CEP Trustworthy Guideline Appraisal Tool

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The purpose of this instrument is to focus on the aspects of a guideline that may reduce the trust a clinical user can have in the guideline and distinguish weaknesses in documentation (e.g. guideline does not have a documented updating process) from weaknesses in the guidance itself (e.g. recommendations are outdated). It is based on the eight domains included in the Institute of Medicine's publication: Clinical Practice Guidelines We Can Trust (1).

Current appraisal instruments like AGREE (2) and the G-I-N standards (3) emphasize documentation. They are important standards for guideline developers but may be harder for clinicians and other persons who are not methodology experts to apply, and their length may discourage their use outside of formal systematic reviews and healthcare technology assessment (HTA) reports. This new instrument is designed to be brief, and easy and consistent to apply.

1. Transparency

	A	Guideline development methods are fully disclosed.
	B	Guideline development methods are partially disclosed.
	C	Guideline development methods are not disclosed.

The grader must refer to any cited methods supplements or other supporting material when evaluating the guideline. Methods should include:

- Who wrote the initial draft
- How the committee voted on or otherwise approved recommendations

Evidence review, external review and methods used for updating are not addressed in this standard.

2. Conflict of interest

	A	Funding of the guideline project is disclosed, disclosures are made for each individual author, and there are no potential financial or other conflicts in the guideline project funding or among the lead authors.
	B	Guideline states that the lead authors have no potential financial or other conflicts, but does not disclose the funding source for the guideline project.
	C	One or more lead authors, or the guideline project as a whole, is funded by a sponsor with potential financial or other conflicts of interest.
	NR	Guideline does not report on potential conflicts of individual authors or the funding of the guideline.

For purposes of this checklist, conflicts of interest include employment by, consulting for, or holding stock in companies doing business in fields affected by the guideline, as well as related financial conflicts. This definition should not be considered exclusive.
As much as anything, this is a surrogate marker for thorough reporting, since it may be assumed that guideline projects are funded by the sponsoring organization and many authors think it unnecessary to report a non-conflict.

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3. Guideline development group

	A	Guideline development group includes 1) methodological experts, 2) representatives of multiple specialties, and 3) representatives of patients or the general public.
	B	Guideline development group includes representatives of two of the above numbered categories, but not all three.
	C	Guideline development group includes only one or none of the above.
	NR	Affiliations of guideline developers not reported.

The purpose of this standard is to ensure that supporters of competing procedures, clinicians with no vested interest in utilization of one procedure or another, methodologists, and patients or potential patients are involved in development of the guideline. Involvement of methodologists or HTA specialists in the systematic review represents sufficient involvement in the guideline development group for our purposes. In the absence of any description of the guideline group, assume the named authors of the guideline and any corresponding systematic reviews are the guideline group.

4. Systematic review

	A	Guideline is based on a systematic review of the evidence.
	B	Guideline is based on a review which does not meet systematic review criteria, or cannot be readily obtained.
	C	Guideline is not based on a review of the evidence.

In order to qualify as a systematic review, the review must do all of the following:

- Describe itself as systematic or report search strategies using multiple databases
- Define the scope of the review (including key questions and the applicable population)
- Either include quantitative or qualitative synthesis of the data or explain why it is not indicated

Note: the review can be incorporated into the guideline document or published separately and referenced in the guideline document. The review does not need to be performed by the same group that develops the guideline.

Note: this element does not address the quality of the systematic review: simply whether it exists. Concerns about quality or bias of the review will be discussed in text, where the analyst will explain whether the weaknesses of the review weaken the validity or reliability of the guideline.

Note: a guideline may be rated B on this domain even if the review on which it is based is not available to us. This potential weakness of the guideline should be discussed in the report.

5. Citing and grading the supporting evidence

	A	Specific supporting evidence (or lack thereof) for each recommendation is cited and graded.
	B	Specific supporting evidence (or lack thereof) for each recommendation is cited but the evidence is not graded.
	C	Recommendations are not supported by specific evidence.

To score a B on this domain, recommendations should include specific citations to the relevant evidence, specific references to evidence tables or written evidence summaries that include

citations, or an indication that no evidence was available. The use of any standardized system to grade the evidence supporting a recommendation is acceptable for purposes of supporting an A rating.

