria for selecting the evidence are clearly described.	No change in item. Renumbered to 8.
	NEW Item 9. The strengths and limitations of the body of evidence are clearly described.
10. The methods for formulating the recommendations are clearly described.	No change
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	No change
12. There is an explicit link between the recommendations and the supporting evidence.	No change
13. The guideline has been externally reviewed by experts	No change

Original AGREE Item	AGREE II Item
prior to its publication.	
14. A procedure for updating the guideline is provided.	No change
Domain 4. Clarity of Presentation	
15. The recommendations are specific and unambiguous.	No change
16. The different options for management of the condition are clearly presented.	The different options for management of the condition or health issue are clearly presented.
17. Key recommendations are easily identifiable.	No change
Domain 5. Applicability	
18. The guideline is supported with tools for application.	The guideline provides advice and/or tools on how the recommendations can be put into practice. AND Change in domain (from Clarity of Presentation) AND renumbered to 19
19. The potential organizational barriers in applying the recommendations have been discussed.	The guideline describes facilitators and barriers to its application. AND change in order – renumbered to 18
20. The potential cost implications of applying the recommendations have been considered.	The potential resource implications of applying the recommendations have been considered.
21. The guideline presents key review criteria for monitoring and/ or audit purposes.	The guideline presents monitoring and/ or auditing criteria.
Domain 6. Editorial Independence	
22. The guideline is editorially independent from the funding body.	The views of the funding body have not influenced the content of the guideline.
23. Conflicts of interest of guideline development members have been recorded.	Competing interests of guideline development group members have been recorded and addressed.

II. APPLYING THE AGREE II

i) Which guidelines can be appraised with the AGREE II?

As with the original instrument, the AGREE II is designed to assess guidelines developed by local, regional, national or international groups or affiliated governmental organizations. These include original versions of and updates of existing guidelines.

The AGREE II is generic and can be applied to guidelines in any health or disease area targeting any step in the health care continuum, including those for health promotion, public health, screening, diagnosis, treatment or interventions. It is suitable for guidelines presented in paper or electronic format. The AGREE II has not been designed to assess the quality of guidance documents that address health care organizational issues. Its role in the assessment of health technology assessments has not been formally evaluated.

ii) Who can use the AGREE II?

The AGREE II is intended to be used by the following stakeholder groups:

- by **health care providers** who wish to undertake their own assessment of a guideline before adopting its recommendations into their practice;
- by **guideline developers** 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;
- by **policy makers** to help them decide which guidelines could be recommended for use in practice or to inform policy decisions; and
- by **educators** to help enhance critical appraisal skills amongst health professionals and to teach core competencies in guideline development and reporting.

III. AGREE WEBSITE: RESOURCES AND REFERENCES

The AGREE Enterprise website, www.agreetrust.org, contains a variety of tools to assist users in applying the AGREE II.

i) Publications of AGREE Research

- Access publications related to the AGREE II and other AGREE tools.
- The ***Key publications: AGREE II*** page provides access to publications related to the development and testing of the AGREE II.

ii) AGREE II Training Tools

- Two online tools are available to train new users of the AGREE II:
  - AGREE II Overview Tutorial,
  - AGREE II Practice Exercise.

iii) AGREE II Language Translations

- The AGREE II has been translated into various languages, thanks to members of the international practice guideline community.
- Copies of these translations are available to the public on this webpage.
- If you would like to undertake a new translation, please contact the AGREE Project Office by emailing agree@mcmaster.ca.

iv) My AGREE PLUS

- An online platform called My AGREE PLUS is freely available to the public to complete and track AGREE II appraisals.
- The platform can be used to:
  - Complete individual AGREE II appraisals,
  - Contribute to a group AGREE II appraisal, and
  - Coordinate a group AGREE II appraisal.
- Click the ***My AGREE PLUS*** tab at www.agreetrust.org to register and use the platform.

v) Other AGREE tools

- Access other AGREE tools to support the development, reporting and appraisal of clinical practice guidelines and health systems guidance:
  - **AGREE Reporting Checklist:** A checklist based on the AGREE II to guide the reporting of clinical practice guidelines (14).
  - **AGREE GRS:** A 4-item tool to assess the quality of clinical practice guidelines when scarce time or resources make it unfeasible to use the more comprehensive AGREE II.
  - **AGREE Recommendations Excellence (AGREE-REX)**: A tool to assess the quality and direct the development and reporting of clinical practice guideline recommendations.
  - **AGREE Health Systems (AGREE-HS)**: A tool to assess the quality and direct the development and reporting of health systems guidance documents.
  - **CheckUp**: A checklist to guide the reporting of updated clinical practice guidelines (15).

