Do Clinical Practice Guidelines Define Good Medical Care?*

The Need for Good Science and the Disclosure of Uncertainty When Defining ‘Best Practices’

Steven H. Woolf, MD, MPH

Clinical practice guidelines are all around us. They tell us which diagnostic tests and treatments are appropriate and the best way to perform clinical procedures. We encounter them at all levels: locally, in protocols and practice policies issued by community hospitals and provider groups; regionally, in guidelines issued by managed-care organizations, integrated health systems, disease management programs, and state legislation; and nationally, in guidelines issued by federal agencies (eg, Agency for Health Care Policy and Research, Centers for Disease Control and Prevention), medical specialty societies, independent panels, private quality assurance firms, accreditation bodies, and voluntary associations. Estimates of the number of practice guidelines in the United States range from 1,800¹ to >26,000.²

Benefits and Harms

The enthusiasm over practice guidelines stems from the widely held belief that they improve the quality of care,³ By promoting clinical practices of proven effectiveness, guidelines can help optimize patient outcomes and discourage the performance of ineffective or harmful interventions. Adherence to guidelines can improve the consistency of care, so that patients with similar conditions will be treated according to the same protocol regardless of where, or from whom, they receive care. Guidelines developed from a systematic review of the evidence focus attention on gaps in the evidence and thereby help prioritize future research. Guidelines can help avoid inefficiencies and optimize the value of health-care expenditures by identifying practices that are unnecessary or unduly expensive.⁴

There are, however, potential harms from practice guidelines. The attempt to standardize care ignores the heterogeneity of patients and the complexity of medical decisions. The clinical circumstances of each patient may mean that recommendations that are reasonable for patients as a whole may be inappropriate for specific individuals. The encouragement, if not requirement, of physicians to comply with recommendations may mean that the interest of patients with special circumstances may either be sacrificed to achieve compliance or, alternatively, that both clinician and patient may face inconveniences (or more punitive action) for deviating from the guideline. Practice guidelines can create medicolegal difficulties by setting an arbitrary standard of care that can be cited in court.⁵ Guidelines that advocate expensive tests and treatments can, by increasing costs, frustrate the efforts of those who wish to control expenditures.⁴

From the perspective of patients and most clinicians, what matters most about practice guidelines is whether they define good medical care. If they do, both patients and clinicians would support efforts to promote the implementation of such guidelines and would readily accept practitioner compliance with them as a valid indicator of the quality of care. Most people, especially those who are naive about the process of guideline development, assume that guidelines do define optimal care. Those who are experienced with guideline development and astute clinicians know, however, that this is not always the case. The caliber of practice guidelines is not universal and, even when based on scientific evidence, the recommendations may not advocate what is truly best for patients.

*From the Department of Family Practice, Medical College of Virginia, Fairfax.

(CHEST 1998; 113:1668-171S)
WHY WOULD PRACTICE GUIDELINES NOT ADVOCATE OPTIMAL CARE?

There are several reasons why practice guidelines do not always recommend the best options for patients. The first is the general lack of scientific evidence for determining what is and is not optimal care. A data-driven approach to defining best practices is impossible when outcomes data are lacking or when existing studies are of poor quality or produce conflicting results. Even when internally valid evidence is available, attitudes often differ on the appropriateness of generalizing results to other patient populations, providers, and clinical settings that differ from those examined in studies. Under such conditions of uncertainty, the medical community may be blind to what truly constitutes optimal care. Recommendations based on flawed data or misguided interpretations of the evidence may not advocate the best choices for patients.

Second, even when the evidence is clear, the process of guideline development, in which experts in a conference room review the evidence and craft recommendations, introduces a host of human influences on the decision-making process. Expert opinion, although often helpful in outlining prudent clinical care, can also introduce flawed beliefs based on outdated assumptions. The history of medicine is replete with examples of ineffective or harmful treatments that, in their time, received the enthusiastic support of experts convinced of their value.

Opinions about appropriate recommendations are also influenced by other human factors, such as personal biases from clinical experience, how one was trained, self-interest (eg, concerns over how the recommendations will affect one's specialty, reimbursement, and medicolegal liability), and fatigue from the tedious work of guideline development. The recommendations may give special attention to agendas other than those of the patient. For example, cost considerations may be given greater weight if the guideline developer is a payer (“HMOs: How much, not how well,” Washington Post, F1, F3, January 19, 1996). The most effective intervention may be passed over if a more cost-effective alternative is available. The final recommendation may recommend what is best for society but not for patients.

