EDITORIAL

A Review of Clinical Guidelines with Some Thoughts about Their Utility and Appropriate Use

I recently wrote an editorial in *The American Journal of Medicine* exploring physician behavior with respect to guidelines and their use or nonuse. Many readers of *The American Journal of Medicine* responded with examples of the challenges each has faced in following guidelines and building toward quality care. These experiences and my own led me to take those thoughts one step further toward how they can be utilized in everyday practice, and so this essay was born.

“Guidelines” has become one of the most common buzzwords for medical practitioners in the 21st century in our search to define and measure quality in health care. Physicians and other health care workers, administrators, bureaucrats, and politicians have all become involved in discussions concerning the attainment of quality in our medical care system. This is not a new movement. Quality assurance, often referred to as best practices, has been a hot topic in hospitals and health care systems for more than 2 decades. Recently, politicians and bureaucrats in the federal government have begun discussing ways to improve health outcomes in the US, considering various combinations of strategic initiatives that would include electronic health records with embedded recommendations for best practices in diagnosis and therapy. Professional societies have created literally hundreds of guideline documents with discrete best practices recommendations to follow when dealing with a variety of medical and surgical conditions. My colleagues and I at the University of Arizona Health Science Center frequently discuss the utility of these clinical guidelines. A constant concern is how to interpret the recommendations in the face of constantly evolving scientific information and conflicting recommendations from different learned societies. This essay is an attempt to clarify the definition of clinical guidelines, including strengths and weaknesses, as well as to present my suggestion on how best to utilize these recommendations in the daily practice of medicine.

In order to think clearly about guidelines, it is necessary to define exactly what these entities are and what kind of information they contain. Webster’s online dictionary defines guidelines as “guidance relative to setting standards or determining a course of action; a rule or principle that provides guidance to appropriate behavior.” Note that this definition does not describe a guideline as a commandment or a law that must be strictly obeyed. Rather, according to this definition, guidelines are principles or rules that help to define a possible course of action. Thus, a guideline helps to direct appropriate behavior, but it does not mandate that a particular behavior must be followed without fail.

During my career, I have served on a number of task forces charged with writing cardiovascular guidelines for a variety of diseases. I also have served on the parent committee of the American College of Cardiology/American Heart Association (ACC/AHA) charged with the preparation of guidelines. Committee members are all experts in cardiovascular disease with an in-depth knowledge of the condition for which the guideline is being written. Task force members spend many hours reading and summarizing the relevant medical literature pertaining to the disease being addressed. There is a constant and conscious effort to base guideline recommendations on the latest scientific information, that is, to make the guidelines evidence-based. Considerable thought, energy, and even emotion are expended in order to produce a guideline that is comprehensive, up to date, and practical. It is of interest, however, that as many as half of the recommendations contained in these guidelines are based on experienced opinion and not scientific data. The unfortunate truth is that many questions in clinical science have yet to be answered in sufficient detail to allow all of the recommendations in guidelines to be evidence-based.

Following preparation of each ACC/AHA guideline, various reviewers are asked to examine the as-yet-unpublished document and offer criticism. Each guideline document passes through multiple reviews that eventually lead to a number of additions and corrections. Every effort is expended by task force members to reach consensus concerning the specific protocols presented in each guideline. Once the guideline is published, both the ACC and the AHA invest considerable energy and resources in order to call attention to the recommendations. In the daily practice of clinical assessment, the published guidelines are often referred to when “best practices” are discussed. The guidelines are often quoted as the “gold...
standard” for a variety of quality assessments involving hospital and individual practitioner activities.

**POSITIVE CHARACTERISTICS OF GUIDELINES**

Many authorities believe that use of standardized guidelines exerts a positive influence on the quality and efficiency of clinical care. What are some of the potential benefits that accompany guideline implementation? As already noted, guidelines are evidence-based as much as possible, the result of meticulous review of decades of scientific study. In areas where scientific evidence is lacking or incomplete, guideline recommendations are the result of extensive accumulated clinical experience. Thus, they represent consensus opinions assembled by some of the best minds currently involved in clinical medicine. Indeed, clinical studies have documented that when guidelines are followed, patient outcomes are improved compared with care that is not guideline driven.

In addition, the nature of guidelines enables physicians and hospitals to embed standardized order sets into the daily work routine of various care sites, and thereby simplify and shorten the process required for initiating various clinical care protocols. Guidelines also assist caregivers when they explain to patients why a particular strategy is being suggested. Administrators who monitor quality of care for specific diseases usually utilize guideline documents as the basis for their studies. Finally, when standardized guidelines are employed, economic analyses by systems of care are simplified.

**NEGATIVE CHARACTERISTICS OF GUIDELINES**

Unfortunately, guideline usage, when implemented, also has some negative implications. One of the most troublesome characteristics of guidelines is that they represent, as noted above, recommendations and not commandments. At times, this definition is forgotten, and guideline recommendations are implemented without careful thought as to possible contraindications for a particular patient.

A second negative quality embedded in the guideline process is that they are, by nature, evolving documents. Physicians need to bear in mind that recommendations can and will change, often within a very short time frame.