IV. 10 Years of AGREE

In 2013, the AGREE Enterprise marked its 10th anniversary since the original AGREE Instrument was first published and made available for use. To mark this anniversary, an article was published summarizing the academic journey the AGREE instrument has taken, noting the many accomplishments along the way (16).

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AGREE II:

USER'S MANUAL

II. USER'S MANUAL: INSTRUCTIONS FOR USING THE AGREE II

This User's Manual has been designed specifically to guide appraisers in the use of the instrument. We suggest reading the following instructions before using the instrument.

I. Preparing to Use the AGREE II

i) Accompanying Guideline Documents

Before applying the AGREE II, users should first carefully read the guideline document in full. In addition to the guideline document, users should attempt to identify all information about the guideline development process prior to the appraisal. This information may be contained in the same document as the guideline recommendations or it may be summarized in a separate technical report, methodological manual or guideline developer policy statement. These supporting documents may be published or may be available publicly on web sites. While it is the responsibility of the guideline authors to advise readers on the existence and location of relevant additional technical and supporting documents, every effort should be made by the AGREE II users to locate and include them as part of the materials appropriate for assessment.

ii) Number of Appraisers

We recommend that each guideline be assessed by at least 2 appraisers, and preferably 4, as this will increase the reliability of the assessment.

II. Structure and Content of the AGREE II

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 is concerned with the overall aim of the guideline, the specific health questions, and the target population (items 1-3).

Domain 2. Stakeholder Involvement focuses on the extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended users (items 4-6).

Domain 3. Rigour of Development relates to the process used to gather and synthesize the evidence, the methods to formulate the recommendations, and to update them (items 7-14).

Domain 4. Clarity of Presentation deals with the language, structure, and format of the guideline (items 15-17).

Domain 5. Applicability pertains to the likely barriers and facilitators to implementation, strategies to improve uptake, and resource implications of applying the guideline (items 18-21).

Domain 6. Editorial Independence is concerned with the formulation of recommendations not being unduly biased with competing interests (items 22-23).

Overall assessment includes the rating of the overall quality of the guideline and whether the guideline would be recommended for use in practice.

III. Rating Scale and User's Manual Sections

Each of the AGREE II items and the two global rating items are rated on a 7-point scale (1–strongly disagree to 7–strongly agree). The User's Manual provides guidance on how to rate each item using the rating scale and also includes 3 additional sections to further facilitate the user's assessment. The sections include User's Manual Description, Where to Look, and How to Rate.

i) Rating Scale

All AGREE II items are rated on the following 7-point scale:

1 Strongly Disagree	**2**	**3**	**4**	**5**	**6**	**7** Strongly Agree

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, if the concept is very poorly reported, or if the authors state explicitly that criteria were not met.

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.

ii) User's Manual Description

This section defines the concept underlying the item in broad terms and provides examples.

iii) Where to Look

This section directs the appraiser to where the information in the guideline can usually be found. Included in this section are common terms used to label guideline sections or chapters. *These are suggestions only*. It is the responsibility of the appraiser to review the entire guideline and accompanying material(s) to ensure a fair evaluation.

iv) How to Rate

This section includes details about assessment criteria and considerations specific to each item.

- The *criteria* identify explicit elements that reflect the operational definition of the item. The more criteria that are met, the higher the score the guideline should receive on that item.
- The *considerations* are aimed to help inform the assessment. As in any evaluation, judgments by the appraisers are required. The more the considerations have been taken into account in the guideline, the higher the score the guideline should receive on that item.

