

## Drugs in the News – 2/25/09 – Reassessing Clinical Marketing Guidelines

Hi,

Below is an editorial that appeared in the February 25, 2009 *Journal of the American Medical Association* that mentions topics that are often discussed in the Drug Information classes: "... too many current guidelines have become marketing and opinion-based pieces ...."; and that guidelines are developed from the lowest level of evidence "expert opinion." Expert opinion has its roots in clinical experience.

This editorial accompanied research (*JAMA*. 2009; 301(8):831-841) that critically evaluated the scientific support for the current American College of Cardiology/American Heart Association (ACC/AHA) clinical practice guideline that concluded:

"Recommendations issued in current ACC/AHA clinical practice guidelines are largely developed from lower levels of evidence or expert opinion. The proportion of recommendations for which there is no conclusive evidence is also growing. These findings highlight the need to improve the process of writing guidelines and to expand the evidence base from which clinical practice guidelines are derived."

When faced with a clinical practice guideline refer to the MAARIE framework as part of the evaluation of the validity of the guideline.

Best,

## Reassessment of Clinical Practice Guidelines

### Go Gently Into That Good Night

Terrence M. Shaneyfelt, MD, MPH; Robert M. Centor, MD

*JAMA*. 2009;301(8):868-869.

In 1990, the Institute of Medicine proposed guideline development to reduce inappropriate health care variation by assisting patient and practitioner decisions.<sup>1</sup> Unfortunately, too many current guidelines have become marketing and opinion-based pieces, delivering directive rather than assistive statements.

Current use of the term *guideline* has strayed far from the original intent of the Institute of Medicine. Most current articles called "guidelines" are actually expert consensus reports. It is not surprising, then, that the article by Tricoci et al<sup>2</sup> in this issue of *JAMA* demonstrates that revisions of the American College of Cardiology (ACC)/American Heart Association (AHA) guidelines have shifted to more class II recommendations (conflicting evidence and/or divergence of opinion about the usefulness/efficacy of a procedure or treatment) and that 48% of the time, these recommendations are based on the lowest level of evidence (level C: expert opinion, case studies, or standards of care). This trend is especially disconcerting given the quantity of cardiovascular scientific literature published during the last decade.

The overreliance on expert opinion in guidelines is problematic. All guideline committees begin with implicit biases and values, which affects the recommendations they make.<sup>3</sup> However, bias may occur subconsciously and, therefore, go unrecognized. Converting data into recommendations requires subjective judgments; the value structure of the panel members molds those judgments.<sup>4</sup> Guideline consumers could adjust for these biases if guideline panels made their values and goals explicit, but usually they remain opaque.<sup>5</sup>

The most widely recognized bias is financial. Guidelines often have become marketing tools for device and pharmaceutical manufacturers. While the ACC and AHA receive no industry funding for guideline development, they do receive industry support to disseminate guideline products such as pocket guides. Financial ties between guideline panel members and industry are common. "Experts" on guideline panels are more likely to receive industry funding for research, consulting fees, and speakers' honoraria. In 1 study of 44 guidelines, 87% of the guideline authors had some form of industry tie.<sup>6</sup>

Other biases are also important. The specialty composition of a guideline panel likely influences guideline development. Specialty societies can use guidelines to enlarge that specialty's area of expertise in a competitive medical marketplace. Federal guideline committees may focus on limiting costs; committees influenced by industry are more likely to shape recommendations to accord with industry needs.

Guidelines have other limitations. Guidelines are often too narrowly focused on single diseases and are not patient focused. Patients seldom have single diseases, and few if any guidelines help clinicians in managing complexity.<sup>7</sup> Paradoxically, guidelines are also often too comprehensive, covering every possible intervention that could be appropriate for a patient with that single disease. Tricoci et al<sup>2</sup> found that in ACC/AHA guidelines with at least 1 revision, the number of recommendations increased 48% from the first guideline to the most recent version. If there is a main message in such guidelines, it is likely to be lost in the minutiae. Guidelines are not patient-specific enough to be useful and rarely allow for individualization of care. Most guidelines have a one-size-fits-all mentality and do not build flexibility or contextualization into the recommendations.<sup>5,7</sup> There are simply too many guidelines, often on the same topic. For instance, clinicians really do not need 10 different adult pharyngitis guidelines.<sup>8</sup> Moreover, guidelines are often out of date. The evidence base used to create guidelines changes quickly. Most guidelines become outdated after 5 years, and most guideline developers lack formal procedures for updating their guidelines.<sup>9-10</sup> The ACC/AHA guidelines are periodically updated, with updates taking a mean of 4.6 to 8.2 years until publication.<sup>2</sup>

As a result, many clinicians do not use guidelines. An even greater concern, however, is that some of these consensus statements are being turned into performance measures and other tools to critique the quality of physician care. This potential problem could be minimized if performance measures were derived from high-quality guidelines based on the highest level of evidence and applied to patients with a single disease requiring little clinical judgment and no attention to patient preferences. Using multiple single disease-focused quality indicators to judge the quality of care provided to older patients with multiple comorbidities creates another level of difficulty.<sup>7</sup> These patients require collaborative efforts to balance each patient's overall health status with the burdens, risks, and benefits of complex care, something single disease guidelines and their resultant quality indicators do not address.

If guidelines continue to exist, they need to undergo major changes. Recently, Sniderman and Furberg<sup>11</sup> called for reforming the guideline development process. Their suggestions could be strengthened further by not only creating codes to "govern conflict of interest," as

disclosure and governance alone will not ensure unbiased recommendations, but also by guideline panel membership limiting (if not excluding) those with financial or other potential conflicts of interest or at least being balanced by members having no conflicts of interest. Only when likely biases of industry and specialty societies have been either removed or overcome by countervailing interests can impartial recommendations be achieved.

The time has come for guideline development to again be centralized, for example under the guidance of the Agency for Healthcare Research and Quality or a group similar to the US Preventive Services Task Force. Such centralization should help reduce bias and redundancy and better guide the research agenda. The US Department of Health and Human Services seems best suited to fund guideline endeavors.

In addition, guideline development needs to be prioritized. Guidelines are not necessary for every disease but are needed for diseases having significant practice variability and for which a valid evidence base can guide recommendations. Within a guideline document, individual recommendations also need to be prioritized. For instance, recommending that a symptomatic heart failure patient with decreased ejection fraction should receive an angiotensin-converting enzyme inhibitor is clearly more important than repeatedly documenting left ventricular systolic function.<sup>12</sup>

Finally, guidelines need flexibility. Clinical guidelines are supposed to be guides, not rules, and one size certainly does not fit all patients. Recommendations should vary based on patient comorbidities, the health care setting, and patient values and preferences. If flexibility is to be taken seriously, the nearly automatic translation of guidelines into performance measures would require renewed attention.

These recommendations are not new but need to be heeded. However, it seems unlikely that substantial change will occur because many guideline developers seem set in their ways. If all that can be produced are biased, minimally applicable consensus statements, perhaps guidelines should be avoided completely. Unless there is evidence of appropriate changes in the guideline process, clinicians and policy makers must reject calls for adherence to guidelines. Physicians would be better off making clinical decisions based on valid primary data.

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