Assessing the Trustworthiness of the Guideline for Management of High Blood Pressure in Adults

Harold C. Sox, MD

The article by James and colleagues published in JAMA contains the long-awaited guideline for hypertension issued by the panel members appointed by the National Heart, Lung, and Blood Institute (NHLBI) to the Eighth Joint National Committee (JNC 8). In the past decade, the effect of guidelines on clinical practice has increased because organizations that develop quality measures and make coverage decisions depend on guideline developers to uncover the best evidence and make specific recommendations. Because guidelines matter more, critics have questioned the processes that professional associations have used to develop guidelines. The title of the 2011 Institute of Medicine (IOM) report on quality standards for practice guidelines, Clinical Practice Guidelines We Can Trust, captures current concerns. Despite the efforts of the expert panel that developed the new guideline for management of hypertension, some aspects of the external review process may undermine public confidence.

The NHLBI convened the JNC 8 panel in 2008. The panel decided to adhere to the standards set by the IOM study committee instead of following the practices of earlier JNC panels. The JNC 7 committee produced a comprehensive overview of the management of hypertension. The committee did not commission systematic reviews of the evidence. The report did not state the extent and quality of the evidence for many topics, so that the logical connection between the evidence and some recommendations was not clear. The report described conflicts of interest for committee members but did not say whether members recused themselves from voting when they had a conflict.

As part of the guideline development process, the present hypertension guideline panel commissioned a systematic review of randomized trial evidence, evaluated the evidence, made recommendations, indicated the level of evidence supporting those recommendations, reported conflicts of interest, and recused conflicted panel members from voting. Because of these changes, this guideline adheres much more closely to the IOM standards than the JNC 7 guideline.
What Are the Key Elements of a Trustworthy Guideline?

The IOM committee listed 8 standards. This editorial focuses on 4 of them. First, active management of conflict of interest is essential. The IOM committee thought that conflicts should be disclosed to the public and panelists should not vote on questions if they have a conflict. Second, a systematic review should be the starting point for developing a guideline. An IOM committee worked in parallel with the IOM guidelines committee to develop standards for systematic reviews. A systematic review should minimize the possibility that the guideline panel will fail to take account of relevant evidence. Third, the panel must explain the reasoning that led from the evidence to its recommendation. Fourth, the panel should involve relevant stakeholders in the external review process, publish a draft of the report for public comment, and record reviewer comments and the panel’s response.

What Is the Role of Expert Review of Guidelines?

External reviewers may point out evidence that the committee missed, identify flawed studies, or cite illogical reasoning, poor writing, or unjustified recommendations. The credibility of a guideline depends on the thoroughness of the external reviewers and the integrity of the panel in responding to concerns. In the case of this hypertension guideline, the reader has a rare opportunity to see the review process in action and judge its integrity. The authors kept detailed records of the comments of the reviewers, the panel’s responses to those comments, and how the panel considered the comments when it revised the guidelines. Remarkably, the authors have said that they will send this record to interested parties on request. This form of transparency sets an important precedent that, if adopted widely, could increase public confidence in guidelines. In this case, the record of verbatim reviewer comments and the panel’s response should convince most readers that little would have been gained by additional review by specialty society-designated reviewers.

Expert review is necessary, but the review process must be managed so that unfair criticism by reviewers is exposed while the committee is held accountable for its response to credible criticism. This approach sounds difficult to achieve in practice, but one organization, the US National Academies, which includes the IOM, uses it routinely for its reports. According to the approach of this organization, good management of review should include 4 features. First, reviewers should declare all of their financial conflicts of interest. Second, the review process should be managed by an impartial organization. Third, the dialogue between reviewers and guidelines committees should distinguish evidence-based assertions from those based on opinion and personal clinical experience. This principle can help to distinguish a credible criticism from one that is suspect. Fourth, if the organization that manages the review is dissatisfied with the committee’s response to reviewers’ comments, it should be empowered to withhold its endorsement of the review process. The hypertension guideline committee’s willingness to make public the content of the review process suggests a fifth operational principle: publish the dialogue between reviewers and guidelines committees as an online appendix to the guidelines report. This suggestion is in keeping with an overarching principle of guidelines, which is to help the health professions and the public make informed choices, not simply tell them what to do.

What Is the Pathway to Trustworthy Guidelines?

In response to the uneven quality of practice guidelines, an IOM study in 2006 proposed creating a marketplace in which guideline users can compare guidelines from different organizations. If users could identify the best-quality guidelines, they would gravitate toward them, which would compel guideline developers to raise their game or be ignored. With the publication of the GRADE standards and the IOM committee’s quality standards, this concept is gaining momentum. This approach requires metrics of adherence to the quality standards, which are still in the early stages of development.
A rigorous, transparent process for developing and reviewing guidelines matters a great deal because guidelines are increasingly driving the practice of medicine. This Editorial focuses on the external review process for the hypertension guideline because it raised some concerns. The panel addressed them head-on by agreeing to share its record of the review process with anyone who asks. Reading the critiques and responses, many readers will conclude that the panel was on solid ground in its interpretation of high-quality evidence about the limited but important set of questions that it chose to address. However, a discussion of external review should include several additional questions. Should guideline users shun a guideline that has not been posted in draft form for public comment per the practice of the US Preventive Services Task Force? Have practice guidelines become so important that they require a review process managed by an impartial third party, like that used by the National Academies? The answers to those questions await public debate. Meanwhile, the panel’s decision to open the review process to public scrutiny challenges other guidelines programs to follow suit.

ARTICLE INFORMATION
Author Affiliation: Dartmouth Institute for Health Policy and Clinical Practice, Geisel School of Medicine, Hanover, New Hampshire.
Corresponding Author: Harold C. Sox, MD, Dartmouth Institute for Health Policy and Clinical Practice, Geisel School of Medicine, 31 Faraway Ln, West Lebanon, NH 03784 (hsox@comcast.net).
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REFERENCES

Recommendations for Treating Hypertension
What Are the Right Goals and Purposes?

Eric D. Peterson, MD, MPH; J. Michael Gaziano, MD; Philip Greenland, MD

Hypertension is the most common cardiovascular risk factor in the United States, affecting approximately two-thirds of adults aged 60 years or older. Observational studies have demonstrated a linear relationship between blood pressure (BP) and risk of cardiovascular events. Randomized controlled trials (RCTs) have found that lowering BP by as little as 10 mm Hg in patients with hypertension can reduce a person’s lifetime risk for cardiovascular and stroke death by 25% to 40%. Yet for such a common and treatable condition, the ideal treatment goal remains uncertain—both overall and as a function of a patient’s age. Compared with younger patients, older patients with hypertension are at increased risk for cardiovascular and stroke events yet are more vulnerable to complications related to pharmacological treatment of hypertension.

The last Joint National Committee (JNC 7) Guideline, sponsored by the National Heart, Lung, and Blood Institute (NHLBI), was released more than a decade ago. The updated recommendations for management of high blood pressure from the panel members appointed to the JNC 8 Committee was launched 5 years ago. The process used in the most recent update differed from the prior guideline by focusing on select clinical questions that were to be answered solely using evidence from RCTs. Despite this empirical approach, the panel’s summary recommendations were ultimately not sanctioned by the NHLBI. The panel’s report is now published in JAMA as a stand-alone document, and it remains unclear as to whether, or when, or by whom another consensus national hypertension guideline will again be formulated.