It is important to note that guideline ratings require a level of judgment. The criteria and considerations are there to guide, not to replace, these judgments. Thus, none of the AGREE II items provide explicit expectations for each of the 7 points on the scale.

v) Other Considerations when Applying the AGREE II

On occasion, some AGREE II items may not be applicable to the particular guideline under review. For example, guidelines narrow in scope may not provide the full range of options for the management of the condition (see item 16). The AGREE II does not include a "*Not Applicable"* response item in its scale. There are different strategies to manage this situation including having appraisers skip that item in the assessment process or rating the item as 1 (absence of information) and providing context about the score. *Regardless of strategy chosen, decisions should be made in advance, described in an explicit manner, and if items are skipped, appropriate modifications to calculating the domain scores should be implemented. As a principle, excluding items in the appraisal process is discouraged.*

IV. Scoring the AGREE II

A quality score is calculated for each of the six AGREE II domains. The six domain scores are independent and should not be aggregated into a single quality score.

i) Calculating Domain Scores

Domain scores are calculated by summing up all the scores of the individual items in a domain and by scaling the total as a percentage of the maximum possible score for that domain.

Example:

If 4 appraisers give the following scores for Domain 1 (Scope & Purpose):

	Item 1	Item 2	Item 3	**Total**
Appraiser 1	5	6	6	**17**
Appraiser 2	6	6	7	**19**
Appraiser 3	2	4	3	**9**
Appraiser 4	3	3	2	**8**
Total	**16**	**19**	**18**	**53**

Maximum possible score = 7 (strongly agree) x 3 (items) x 4 (appraisers) = 84
Minimum possible score = 1 (strongly disagree) x 3 (items) x 4 (appraisers) = 12

The scaled domain score will be:

$$\frac{\text{Obtained score} - \text{Minimum possible score}}{\text{Maximum possible score} - \text{Minimum possible score}}$$

$$\frac{53 - 12}{84 - 12} \times 100 = \frac{41}{72} \times 100 = 0.5694 \times 100 = 57\ \%$$

If items are not included, appropriate modifications to the calculations of maximum and minimum possible scores are required.

ii) Interpreting Domain Scores

Domain scores can be used to identify strengths and limitations of guidelines, to compare methodological quality between guidelines, or to select high quality guidelines for adaptation, endorsement, or implementation. At present, there are no empirical data to link specific quality scores with specific implementation outcomes (e.g., speed of adoption, spread of adoption) or specific clinical outcomes; this makes selection of quality thresholds to differentiate between high, moderate, and low quality guidelines a challenge. In the absence of these data, we provide examples of approaches that can be used to set quality thresholds:

- Prioritizing one domain: Through consensus or based on decisions by leadership, one quality domain may be prioritized over the others. Thus, thresholds can be created based on scores for the prioritized domain (e.g., high quality guidelines are those with a Domain 3 score >70%).
- Staged AGREE II appraisal: If users value one domain over the others, they can first appraise the guidelines using that domain only. Only those guidelines that meet a quality threshold for that domain (e.g., >70%) are then appraised using the other five AGREE II domains.
- Considering all domain scores: Users can create a threshold across all six domain scores based on consensus or decisions by leadership (e.g., high quality guidelines are those with domain scores that are all >70%). Alternatively, users might create different thresholds for each of the domains.
- Thresholds for improvement over time: If evaluating changes in scores for guidelines over time, users can create thresholds for improvement (e.g., at least 10% improvement in each domain score for guidelines by a particular developer over a period of five years).

Any decisions about how to define quality thresholds should be made by a panel of all relevant stakeholders before beginning the AGREE II appraisals. Decisions should be guided by the context in which the guideline is to be used and by evaluating the importance of the different domains and items in that context.

V. Overall Assessment

Upon completing the 23 items, AGREE II users will provide 2 overall assessments of the guideline. The overall assessment requires the user to make a judgment as to the quality of the guideline, taking into account the criteria considered in the assessment process. The user is also asked whether he/she would recommend use of the guideline.

The next pages include, by domain, guidance for rating each of the 23 items of the AGREE II when appraising a guideline. Each item includes a description, suggestions for where to find the item information, and guidance for how to rate.

DOMAIN 1. SCOPE AND PURPOSE

1. The overall objective(s) of the guideline is (are) specifically described.
2. The health question(s) covered by the guideline is (are) specifically described.
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

SCOPE AND PURPOSE

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

This deals with the potential health impact of a guideline on society and populations of patients or individuals. 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. For example, specific statements would be:

- Preventing (long term) complications of patients with diabetes mellitus
- Lowering the risk of subsequent vascular events in patients with previous myocardial infarction
- Most effective population-based colorectal screening strategies
- Providing guidance on the most effective therapeutic treatment and management of patients with diabetes mellitus.