6. Recommendations

	A	1) Considerations for each recommendation (i.e. benefits and harms of a particular action) are documented and a strength of recommendation is provided; and 2) recommendations are presented in an actionable form.
	B	Either one or the other of the above numbered criteria is met.
	C	Neither of the above criteria are met.

The use of any standardized system to grade the strength of a recommendation is acceptable for purposes of this appraisal. In order to be actionable, the guideline recommendation should specify the population to which the recommendation applies, the intervention in question, and the circumstances under which it should be carried out (or not carried out). The language used in the recommendations should also be consistent with the strength of the recommendation (e.g. directive and active language like "should" or "should not" for strong recommendations, and passive language like "consider" for weak recommendations). A figure or algorithm is considered actionable as long as it is complete enough to incorporate all the applicable patients and interventions. Please see the NICE manual (4) for a helpful discussion of actionability in guidelines.

7. External review

	A	Guideline was made available to external groups and/or the public for review.
	B	Guideline was reviewed by officers or members of the sponsoring body only.
	C	Guideline was not reviewed by anyone outside of the authoring committee.
	NR	No external review process is described.

The purpose of this domain is to report whether or not there was consultation with persons or groups who might have a different perspective than members of the organization developing the guideline. If the guideline was reviewed and/or voted on by the board of the sponsoring body only, that is not an outside review, and this domain would be marked "B." NR is likely to be common for this domain.

8. Updating and currency of guideline

	A	Guideline is current and an expiration date or update process is specified.
	B	Guideline is current but no expiration date or update process is specified.
	C	Guideline is outdated.

A guideline is considered current if it is within the developers' stated validity period, or if no period or expiration data is stated, the guideline was published in the past three years (NOTE: the specific period may be changed at the discretion of the analyst reviewing the guideline, based on whether the technology is mature and whether there is a significant amount of recent evidence). A guideline must address new evidence when it is updated. A guideline which is simply re-endorsed by the panel without searching for new evidence must be considered "outdated."

Reporting the results of this appraisal

We do not attempt to convert the results of this appraisal into a numeric score. Instead we present a table listing the guidelines and how they are rated on each standard. Colored cells in the table reinforce the grades in the table, though use of color is optional. This facilitates qualitative understanding by the reader, who can see for what areas the available guidelines as a group are weak or strong as well as which guidelines are weaker or stronger.

Sample guideline appraisal table

Domain	Guideline A	Guideline B	Guideline C	Guideline D
1. Transparency	A	B	B	C
2. Conflict of interest	A	B	NR	C
3. Development group	C	C	C	C
4. Systematic review	A	A	B	B
5. Grading of evidence	B	NR	NR	B
6. Recommendations	A	B	A	B
7. External review	B	NR	NR	C
8. Updating	A	B	B	C

Reporting the level of evidence

The purpose of the Trustworthy Guideline appraisal is to assess the methodologic reliability of the guideline and its development, and not to assess the level or quality of evidence for specific guideline recommendations. This is because guidelines usually include multiple recommendations, some of which may be supported by better evidence than others.

The suggested place for reporting level of evidence is in the table of recommendations, beside or immediately below each recommendation from each guideline developer. That way the reader can easily determine which recommendations are supported by reliable evidence and which have to be based on expert opinion. Numerous scales are already available, such as the one from the GRADE Working Group (5).

References

1. Institute of Medicine (U.S.). Committee on Standards for Developing Trustworthy Clinical Practice Guidelines. Clinical practice guidelines we can trust. Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E, editors. Washington, DC: National Academies Press; 2011. http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx
2. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. AGREE II: Advancing guideline development, reporting and evaluation in health care. J Clin Epidemiol. 2010 Dec; 63(12):1308-11.
3. Qaseem A, Forland F, Macbeth F, Ollenschlager G, Phillips S, van der Wees P, et al. Guidelines International Network: toward international standards for clinical practice guidelines. Ann Intern Med. 2012 Apr 3;156(7):525-31.
4. National Institute for Health and Clinical Excellence. The guidelines manual. London: National Institute for Health and Clinical Excellence; November 2012. http://publications.nice.org.uk/the-guidelines-manual-pmg6
5. Guyatt GH, Oxman AD, Kunz R, Falck-Ytter Y, Vist GE, Liberati A, et al. GRADE: Going from evidence to recommendations. BMJ. 2008;336(7652):1049-51.