Third, even if the guideline advocates what is best for patients as a group, the recommended approach may be inoptimal for individuals with special clinical circumstances. The patient’s medical history, family history, health status, life expectancy, social circumstances, and personal preferences may mean that he or she would do better with an approach other than that recommended for most persons with the condition. Practice guidelines that do not accommodate these differences in clinical presentation and personal preferences may consistently promote inoptimal care for an important subgroup of patients in need.

Given these considerations, it seems obvious that the veracity of practice guidelines cannot be accepted on face value, yet such wholesale acceptance is common. Health plans and practice managers often “demonstrate” the quality of their care by simply indicating that they have developed and follow practice guidelines, saying little about what the guidelines recommend or how they were developed. Without this critical information, adherence to guidelines only proves that practice patterns are consistent, not that patients are receiving the best care possible. Conclusions about the quality of the guidelines and whether they advocate good medical practice can only be reached when the content of the recommendations and rationale are made available for critical appraisal.

How, then, should one determine whether a practice guideline advocates the best care for patients? Key factors that warrant consideration are described elsewhere, but the two most important are the quality of the science and the disclosure of uncertainty.

QUALITY OF THE SCIENCE

Interventions recommended in practice guidelines are most likely to benefit patients if well-designed clinical studies have demonstrated that patients who receive the interventions enjoy better health outcomes than those treated by other methods. Practice guidelines often make this claim by simply citing references, but they cannot be considered “evidence-based” unless they properly describe how the evidence was collected and evaluated and how the results were translated into recommendations. Without knowing how the evidence was collected and evaluated, one cannot determine whether the interpretation of the evidence was biased by the selective retrieval of supportive publications and whether study results were mistakenly accepted on face value irrespective of their quality and design flaws. Without knowing how the results were translated into recommendations, one cannot know how (or whether) the evidence influenced the final guidelines and the extent to which the strength of the recommendations was linked to the quality of the evidence.

Part of good science is clarifying where evidence ends and opinion begins. Guidelines should specify what has been proved and what remains uncertain.
Expert opinion and first-hand experience can play a legitimate role in filling these gaps; one need not always have formal research evidence to know what is the best care for patients.\textsuperscript{20} The need for immediate surgical intervention for a lacerated aorta does not require a clinical trial. Regardless of how self-evident the arguments seem, however, the rationale for the recommendations must be stated explicitly so that the extent to which the arguments derive from expert opinion and clinical experience is made clear to the reader. This disclosure is important because clinicians have different views about the appropriateness of relying on opinion and experience to infer benefit.\textsuperscript{21} Providing a clear rationale statement “puts all the cards on the table,” allowing clinicians and patients to judge whether they agree with the arguments and giving them the freedom to reach their own conclusions.

**DISCLOSURE OF UNCERTAINTY**

Given the three causes of inoptimal guidelines outlined above, it follows that complete confidence that a practice guideline recommends the best care for patients can exist only when there is (1) no controversy about the magnitude of benefits and harms of the intervention(s), (2) no bias or self-interest in the process of making the recommendations, and (3) no circumstances in which an individual patient would do better to follow a different approach. Although there are occasions in which all three of these conditions apply, they are extremely uncommon. For most practice guidelines, uncertainty exists in each area.

Guidelines that recommend the best care for patients are honest about these uncertainties and incorporate appropriate flexibility to accommodate them. In describing the likely benefits and harms, they acknowledge the uncertainties in the scientific evidence, catalog the weaknesses in study designs, and display the width of confidence intervals for estimated outcomes. They admit the statistical uncertainty of their assumptions, noting for example that the failure of a clinical trial to prove effectiveness does not necessarily prove ineffectiveness or, conversely, that an observed effect may be due to chance.

When recommendations are based on opinion, good guidelines document the use of opinion, acknowledge the existence of differing opinions, and leave room for legitimate disagreement. They disclose the factors other than health outcomes (eg, concerns about costs, feasibility, medicolegal consequences) that influenced the conclusions and allow that those who are not constrained by such concerns might consider other choices that could achieve better patient outcomes. Finally, good guidelines clarify that patients and clinical circumstances are not homogeneous and should state explicitly that it is often appropriate to depart from the recommendations to individualize care.