Where to Look:

Examine the opening paragraphs/chapters for a description of the scope and purpose of the guideline. In some cases, the rationale or need for the guideline is described in a document separate from the guideline, for instance, in the guideline proposal. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: introduction, scope, purpose, rationale, background, and objectives.

How to Rate:

Item content includes the following *CRITERIA:*

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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?

SCOPE AND PURPOSE

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

A detailed description of the health questions covered by the guideline should be provided, particularly for the key recommendations (see Item 17), although they need not be phrased as questions. Following the examples provided in question 1:

- How many times a year should the HbA1c be measured in patients with diabetes mellitus?
- What should the daily aspirin dosage for patients with proven acute myocardial infarction be?
- Does population-based colorectal screening using the fecal occult blood test reduce mortality of colorectal cancer?
- Is self-monitoring effective for blood glucose control in patients with Type 2 diabetes?

Where to Look:

Examine the opening paragraphs/chapters for a description of the scope and purpose of the guideline. In some cases, the questions are described in a document separate from the guideline, for instance in a search specification. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: questions, scope, purpose, rationale, and background.

How to Rate:

Item content includes the following *CRITERIA:*

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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Is there enough information provided in the question(s) for anyone to initiate the development of a guideline on this topic or to understand the patients/populations and contexts profiled in the guideline?

SCOPE AND PURPOSE

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

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. For example:

- A guideline on the management of diabetes mellitus only includes patients with non-insulin dependent diabetes mellitus and excludes patients with cardiovascular comorbidity.
- A guideline on the management of depression only includes patients with major depression according to the DSM-IV criteria, and excludes patients with psychotic symptoms and children.
- A guideline on screening of breast cancer only includes women, aged between 50 and 70 years, with no history of cancer and with no family history of breast cancer.

Where to Look:

Examine the opening paragraphs/chapters for a description of the target population of the guideline. The explicit exclusion of some populations (for instance children) is also covered by this item. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: patient population, target population, relevant patients, scope, and purpose.

How to Rate:

Item content includes the following *CRITERIA:*

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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Is the population information specific enough so that the correct and eligible individuals would receive the action recommended in the guideline?

DOMAIN 2. STAKEHOLDER INVOLVEMENT

4. The guideline development group includes individuals from all relevant professional groups.
5. The views and preferences of the target population (patients, public, etc.) have been sought.
6. The target users of the guideline are clearly defined.

STAKEHOLDER INVOLVEMENT

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

This item refers to the professionals who were involved at some stage of the development process. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence and individuals involved in formulating the final recommendations. *This item excludes individuals who have externally reviewed the guideline (see Item 13). This item excludes target population representation (see Item 5)*. Information about the composition, discipline, and relevant expertise of the guideline development group should be provided.

Where to Look:

Examine the opening paragraphs/chapters, acknowledgement section or appendices for the composition of the guideline development group. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, guideline panel member list, acknowledgements, and appendices.

How to Rate:

Item content includes the following *CRITERIA:*

- For each member of the guideline development group, the following information is included:
  - name
  - discipline/content expertise (e.g., neurosurgeon, 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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Are the members an appropriate match for the topic and scope? Potential candidates include relevant clinicians, content experts, researchers, policy makers, clinical administrators, and funders.
- Is there at least one methodology expert included in the development group (e.g., systematic review expert, epidemiologist, statistician, library scientist, etc.)?

STAKEHOLDER INVOLVEMENT

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

Information about target population experiences and expectations of health care should inform the development of guidelines. There are various methods for ensuring that these perspectives inform the different stages of guideline development by stakeholders. For example, formal consultations with patients/public to determine priority topics, participation of these stakeholders on the guideline development group, or external review by these stakeholders on draft documents. Alternatively, information could be obtained from interviews of these stakeholders or from literature reviews of patient/public values, preferences or experiences. There should be evidence that some process has taken place and that stakeholders' views have been considered.

Where to Look:

Examine the paragraphs on the guideline development process. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: scope, methods, guideline panel member list, external review, and target population perspectives.