Another troublesome aspect of guidelines involves preparation and promulgation by different professional societies, with the result that conflicting recommendations may be advised. It is easy to see how difficult decision-making can be for a clinician facing 2 guideline recommendations, with one guideline suggesting a particular strategy and another guideline for the same illness advising a different approach. At times, these differences in guideline recommendations are the result of different national approaches to clinical care, for example, North American versus European guidelines. At other times, differences are the result of conflicting philosophies of care, for example, guidelines prepared by primary care versus specialist societies.

Yet one more vexing problem associated with guideline use relates to physician failure to follow the practices advised in the guidelines. In the editorial that I referred to at the beginning of this essay, 5 reasons are cited for physician failure to follow guideline advice:

1. Many hundreds of guidelines currently exist, some of which are hundreds of pages in length. This large volume of material represents a nearly insurmountable burden for physicians whose clinical workload is already considerable.
2. Over years of practice, clinicians develop “tried and true” treatment approaches for common diseases. Changing successful personal practices may be seen by physicians as an unnecessary imposition.
3. Traditionally, physicians-in-training have been encouraged to provide individualized patient care and avoid a “cookbook” approach to medicine.
4. Physicians and patients often feel that some of the diagnostic or therapeutic recommendations embedded in guidelines are burdensome or associated with potentially unpleasant outcomes, thereby leading to rejection of that particular recommendation.
5. The results of large clinical trials are applicable to most patients but not all. Physicians may offer a disease management approach that is different from what is recommended by the guidelines because their patient does not have the same characteristics as those included in the research trials.

Undoubtedly, other reasons also exist for physician and patient noncompliance with guideline advice. This topic is currently of great interest in the academic and private practice medical communities. Hardly a week passes without an article on quality appearing in one or another of the major peer-reviewed medical journals published in the US. Many of these investigations involve physician behavior with respect to guidelines.

**RECOMMENDATIONS FOR USING GUIDELINES EFFECTIVELY**

Despite some potential negative consequences associated with guideline usage, I am convinced that clinical guidelines do represent an important instrument for managing patients. However, these recommendations need to be employed in a rational and commonsense manner, with careful attention paid to exceptions and contraindications. Below are listed 10 recommendations for improved utilization of guidelines.

1. Physicians should strive to utilize standardized, evidence-based guideline recommendations as much as possible when such advice seems reasonable and appropriate for a particular patient.
2. Physicians should bear in mind that clinical guidelines are recommendations and not commandments or laws that must be strictly followed. There will be
many exceptions, contraindications, and reasons not to implement a particular guideline in a specific patient. It should be borne in mind that guidelines are always in evolution: today’s guideline will almost certainly not be the same document in 2 or 5 or 10 years.

3. It is very nearly impossible for clinicians to memorize all the details of relevant guidelines, especially those with frequent updates and revisions. Consequently, updated, standardized order sets (printed or digital) are needed to provide clinicians with an opportunity to utilize guidelines efficiently. Standardized order sets should contain options for physicians to delete or refuse the recommended course of action. Such exceptions must contain a means whereby the doctor can document why this particular recommendation was not followed. In my opinion, the ideal solution would be to have these standardized orders embedded in the electronic medical record. These standard protocols would be automatically activated when the clinical record was accessed and a specific diagnosis was entered. Each time the doctor chose *not* to implement a particular strategy, another drop-down box would appear with a number of alternative choices explaining why this particular recommendation was not chosen. For example, “patient refuses.” Of course, within this list, one choice would always have to be “other” and would require explanation.

4. Documentation in the medical record of reasons why a particular option was deleted or not chosen is essential when guideline recommendations are not followed. This is necessary because quality reviews or “pay for performance” reimbursement will downgrade physician performance if an explanation for failure to follow a guideline suggestion is not included in the patient’s medical record.

5. Common sense and knowledgeable, experienced clinical judgment is required when standardized order sets are utilized. Physicians need to consider contraindications, patient preference, likelihood of compliance, and cost when selecting or avoiding a guideline recommendation. It is not rational to select a guideline recommendation, for example, a specific drug prescription, if it is unlikely that the patient will comply with this therapy either because of cost or other personal choice.

6. Guideline writing committees need to exercise economy of word when preparing guidelines. Every effort should be made to make guideline recommendations straightforward, terse, and comprehensible. I suggest the following maxim in guideline preparation: “No document exists that would not be improved by condensation.”

7. Undergraduate, postgraduate, and continuing medical education programs should emphasize evidence- and experience-based clinical strategies contained within guidelines.

8. Grant funding agencies and industry should strongly support outcomes-oriented clinical research that will expand the knowledge leading to evidence-based guideline recommendations. Current guidelines are based on scientific evidence for approximately 50% of recommendations. The remainder of these recommendations is based on experiential consensus among the writers of the guideline.

9. Strong encouragement should be given to potentially competing professional societies to work collaboratively in preparing clinical guidelines in order to avoid confusing and opposing recommendations.

10. Hospitals, clinics, offices, and integrated health systems should have a well-developed program in place for updating guideline recommendations in standard order sets as these become available.

I do not anticipate that all of the approaches recommended in this essay will be adopted or effectively implemented in the near future. However, if physicians are to practice efficient, scientifically based medicine resulting in the best possible outcomes for patients, incorporation of clinical guidelines into daily practice is a necessity.

As always, feel free to comment on this editorial or other *Journal* articles on our blog: http://amjmed.blogspot.com.

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