In 1990, the Institute of Medicine proposed guideline development to reduce inappropriate health care variation by assisting patient and practitioner decisions. Clinical guidelines for cardiac arrhythmias, like guidelines in other disciplines of medicine, are developed by organizations primarily to assist health care providers in clinical decision-making. They describe a range of generally acceptable approaches for the diagnosis, management, and prevention of specific diseases or conditions. Practice guidelines represent a consensus of expert opinion after a thorough and systematic review of the available current scientific evidence. The primary objective of guidelines is to improve the quality of clinical care and thereby improve patient outcomes.

Although formal methodologies for guideline development exist for all organizations, there is some variation in policies. Common elements of all include development of recommendations using the familiar class I, IIa, IIb, and III scheme, based on a comprehensive review of the literature using the principles of evidence-based medicine. The level of evidence is classified as A, B, or C, based on standard criteria. If the data were derived from multiple randomized clinical trials or meta-analyses, it is currently considered level A. In less contemporary guidelines, a single randomized trial was considered adequate for the evidence to be classified as level A. Currently, guideline committees rank evidence as level B when data were derived from a single randomized trial or nonrandomized studies. Evidence is ranked as level C when data were correctly cited and met the criteria of multiple prospective randomized trials. Only clearly defined positive (class I) recommendation was analyzed to assess if the references were correctly cited and met the criteria of multiple prospective randomized trials. Only clearly defined positive (class I) and negative (class III) recommendations with level of evidence A were assessed. A median of 5.4% of all recommendations per guideline were categorized as level of evidence A. However, only 3.7% of the total references were accurately referenced as level of evidence A according to the review of the primary references performed by the authors. On the basis of their analysis, the authors conclude that their findings raise the question of the accuracy of level of evidence in medical guidelines in general. The authors highlight the importance of a “critical use of all recommendations.” They also note that their findings underline the need for improving the guideline writing process. Finally, they...
conclude that further randomized double-blinded and/or crossover designed studies should focus on areas with a gap in the evidence, such as existing but not yet convincing (level of evidence B) or conflicting (class II) evidence.  

Guidelines guide. Physicians and patients decide. Despite these fundamental principles of evidence-based medicine, the authors of this analysis note that guidelines are “often perceived as evidence-based and valid and have become the final arbiters of care for many clinicians.” Other critics of guidelines have a similar refrain that “for many clinicians guidelines have become the final arbiter of care.” This premise is unrefereed and is not aligned with the guidance provided by organizations and guideline writing groups. The notion that guidelines are the “final arbiter of care” is inconsistent with the principle that guidelines attempt to define practices that meet the needs of most patients in most circumstances. These guidelines related to cardiac arrhythmias, like guidelines in other areas of medicine, contain language indicating that the ultimate judgment regarding care of a particular patient must be made by the health care provider and patient in light of the patient’s circumstances. All clinicians should understand that circumstances arise in the practice of medicine in which deviations from recommendations made in the guidelines are appropriate. Guideline documents emphasize that clinical decision making should carefully weigh the quality and availability of the evidence in making decisions for the individual patient. Guideline committees recognize in their published documents that situations arise for which additional data are needed to better inform patient care. These areas are now routinely identified within each respective guideline, with suggestions for clinical studies to bridge the knowledge gaps.

Under ideal circumstances, the practice of clinical medicine should be entirely based on the highest standards of evidence-based medicine. A fundamental principle of evidence-based medicine is that clinical practice should be based on the results of appropriately designed clinical trials, using meaningful end points. It is evident that only a minority of the decisions made in the practice of medicine are based on prospective randomized trials. Practicing evidence-based medicine, defined as the integration of the best research evidence with the patient’s values in clinical decision-making, is a process that falls far short of perfection. Although the practice of medicine, like the writing of guidelines, strives to be evidence-based, neither can it be derived solely from the highest levels of evidence. On most issues in clinical medicine, the evidence is less than complete and conclusive. When gaps in evidence are present, the need exists to provide guidance to clinicians, based on lower levels of evidence. These lower levels include single randomized trials, observational studies, registries, case reports, experience, and clinical judgment. It is evident that gaps in knowledge are a shortcoming of the process of clinical investigation rather than a shortcoming of the guideline methodology. All contemporary guidelines note gaps in knowledge and encourage appropriately designed trials to address them.

Guidelines remain a constructive response to the reality that the practicing physician requires assistance to assimilate and apply the exponentially expanding body of medical knowledge. The methodology has been continuously improved over the last 2 decades. Higher standards of evidence have evolved. More systematic and robust methodological approaches are now required. Guideline committees are now chaired and constituted by a majority of members who are free of relationships with industry. Statisticians and methodologists have been added to many committees. Rigorous critical peer review processes are in place, with modifications of the documents and written responses to all comments required. Transparency and accountability are fundamental principles that guide the policies related to guideline development. Conflicts of interest for members of the writing committees and reviewers are published.

Recently, a focused update process has been instituted to revise the existing guideline recommendations that are affected by evolving science. Before the initiation of this focused approach, periodic updates and revisions of existing guidelines required up to 3 years to complete. Now, however, new evidence will be reviewed in an ongoing fashion to more efficiently respond to important science and treatment trends that could have a major impact on patient outcomes and quality of care. Despite the sincere efforts of organizations and guideline writing committee members to constructively address shortcomings, both the evidence base and the methodology are, and will, remain imperfect.

There have been 2413 guidelines published by 267 organizations over the last 2 decades. Although the evidence base and process for guideline writing remain imperfect, there has been a sincere effort by all involved to continuously improve the process and provide the best guidance using the best available data to guide clinicians. Despite the acknowledged limitations, there is ample evidence that the use of guidelines improves patient outcomes. Quality improvement programs based on guidelines have been demonstrated to increase the use of appropriate medical therapies and to enhance patient outcomes. Guideline writing committees and oversight bodies have been extremely responsive to the limitations noted to the process with multiple modifications to objectively assess and classify the best available evidence in a timely and unbiased fashion.

In this respect, the critical review published in this issue of Circulation Arrhythmias and Electrophysiology should be considered as an opportunity for continued improvement with attention to reviewing and accurately citing the primary data rather than secondary sources. However, when considered in a balanced and larger context, even if as this analysis states, the references related to the level A evidence are not entirely accurate in their attribution to the primary data in randomized controlled trials, it would have minimal impact on the recommendation in the guidelines evaluated. The implications for the guideline writing committees might be that the systematic review of references and primary data may need improvement to more accurately assess the level of evidence. The implications for clinicians using the guidelines to make informed decisions to improve the quality of clinical care and thereby improve patient outcomes are inconsequential. It is clear that there has been considerable progress in adhering to the fundamental principles of evidence-based medicine and refinement of the guideline methodology over the last 2
decades. It is also evident that despite continued progress of the guideline methodology with more robust clinical evidence analysis and assessment of patient outcomes, this process will never achieve perfection.

**Disclosures**

Dr Estes has received modest consulting fees from Boston Scientific.

**References**