How to Rate:

Item content includes the following *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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?

STAKEHOLDER INVOLVEMENT

6. The target users of the guideline are clearly defined.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

The target users should be clearly defined in the guideline, so the reader can immediately determine if the guideline is relevant to them. For example, the target users for a guideline on low back pain may include general practitioners, neurologists, orthopaedic surgeons, rheumatologists, and physiotherapists.

Where to Look:

Examine the opening paragraphs/chapters for a description of the target users of the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: target user and intended user.

How to Rate:

Item content includes the following *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)

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Are the target users appropriate for the scope of the guideline?

DOMAIN 3. RIGOUR OF DEVELOPMENT

7. Systematic methods were used to search for evidence.
8. The criteria for selecting the evidence are clearly described.
9. The strengths and limitations of the body of evidence are clearly described.
10. The methods for formulating the recommendations are clearly described.
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.
12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by experts prior to its publication.
14. A procedure for updating the guideline is provided.

RIGOUR OF DEVELOPMENT

7. Systematic methods were used to search for evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

Details of the strategy used to search for evidence should be provided including search terms used, sources consulted, and dates of the literature covered. Sources may include electronic databases (e.g. MEDLINE, EMBASE, CINAHL), databases of systematic reviews (e.g. the Cochrane Library, DARE), handsearching journals, reviewing conference proceedings, and other guidelines (e.g. the US National Guideline Clearinghouse, the German Guidelines Clearinghouse). The search strategy should be as comprehensive as possible and executed in a manner free from potential biases and sufficiently detailed to be replicated.

Where to Look:

Examine the paragraphs/chapters describing the guideline development process. In some cases the search strategies are described in separate documents or in an appendix to the guideline. Examples of commonly labelled sections or chapters in a guideline where this information can be found include: methods, literature search strategy, and appendices.

How to Rate:

Item content includes the following *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)

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Is the search relevant and appropriate to answer the health question? (e.g., all relevant databases and, appropriate search terms used)
- Is there enough information provided for anyone to replicate the search?

RIGOUR OF DEVELOPMENT

8. The criteria for selecting the evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

Criteria for including/excluding evidence identified by the search should be provided. These criteria should be explicitly described and reasons for including and excluding evidence should be clearly stated. For example, guideline authors may decide to only include evidence from randomized clinical trials and to exclude articles not written in English.

Where to Look:

Examine the paragraphs/chapters describing the guideline development process. In some cases, the inclusion or exclusion criteria for selecting the evidence are described in separate documents or in an Appendix to the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, literature search, inclusion/exclusion criteria, and appendices.

How to Rate:

Item content includes the following *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; e.g., *French only* listed in the inclusion criteria statement could logically preclude *non-French* listed in the exclusion criteria statement)

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Is there a rationale given for the chosen inclusion/exclusion criteria?
- Do inclusion/exclusion criteria align with the health question(s)?
- Are there reasons to believe that relevant literature may not have been considered?

RIGOUR OF DEVELOPMENT

9. The strengths and limitations of the body of evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

Statements highlighting the strengths and limitations of the evidence should be provided. This ought to include explicit descriptions - using informal or formal tools/methods - to assess and describe the risk of bias for individual studies and/or for specific outcomes and/or explicit commentary of the body of evidence aggregated across all studies. This may be presented in different ways, for example: using tables commenting on different quality domains; the application of a formal instrument or strategy (e.g., Jadad scale, GRADE method); or descriptions in the text.

Where to Look:

Examine the paragraphs/chapters describing the guideline development process for information on how the methodological quality of the studies (e.g., risk of bias) were described. Evidence tables are often used to summarize quality features. Some guidelines make a clear distinction between description and interpretation of evidence, for instance, in a results section and a discussion section, respectively.

How to Rate:

Item content includes the following *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 (sampling, blinding, allocation concealment, analytical methods)
- 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

Additional *CONSIDERATIONS*:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Are the descriptions appropriate, neutral, and unbiased? Are the descriptions complete?

