

# Are the Institute of Medicine's Trustworthiness Guidelines Trustworthy?

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## ABSTRACT

The Institute of Medicine (IOM) has published a set of eight standards for guideline development groups (GDGs) to derive trustworthy clinical practice guidelines (CPGs). We investigated the adherence of these IOM guidelines to its own standards. The IOM document passed two of its own standards ("GDG-Systematic Review Team Interaction" and "GDG Composition"), only partially passed two others ("Articulation of Recommendation" and "External Review") and failed to pass four ("Establishing Transparency," "Management of Conflict of Interest," "Establishing Evidence Foundations" and "Updating"). The IOM standards for the development of CPGs do not meet their own criteria of trustworthiness. Further study is needed to determine the best methodology to evaluate CPGs.

**KEYWORDS:** Clinical Practice Guidelines, trustworthiness

In March 2011, the Institute of Medicine (IOM) released the "Standards for Developing Trustworthy Clinical Practice Guidelines," a set of eight recommendations developed to guide guideline development groups (GDG) in deriving clinical practice guidelines (CPG) from formation of the GDG to updating the CPG based on new evidence.<sup>1</sup> A recent editorial highlighted the importance of rigorous and trustworthy standards in light of the recent breast cancer screening controversy.<sup>2</sup> However, the editorial also criticized the IOM standards on the grounds of setting standards too high and also as inflexible, since a guideline needs to meet all eight standards to be considered "trustworthy." The only study to examine guidelines with respect to the IOM standards found 0/130 CPGs met all standards.<sup>3</sup> In light of this controversy, we thought it would be instructive to determine if the IOM standards would be considered trustworthy by their own criteria.

We evaluated the adherence of the "Clinical Practice Guidelines We Can Trust" document to its eight listed standards for developing CPGs. The analysis of each IOM standard is outlined in **Table 1** (next page). The IOM document passed two of its own standards, partially passed two standards, and failed four.

These findings call into question the trustworthiness of the IOM standards for developing trustworthy CPGs. It can be argued that the IOM document is not a CPG and thus cannot be evaluated as such; however, we disagree, given that the IOM document purports to be a blueprint for developing CPGs to optimize care. Thus, it appears premature to recommend that all CPGs meet the IOM standards. Further study is needed to determine the best criteria for evaluating CPGs.

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## Disclaimer

The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States government.

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**Table 1.** Evaluation of Institute of Medicine Standards for Clinical Practice Guidelines

STANDARD	DESCRIPTION	EVALUATION
1. Establishing Transparency	1.1 GDG methods should be detailed explicitly and publicly accessible	<b>Fail:</b> The IOM uses grey literature*, and does not supply the reasoning for all sub-recommendations (2.3, 8.1).
2. Management of Conflict of Interest (COI)	COI should be: <ul style="list-style-type: none"> <li>• 2.1 Disclosed</li> <li>• 2.2 Discussed</li> <li>• 2.3 Divested</li> </ul> 2.4 Members of the GDG should exclude: <ul style="list-style-type: none"> <li>• A majority of those with COI</li> <li>• A chair or co-chair with COI</li> <li>• Funders</li> </ul>	<b>Fail:</b> There is a lack of a clear or dedicated conflict of interest (COI) section in the IOM document. While affiliations of committee members are listed, whether any of the affiliations pose a potential conflict of interest is not disclosed or discussed; it is unknown whether potential COIs were divested prior to the production of this document.
3. Guideline Development Group Composition	GDG should: <ul style="list-style-type: none"> <li>• 3.1 Be multidisciplinary</li> <li>• 3.2 Involve patients or patient advocates</li> <li>• 3.3 Use strategies to better involve patients in CPG development</li> </ul>	<b>Pass:</b> The IOM committee was multidisciplinary, including clinical experts, methodological experts, and a former patient/patient organization representative.
4. Clinical Practice Guideline-Systematic Review Intersection	The systematic review team should: <ul style="list-style-type: none"> <li>• 4.1 Meet IOM standards</li> <li>• 4.2 Interact with the GDG</li> </ul>	<b>Pass:</b> The IOM committee's literature search met IOM standards, and the systematic review team had full interaction with the development team.
5. Establishing evidence foundations for and rating strength of recommendations	5.1 Recommendations should be clearly described – including: <ul style="list-style-type: none"> <li>• Summary of evidence</li> <li>• Quality, quantity, and consistency of evidence</li> <li>• Evidentiary gaps</li> <li>• A rating of level of confidence and strength of recommendation</li> </ul>	<b>Fail:</b> While a rating of highest possible strength is implied for all recommendations, a rating of level of confidence is not considered. Some sub-recommendations have insufficient or non-publicly available evidence to support them: (2.2, 2.3, 7.1†, 7.2, 7.4, and 8.1). Quality, quantity, and consistency of evidence are not consistently considered. Evidentiary gaps are occasionally mentioned.
6. Articulation of Recommendation	Recommendations should be: <ul style="list-style-type: none"> <li>• 6.1 Described precisely</li> <li>• 6.2 Be able to be evaluated discretely</li> </ul>	<b>Partial pass:</b> While all recommendations are described precisely, using standards 2, 4, 7, and 8 to evaluate CPGs can be impossible for an external evaluator since full evaluation would require access to knowledge of GDG internal structure and discussions (discussion of the impact COI and record keeping of review comments, respectively). Additionally, standards 4, 7, and 8 have been called into question as vague and subjective. <sup>3</sup>
7. External Review	7.1 External review board should include all of: <ul style="list-style-type: none"> <li>• Experts</li> <li>• Organizations</li> <li>• Federal Agencies or an analogue</li> <li>• Representatives of the public.</li> </ul> Additionally: <ul style="list-style-type: none"> <li>• 7.2 Confidentiality of the reviewers should be preserved,</li> <li>• 7.3 Meticulous record of review comments should be kept</li> <li>• 7.4 The review draft should be publicly available</li> </ul>	<b>Partial pass:</b> The external review board does not have members of federal agencies or an analogue, or representatives of the public. It does have clinical and scientific experts, as well as representatives from national organizations. Confidentiality of the reviewers was preserved, and a record of review comments was kept. The public was invited to comment on key issues. A review draft was made available to the public.
8. Updating	<ul style="list-style-type: none"> <li>• 8.1 Dates of systematic evidence review and date for future CPG review should be documented</li> <li>• 8.2 Literature should be regularly monitored for new evidence</li> <li>• 8.3 CPG should be updated when new evidence is found</li> </ul>	<b>Fail:</b> The IOM standards use evidence from the literature to support and develop its recommendations. Hence, it is entirely plausible that new literature could modify these recommendations. However, no updating schedule or procedure is described within the IOM document.

\*Grey literature is unpublished material that has had limited distribution and is not included in bibliographic retrieval systems.<sup>4</sup>

†In support of sub-recommendation 7.1 (inclusion of scientific experts, clinical experts, patients, and representatives of the public in the external review panel), the reference provided by the IOM only mentions that these groups can potentially be used, but does not state that all must be used; furthermore it does not provide evidence that these groups used in combination will increase the perception of trustworthiness.