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Clinical Practice Guidelines We Can Trust

**CLINICAL PRACTICE
GUIDELINES
WE CAN TRUST**INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Healthcare providers often are faced with difficult decisions and considerable uncertainty when treating patients. They rely on the scientific literature, in addition to their knowledge, skills, experience, and patient preferences, to inform their decisions. Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Rather than dictating a one-size-fits-all approach to patient care, clinical practice guidelines offer an evaluation of the quality of the relevant scientific literature and an assessment of the likely benefits and harms of a particular treatment. This information enables healthcare providers to proceed accordingly, selecting the best care for a unique patient based on his or her preferences.

The U.S. Congress, through the *Medicare Improvements for Patients and Providers Act of 2008*, asked the Institute of Medicine (IOM) to undertake a study on the best methods used in developing clinical practice guidelines. To ensure that organizations developing such guidelines have information on approaches that are objective, scientifically valid, and consistent, the IOM formed an expert committee. The committee developed eight standards for developing rigorous, trustworthy clinical practice guidelines.

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Developing Trustworthy Guidelines

The Guidelines International Network database currently contains more than 3,700 clinical practice guidelines from 39 countries. Additionally, there are nearly 2,700 guidelines in the National Guidelines Clearinghouse (NGC),

part of the Agency for Healthcare Research and Quality (AHRQ). Because of the large number of clinical practice guidelines available, guideline users, including practitioners, find it challenging to determine which guidelines are of high quality. If guideline users had a mechanism to immediately identify high quality, trustworthy clinical practice guidelines, their health-related decision making would be improved, potentially resulting in enhanced health care quality and outcomes. Likewise, a set of standards for trustworthy clinical guidelines would help developers create such guidelines, which, in turn, has the potential to improve healthcare decision making and health care quality and outcomes.

Most guidelines used today suffer from shortcomings in development. Dubious trust in guidelines is the result of many factors, including failure to represent a variety of disciplines in guideline development groups, lack of transparency in how recommendations are derived and rated, and omission of a thorough external review process. To be trustworthy, clinical practice guidelines should:

- Be based on a systematic review of the existing evidence;
- Be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups;
- Consider important patient subgroups and patient preferences, as appropriate;
- Be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest;
- Provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations; and
- Be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.

Additionally, as reflected in the committee's standards for developing trustworthy clinical practice guidelines, guideline development groups optimally comprise members without conflict of interest. The committee recognizes that in some circumstances, a guideline development group may not be able to perform its work without members who have conflicts of interest—for example, relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the guideline. Therefore, the committee specifies that members of the guideline development group who have a conflict of interest should not represent more than a minority of the group.

The committee standards also emphasize that in making guideline recommendations, the guideline development group should provide a summary of relevant available evidence that describes the quality, quantity, and consistency of that aggregate evidence.

Setting Standards for Trustworthy Guidelines

The committee proposes eight standards for developing trustworthy guidelines. These standards reflect the latest literature, expert consensus, and public input. The committee recommends that all guidelines comply with these standards (see Standards document for more detailed information). The standards reflect best practices across the entire guideline development process, including attention to:

- Establishing transparency;
- Management of conflict of interest;
- Guideline development group composition;
- Clinical practice guideline–systematic review intersection;
- Establishing evidence foundations for and rating strength of recommendations;

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- Articulation of recommendations;
- External review; and
- Updating.

The committee's proposed standards have yet to be tested by clinical practice guideline developers and users to determine whether the standards produce unbiased, scientifically valid, and trustworthy clinical practice guidelines, and whether implementation of the clinical practice guidelines based on the committee's standards improve health outcomes.

Promoting Adoption

To promote adoption of the standards, the committee recommends that the U.S. Department of Health and Human Services (HHS) create a mechanism to identify trustworthy guidelines. Such identification will serve three purposes: promote wider adoption of the IOM standards by developers since there will be an advantage to clinical practice guidelines publicly identified as trustworthy, provide users of clinical practice guidelines with an easy guide to identify guidelines that are trustworthy, and promote adoption of trustworthy clinical practice guidelines.

To affect quality of care and patient outcomes, implementers should ensure that trustworthy guidelines are made available to clinicians and health systems. Therefore, the committee recommends that implementers employ effective,

multi-faceted strategies targeting both individuals and healthcare systems to promote adherence to trustworthy clinical practice guidelines. Increased adoption of electronic health records and computer-aided clinical decision support (CDS) will open new opportunities to rapidly promote clinical practice guidelines to healthcare providers and patients. To advance this goal, guideline developers should structure the format, vocabulary, and content of clinical practice guidelines to help ease the implementation of computer-aided CDS by end-users.

Evaluating Trustworthy Guidelines

It is important that the committee's standards are properly evaluated. The committee encourages AHRQ to direct a portion of its research funds to pilot-test the standards, to assess their reliability and validity, and to evaluate the effects of the standards on clinical practice guideline development and health care quality and outcomes. While AHRQ is not directly involved in clinical practice guideline development, it does play a vital role in disseminating guidelines through its NGC. The committee recommends that AHRQ require the NGC to discontinue the inclusion of guidelines whose development is not sufficiently documented, and to prominently identify guidelines that reflect the committee's proposed standards for trustworthiness.



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Conclusion

Patients rely on healthcare providers for quality care and expect that those providers have the knowledge and expertise to make health-related decisions. Clinical practice guidelines can aid clinicians and patients alike in determining the best treatment options for a particular disease or condition. While there always will be uncertainty in clinical practice, ensuring that clinicians have trustworthy guidelines will bring more evidence to bear on clinician and patient decision making. Trustworthy guidelines hold the promise of improving health care quality and outcomes. 

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