SCOPE AND PURPOSE

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

1 Strongly Disagree234	5	6	7 Strongly Agree
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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)

- 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 Disagree234	5	6	7 Strongly Agree
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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:

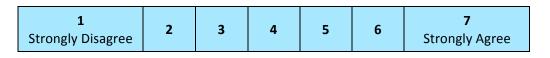
• Is the item well written? Are the descriptions clear and concise?

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.



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?

Image: Strongly Disagree <th Image: Strongly

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

- 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

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
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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:

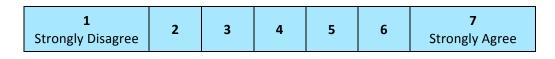
Item content includes the following CRITERIA:

- 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

- 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.



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?

CLARITY OF PRESENTATION 15. The recommendations are specific and unambiguous. 1 2 3 4 5 6 7 Strongly Disagree 2 3 4 5 6 7 Comments Strongly Disagree 2 3 4 5 6 7

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
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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 2 3 4 5 6 7 Strongly Disagree 2 3 4 5 6 7 Comments Image: Strongly Agree Image: Strongly A

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

- 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?

APPLICABILITY

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

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
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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

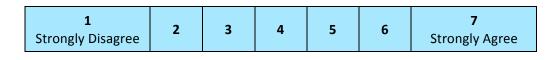
Additional CONSIDERATIONS:

- 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.



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

- 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?

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						7
Lowest possible	2	3	4	5	6	Highest possible
quality						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.