



PROFESSION

Few clinical guideline panels follow financial-conflict standards

It is time for a stricter process to vet which clinical guidelines meet muster for inclusion in a federal government clearinghouse, some experts argue.

By **KEVIN B. O'REILLY**, amednews staff. **Posted Nov. 12, 2012.**

Clinical guideline developers are not adhering to standards on minimizing financial conflicts, increasing transparency and explaining the evidence used to make their recommendations, according to an *Archives of Internal Medicine* study.

Fewer than half of the 114 guidelines randomly sampled from the National Guideline Clearinghouse met most of the "standards for developing trustworthy clinical practice guidelines" set forth by an Institute of Medicine committee in March 2011. The typical guideline met 44% of the IOM standards, said the study, published Oct. 22. For example, the IOM said panel chairs and co-chairs should not have financial conflicts. More than 70% of guideline panel chairs listed a financial conflict, and more than 90% of co-chairs had a conflict.

"If past is prologue, we're not going to see much of a change," said Philip A. Mackowiak, MD, lead author of the study. "Anybody who wants to can basically produce guidelines. ... To a certain extent, it's like herding cats. There are too many different organizations out there, and no central authority they have to respond to."

The study appears to be the first since a May 26, 1999, article in *The Journal of the American Medical Association* to systematically examine guideline adherence to methodological standards. In that study, developers on average followed 43% of earlier standards promulgated by the American Medical Association and others.

In its 2011 standards, the IOM said guideline developers should make public how committee members were selected and what financial conflicts they have. Yet only 30% of guidelines included information about the committee selection process, and less than half included information on panel members' financial conflicts.

"We felt the most critical guidelines to insist that be followed are the ones on conflict of interest," said Dr. Mackowiak, vice chair of the Dept. of Medicine at the University of Maryland School of Medicine in Baltimore.

Evidence not always cited

Making a good guideline is about more than avoiding conflicts of interest, according to the IOM. The institute calls for guideline developers to include experts on statistics and methodology. Less than a quarter of guidelines had such experts as members. Also, about 35% of guidelines lacked information about the evidence supporting each individual recommendation in a guideline. Less than 10% of the guidelines studied described differences of opinion on the panel — another IOM standard.

The Agency for Healthcare Research and Quality's National Guideline Clearinghouse should require that guidelines meet IOM standards to be included on the website, said Terrence M. Shaneyfelt, MD, MPH, lead author of the 1999 *JAMA* study.

"They would have to meet a certain level of quality to be on there," said Dr. Shaneyfelt, associate professor of medicine at the University of Alabama School of Medicine at Birmingham. "Then you could go and use these guidelines and be fine. They would meet IOM criteria or be an AHRQ-certified guideline that was done properly. Then people could trust and use them."

Jean Slutsky, director of the AHRQ Center for Outcomes and Evidence, said the agency is determining how to apply the IOM's standards.

"We are reassessing the inclusion criteria for guidelines to be accepted on the clearinghouse in light of these new recommendations by the IOM," she said. "It will take a while to implement."

Any new criteria must be tested with developers and others to ensure that they are effective and widely understood, Slutsky said. The current standards for inclusion on the clearinghouse do not cover conflicts of interest, but do require documentation of a "systematic literature search and review of existing scientific evidence." More than 2,600 guidelines are listed.

Why standards adoption is sluggish

Several experts argued that it will take some time for the IOM's standards to be embraced more fully by clinical guideline developers such as physician organizations and government agencies. It takes about two years to develop a clinical practice guideline.

"It takes a while for momentum to build," said James N. Kirkpatrick, MD, assistant professor in the Division of Cardiovascular Medicine at the Perelman School of Medicine at the University of Pennsylvania. "If you're an organization you may say, 'This is tough for us to do. Let's wait' — until you can't ignore it anymore. That does tend to happen."

One difficulty is finding qualified people to serve on guideline panels who do not have financial ties to industry. Dr. Kirkpatrick is lead author of a March 28, 2011, *Archives of Internal Medicine* study that found financial conflicts among more

than half of the people serving on cardiovascular guideline panels between 2004 and 2008. That means, he said, that 44% of members had no financial conflicts, showing it is possible to find able individuals without conflicts of interest to staff guideline panels.