RIGOUR OF DEVELOPMENT

10. The methods for formulating the recommendations are clearly described.

1 Strongly Disagree	**2**	**3**	**4**	**5**	**6**	**7** Strongly Agree

Comments

User's Manual Description:

A description of the methods used to formulate the recommendations and how final decisions were arrived at should be provided. For example, methods may include a voting system, informal consensus, and formal consensus techniques (e.g., Delphi, Glaser techniques). Areas of disagreement and methods of resolving them should be specified.

Where to Look:

Examine the paragraphs/chapters describing the guideline development process. In some cases, the methods used to formulate the recommendations are described in separate documents or in an appendix to the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include methods and guideline development process.

How to Rate:

Item content includes the following *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)

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Was a formal process used to arrive at the recommendations?
- Were the methods appropriate?

RIGOUR OF DEVELOPMENT

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

The guideline should consider health benefits, side effects, and risks when formulating the recommendations. For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes. These may include: survival, quality of life, adverse effects, and symptom management or a discussion comparing one treatment option to another. There should be evidence that these issues have been addressed.

Where to Look:

Examine the paragraphs/chapters describing the guideline development process for a description of the body of evidence, its interpretation, and the translation to practice recommendations. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, interpretation, discussion, and recommendations.

How to Rate:

Item content includes the following *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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Is the discussion an integral part of the guideline development process? (i.e., taking place during recommendation formulation rather than post-formulation as an afterthought)
- Has the guideline development group considered the benefits and harms equally?

RIGOUR OF DEVELOPMENT

12. There is an explicit link between the recommendations and the supporting evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

An explicit link between the recommendations and the evidence on which they are based should be included in the guideline. The guideline user should be able to identify the components of the body of evidence relevant to each recommendation.

Where to Look:

Define and examine the recommendations in the guideline and the text describing the body of evidence that underpins them. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: recommendations and key evidence.

How to Rate:

Item content includes the following *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

Additional *CONSIDERATIONS*:

- Is there congruency between the evidence and recommendations?
- Is the link between the recommendations and supporting evidence easy to find in the guideline?
- When evidence is lacking or a recommendation is informed primarily by consensus of opinion by the guideline group, rather than the evidence, is this clearly stated and described?

RIGOUR OF DEVELOPMENT

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

A guideline should be reviewed externally before it is published. Reviewers should not have been involved in the guideline development group. Reviewers should include experts in the clinical area as well as some methodological experts. Target population (patients, public) representatives may also be included. A description of the methodology used to conduct the external review should be presented, which may include a list of the reviewers and their affiliation.

Where to Look:

Examine the paragraphs/chapters describing the guideline development process and the acknowledgement section. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, results, interpretation, and acknowledgements.

How to Rate:

Item content includes the following *CRITERIA:*

• purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, 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 (e.g., guideline panel considered results of review in forming final recommendations)

Additional *CONSIDERATIONS*:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Are the external reviewers relevant and appropriate to the scope of the guideline? Was there a rationale given for choosing the included reviewers?
• How was information from the external review used by the guideline development group?

RIGOUR OF DEVELOPMENT

14. A procedure for updating the guideline is provided.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

Guidelines need to reflect current research. A clear statement about the procedure for updating the guideline should be provided. For example, a timescale has been given or a standing panel is established who receives regularly updated literature searches and makes changes as required.

Where to Look:

Examine the introduction paragraph, the paragraphs describing the guideline development process and the closing paragraphs. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, guideline update, and date of guideline.

How to Rate:

Item content includes the following *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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Is there enough information provided to know when an update will occur or what criteria would trigger an update?

DOMAIN 4. CLARITY OF PRESENTATION

15. The recommendations are specific and unambiguous.
16. The different options for management of the condition or health issue are clearly presented.
17. Key recommendations are easily identifiable.

CLARITY OF PRESENTATION

15. The recommendations are specific and unambiguous.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

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.

- An example of a specific recommendation is: Antibiotics should be prescribed in children two years or older with a diagnosis of acute otitis media if the pain lasts longer than three days or if the pain increases after the consultation despite adequate treatment with painkillers; in these cases, amoxicillin should be given for 7 days (supplied with a dosage scheme).
- An example of a vague recommendation is: Antibiotics are indicated for cases with an abnormal or complicated course.

It is important to note that in some instances, evidence is not always clear cut and there may be uncertainty about the best care option(s). In this case, the uncertainty should be stated in the guideline.

