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Guidelines for treating patients with cardiovascular disease often based on weaker evidence

An examination of clinical practice guidelines for treating cardiovascular disease finds that current recommendations are largely based on lower levels of evidence or expert opinion, according to a study in the February 25 issue of *JAMA*.

Clinical practice guidelines are developed to assist practitioners with decisions about appropriate health care for specific patients' circumstances, and are often assumed to be the standard of evidence-based medicine, according to background information in the article.

For more than 20 years, the American College of Cardiology (ACC) and the American Heart Association (AHA) have released clinical practice guidelines to provide recommendations on care of patients with cardiovascular disease. The ACC/AHA guidelines currently use a grading scheme based on level of evidence and class of recommendation. The level of evidence classification combines an objective description of the existence and the types of studies supporting the recommendation and expert consensus, and are categorized as A (higher level of evidence), B, or C [lower level of evidence].

The class of recommendation designation indicates the strength of a recommendation and requires guideline writers not only to make a judgment about the relative strengths and weaknesses of the study data but also to make a value judgment about the relative importance of the risks and benefits identified by the evidence. Classes include I (evidence that a treatment or procedure is effective), II, IIa, IIb and III (evidence that a treatment or procedure is not effective).

Whether the increase in publication of studies concerning cardiovascular disease has resulted in guideline recommendations with more certainty and supporting evidence is not known. Pierluigi Tricoci, M.D., M.H.S., Ph.D., of Duke University, Durham, N.C., and colleagues examined the changes in recommendations in ACC/AHA cardiovascular guidelines and evaluated the adequacy of evidence behind current guideline recommendations. The analysis included data

from ACC/AHA practice guidelines issued from 1984 to September 2008. Fifty-three guidelines on 22 topics, including a total of 7,196 recommendations, were examined.

Considering only the current guidelines with at least 1 revision, the total number of recommendations has increased from 1,330 to 1,973 (48 percent increase) from the first guideline to the current version. Overall, the guidelines shifted to more class II recommendations and fewer class III recommendations, while the use of class I recommendations remained fairly constant over time. The 16 current guidelines reporting levels of evidence, comprising a total of 2,711 recommendations, classify 314 recommendations as level of evidence A (median [midpoint], 11 percent), and 1,246 with level of evidence C (median, 48 percent).

Among all 1,305 class I recommendations of guidelines reporting level of evidence, only 245 have level of evidence A (median, 19 percent), with 481 (median, 36 percent) having a level of evidence C. Level of evidence significantly varies across categories of guidelines (disease, intervention, or diagnostic) and across individual guidelines.

"Our finding that a large proportion of recommendations in ACC/AHA guidelines are based on lower levels of evidence or expert opinion highlights deficiencies in the sources of definitive data available for the generation of cardiovascular guidelines. To remedy this problem, the medical research community needs to streamline clinical trials, focus on areas of deficient evidence, and expand funding for clinical research. In addition, the process of developing guidelines needs to be improved with information about the impact that recommendations based on lower levels of evidence has on clinical practice. Finally, clinicians need to exercise caution when considering recommendations not supported by solid evidence," the authors conclude.

(*JAMA*. 2009;301[8]:831-841. Available pre-embargo to the media at www.jamamedia.org)

Editor's Note: Please see the article for additional information, including other authors, author contributions and affiliations, financial disclosures, funding and support, etc.

Editorial: Reassessment of Clinical Practice Guidelines - Go Gently Into That Good Night

In an accompanying editorial, Terrence M. Shaneyfelt, M.D., M.P.H., and Robert M. Centor, M.D., of the University of Alabama School of Medicine, Birmingham, write that if clinical practice guidelines are going to continue to exist, they need to undergo major changes.

"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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(*JAMA*. 2009; 301[8]:868-869. Available pre-embargo to the media at www.jamamedia.org)

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