The IOM is not alone in pushing for higher standards in guideline development. In June 2011, the AMA adopted ethics policy saying clinical guidelines should not be directly funded by entities with a financial interest in the recommendations. "Scientifically rigorous methods and explicit standards" should be used to review and weigh evidence and expert judgment, the policy says. Also, guideline panels should include qualified clinical experts and methodologists. The ideal is that all members of the panel should have no financial conflicts. Where there are conflicts, they should be disclosed to everyone on the panel and mitigated by means such as barring conflicted individuals from voting or drafting.

The Council of Medical Specialty Societies, whose 39 member organizations together represent more than 700,000 U.S. physicians, adopted guideline-development standards as part of an April 2010 code on interactions with industry. Physician organizations signing the code agreed to require all members of guideline-writing committees to disclose financial relationships with industry, assure that a majority of panel members have no conflicts, and disclose any members' conflicts when publishing guidelines.

Practicing physicians may be frustrated by the plethora of clinical guidelines that vary in reliability and often conflict, Dr. Kirkpatrick said. But, he argued, they are key in the effort to reducing unwarranted clinical practice variation.

"Guidelines serve a purpose," he said. "They will never be perfect, but I still think they're the best we've got."

ADDITIONAL INFORMATION:

11 ways to make clinical guidelines trustworthy

Fewer than half of clinical practice guidelines meet most of the standards set by a 2011 Institute of Medicine committee. To increase the quality and reliability of guidelines, the IOM says guideline developers should:

- Explicitly and publicly detail how the guideline is developed and funded.
- Require all those serving on the guideline panel to declare and explain any conflicts of interest, and require them to divest themselves of financial investments that could be affected by the guideline panel's work.
- Ensure that a majority of the panel does not have conflicts of interest, and bar members with financial conflicts from serving as panel chairs or co-chairs. Exclude funders from any role in guideline development.
- Formulate a panel that is multidisciplinary and balanced, made up of a variety of methodological experts and clinicians, as well as patient representatives of populations likely to be affected by the guideline.
- Acquire training in how to appraise medical evidence. Use systematic reviews that meet IOM comparative effectiveness research standards.
- Include a clear description of potential benefits and harms of each recommendation.
- Summarize relevant available evidence and evidentiary gaps, as well as the quality, quantity and consistency of the evidence. Explain how values, opinion, theory and clinical experience help guide recommendations.
- Rate the level of confidence in the evidence underpinning the recommendations, as well as the strength of the recommendations. Describe any differences of opinion regarding the recommendations.
- Detail precisely what the recommended action is and under what circumstances it should be performed. Word recommendations in a way that compliance can be evaluated.
- Make a draft of the guideline publicly available when it is shared with external reviewers for evaluation.
- Monitor the literature regularly after guideline publication to identify new, potentially relevant evidence. Update the guideline if new evidence shows that a recommended intervention causes previously unknown substantial harm, or that a new intervention is significantly superior to a previously recommended intervention.

Source: "Clinical Practice Guidelines We Can Trust," Institute of Medicine, March 23, 2011 (iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx)

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"Failure of Clinical Practice Guidelines to Meet Institute of Medicine Standards: Two More Decades of Little, If Any, Progress," *Archives of Internal Medicine*, published online Oct. 22 (archinte.jamanetwork.com/article.aspx?doi=10.1001/2013.jamainternmed.56)

"In Guidelines We Cannot Trust: Comment on 'Failure of Clinical Practice Guidelines to Meet Institute of Medicine Standards,'" *Archives of Internal Medicine*, published online Oct. 22 (archinte.jamanetwork.com/article.aspx?doi=10.1001/2013.jamainternmed.335)

"Conflicts of Interest in Cardiovascular Clinical Practice Guidelines," *Archives of Internal Medicine*, March 28, 2011 (archinte.jamanetwork.com/article.aspx?doi=10.1001/archinternmed.2011.96)

"Are Guidelines Following Guidelines? The Methodological Quality of Clinical Practice Guidelines in the Peer-Reviewed Medical Literature," *The Journal of the American Medical Association*, May 26, 1999 (jama.jamanetwork.com/article.aspx?doi=10.1001/jama.281.20.1900)

"Clinical Practice Guidelines We Can Trust," Institute of Medicine, March 23, 2011 (www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx)

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