Where to Look:

Define and examine the recommendations in the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: recommendations and executive summary.

How to Rate:

Item content includes the following *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)

Additional *CONSIDERATIONS*:

- In the event of multiple recommendations (e.g., management guidelines), is there clarity regarding to whom each recommendation applies?
- If there is uncertainty in the interpretation and discussion of the evidence, is the uncertainty reflected in the recommendations and explicitly stated?

CLARITY OF PRESENTATION

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

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.
For example, a recommendation on the management of depression may contain the following treatment alternatives:
a. Treatment with TCA
b. Treatment with SSRI
c. Psychotherapy
d. Combination of pharmacological and psychological therapy

Where to Look:

Examine the recommendations and their supporting evidence. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: executive summary, recommendations, discussion, treatment options, and treatment alternatives.

How to Rate:

Item content includes the following *CRITERIA:*

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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Is this pertaining to a guideline broad or narrow in scope? This item may be more relevant to guidelines that are broad in scope (e.g., covering the management of a condition or issue rather than focusing on a particular set of interventions for a specific condition/issue).

CLARITY OF PRESENTATION

17. Key recommendations are easily identifiable.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

Users should be able to find the most relevant recommendations easily. These recommendations answer the main question(s) that have been covered by the guideline and can be identified in different ways. For example, they can be summarized in a box, typed in bold, underlined or presented as flow charts or algorithms.

Where to Look:

Examples of commonly labeled sections or chapters in a guideline where this information can be found include: executive summary, conclusions, and recommendations. Some guidelines provide separate summaries with key recommendations (e.g., quick reference guide).

How to Rate:

Item content includes the following *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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Are the key recommendations appropriately selected and do they reflect the key messages of the guideline?
- Are specific recommendations grouped in a section placed near the summary of the key evidence?

DOMAIN 5. APPLICABILITY

18. The guideline describes facilitators and barriers to its application.
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.
20. The potential resource implications of applying the recommendations have been considered.
21. The guideline presents monitoring and/or auditing criteria.

APPLICABILITY

18. The guideline describes facilitators and barriers to its application.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

There may be existing facilitators and barriers that will impact the application of guideline recommendations. For example:
i. A guideline on stroke may recommend that care should be coordinated through stroke units and stroke services. There may be a special funding mechanism in the region to enable the formation of stroke units.
ii. A guideline on diabetes in primary care may require that patients are seen and followed up in diabetic clinics. There may be an insufficient number of clinicians available in a region to enable clinics to be established.

Where to Look:

Examine the paragraph/chapter on the dissemination/implementation of the guideline or, if available, additional documents with specific plans or strategies for implementation of the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: barriers, guideline utilization, and quality indicators.

How to Rate:

Item content includes the following *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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Does the guideline suggest specific strategies to overcoming the barriers?

APPLICABILITY

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

For a guideline to be effective it needs to be disseminated and implemented with additional materials. For example, these may include: a summary document, a quick reference guide, educational tools, results from a pilot test, patient leaflets, or computer support. Any additional materials should be provided with the guideline.

Where to Look:

Examine the paragraph on the dissemination/implementation of the guideline and, if available, the specific accompanying materials that have been produced to support the dissemination and implementation of the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: tools, resources, implementation, and appendices.

How to Rate:

Item content includes the following *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 (see Item 18)
  - tools to capitalize on guideline facilitators (see Item 18)
  - outcome of pilot test and lessons learned

- directions on how users can access tools and resources

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Is there information about the development of the implementation tools and validation procedures?

APPLICABILITY

20. The potential resource implications of applying the recommendations have been considered.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

The recommendations may require additional resources in order to be applied. For example, there may be a need for more specialized staff, new equipment, and expensive drug treatment. These may have cost implications for health care budgets. There should be a discussion in the guideline of the potential impact of the recommendations on resources.

Where to Look:

Examine the paragraph(s) on the dissemination/implementation of the guideline or, if available, additional documents with specific plans or strategies for implementation of the guideline. Some guidelines present cost implications in the paragraphs that discuss the evidence or decisions behind the recommendations. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, cost utility, cost effectiveness, acquisition costs, and implications for budgets.

How to Rate:

Item content includes the following *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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Were appropriate experts involved in finding and analyzing the cost information?

APPLICABILITY

21. The guideline presents monitoring and/or auditing criteria.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

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. The criteria may include process measures, behavioural measures, clinical or health outcome measures. Examples of monitoring and audit criteria are:

- The HbA1c should be < 8.0%.
- The level of diastolic blood pressure should be < 95 mmHg.
- 80% of the population aged 50 years should receive colorectal cancer screening rates using fecal occult blood tests.
- If complaints of acute otitis media last longer than three days, amoxicillin should be prescribed.

Where to Look:

Examine the paragraph/chapter on auditing or monitoring the use of the guideline or, if available, additional documents with specific plans or strategies for evaluation of the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: recommendations, quality indicators, and audit criteria.

How to Rate:

Item content includes the following *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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Are a range of criteria provided including process measures, behavioural measures, and clinical or health outcomes?

DOMAIN 6. EDITORIAL INDEPENDENCE

22. The views of the funding body have not influenced the content of the guideline.
23. Competing interests of guideline development group members have been recorded and addressed.

EDITORIAL INDEPENDENCE

22. The views of the funding body have not influenced the content of the guideline.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

Many guidelines are developed with external funding (e.g., government, professional associations, charity organizations, pharmaceutical companies). Support may be in the form of financial contribution for the complete development, or for parts of it (e.g., printing of the guidelines). There should be an explicit statement that the views or interests of the funding body have not influenced the final recommendations.

Where to Look:

Examine the paragraphs/chapters on the guideline development process or acknowledgements section. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: disclaimer and funding source.

How to Rate:

Item content includes the following *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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- How did the guideline development group address potential influence from the funding body?

EDITORIAL INDEPENDENCE

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

User's Manual Description:

There are circumstances when members of the development group may have competing interests. For example, this would apply to a member of the development group whose research on the topic covered by the guideline is also funded by a pharmaceutical company. There should be an explicit statement that all group members have declared whether they have any competing interests.

Where to Look:

Examine the paragraphs/chapters describing the guideline development group or acknowledgements section. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, conflicts of interest, guideline panel, and appendix.

How to Rate:

Item content includes the following *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

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- What measures were taken to minimize the influence of competing interests on guideline development or formulation of the recommendations?

OVERALL GUIDELINE ASSESSMENT

OVERALL GUIDELINE ASSESSMENT

For each question, please choose the response which best characterizes the guideline assessed:

1. Rate the overall quality of this guideline.

1 Lowest possible quality	**2**	**3**	**4**	**5**	**6**	**7** Highest possible quality

2. I would recommend this guideline for use.

Yes	
Yes, with modifications	
No	

NOTES

User's Manual Description:

The overall assessment requires the AGREE II user to make a judgment as to the quality of the guideline, taking into account the appraisal items considered in the assessment process.

AGREE II INSTRUMENT

DOMAIN 1. SCOPE AND PURPOSE

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 2. STAKEHOLDER INVOLVEMENT

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

6. The target users of the guideline are clearly defined.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 3. RIGOUR OF DEVELOPMENT

7. Systematic methods were used to search for evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

8. The criteria for selecting the evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

9. The strengths and limitations of the body of evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 3. RIGOUR OF DEVELOPMENT continued

10. The methods for formulating the recommendations are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

12. There is an explicit link between the recommendations and the supporting evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 3. RIGOUR OF DEVELOPMENT continued

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

14. A procedure for updating the guideline is provided.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 4. CLARITY OF PRESENTATION

15. The recommendations are specific and unambiguous.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

17. Key recommendations are easily identifiable.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 5. APPLICABILITY

18. The guideline describes facilitators and barriers to its application.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

20. The potential resource implications of applying the recommendations have been considered.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 5. APPLICABILITY continued

21. The guideline presents monitoring and/or auditing criteria.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 6. EDITORIAL INDEPENDENCE

22. The views of the funding body have not influenced the content of the guideline.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

OVERALL GUIDELINE ASSESSMENT

For each question, please choose the response which best characterizes the guideline assessed:

1. Rate the overall quality of this guideline.

1 Lowest possible quality	**2**	**3**	**4**	**5**	**6**	**7** Highest possible quality

2. I would recommend this guideline for use.

Yes	
Yes, with modifications	
No	

NOTES