The disclosure of uncertainty takes center stage in the wording of recommendations and the design of algorithms.\textsuperscript{22} Rigid guidelines with inflexible instructions (eg, “All patients should be referred to a nephrologist . . .”) or quantitative thresholds (eg, “Hemodynamic monitoring should be performed for 12 hours . . .”) are only appropriate when there is good scientific evidence that patients treated otherwise will experience poorer health outcomes. More commonly, such recommendations are based on opinion, and numbers (eg, “12 hours”) are chosen arbitrarily and included in guidelines to enhance clarity. This is done partly in response to criticisms that guidelines with more ambiguous statements (eg, “The optimal duration of hemodynamic monitoring is uncertain . . .”) give little practical advice to clinicians.\textsuperscript{23} However, clarity is a double-edged sword, since numbers and thresholds provide a convenient tool for utilization reviewers, malpractice attorneys, and others to judge clinicians and the quality of care they provide.\textsuperscript{24,25} Such tools are justified if there is hard science behind them. A guideline that specifies “12 hours” without scientific grounds, however, might be used punitively in unfair sanctions against clinicians who might have legitimate scientific or clinical arguments to monitor for more or less time.

Similarly, the design of algorithms (eg, decision trees) in practice guidelines, especially when they are simplified to fit on one page to eliminate complexity, can obfuscate uncertainties and oversimplify clinical decisions. Examples of such oversights include the following: reducing a complex medical decision to a binary “yes/no” choice; omitting important options at decision nodes; presenting decisions in a linear fashion that are properly approached in conjugate because of their complex interrelationships; and failing to recognize “feedback loops” that require the repetition of tests and treatments. Medical decisions that must incorporate a multitude of clinical variables and an understanding of the pathophysiology of the disease often cannot be replicated by a simple line diagram with arrows and boxes. Attempting to do so, and requiring clinicians (or staff with less medical training) to follow such algorithms, endangers consistency but, for many medical decisions, bypasses clinical judgment and endangers patients who require a more individualized approach.
The Key Steps in Guideline Development

These potential harms from poorly constructed practice guidelines underscore the importance of using proper methods when they are developed. Guideline development methods include informal consensus development (unstructured, subjective group judgment), formal consensus development (standardized opinion gathering), evidence-based methods (direct linkage of recommendations with supporting science), and explicit approaches (projections of likely benefits, harms, and costs).19 The methods for developing evidence-based practice guidelines, the currently favored approach, are detailed elsewhere.19,26,27 They include the following steps:

Definition of Topic and Process

The topic of the practice guideline should be defined in precise terms, specifying the target condition, intervention(s), patient population, and clinical settings to be included in the review.19,28 The types of scientific evidence that will be considered and the outcome measures to be used for defining effectiveness and safety should also be defined.

Assessment of Clinical Benefits and Harms

For clinicians and patients, the first priority in determining what to recommend is to assess the potential health benefits and harms associated with available interventions. All evidence-based guideline panels examine scientific evidence to make these assessments, and some panels also consider expert opinion.

Review of Scientific Evidence: A systematic review of the evidence involves three steps: (1) literature retrieval, a comprehensive, computerized/manual search of the literature to identify all relevant studies within the boundaries of admissible evidence agreed on by the panel,29 (2) evaluation of individual studies, using systematic methods to judge and grade the quality of the evidence and to abstract the results;30-32 and (3) synthesis of the evidence, summarizing the results of multiple studies using narrative reviews, evidence tables, meta-analysis, decision analysis, and other techniques to pool data.33-35

Consideration of Expert Opinion: Expert opinion can be gathered from the panel itself or by seeking broader input from outside experts, an open forum, or specialty-wide surveys. Methods of assessing opinion and determining when consensus has been reached range from informal methods (eg, open discussion, “show of hands”) to more formal techniques that provide a quantitative basis for analyzing the strength and agreement of opinions.36,37

Consideration of Resource and Feasibility Issues

Resource issues, such as the cost, personnel, and technology required to implement the intervention(s) under consideration must be examined. In an era of limited health-care dollars, practice guidelines must often include cost-effectiveness and cost-utility analyses to justify the affordability of recommendations.12,38 Feasibility issues must also be considered, such as whether clinicians have the time, training, and staff support to implement the intervention(s) and the potential medicolegal, reimbursement, and public policy implications.

Development of Recommendations

The above considerations (science and opinion about the benefits and harms, resource and feasibility issues) provide the basis for deciding what to recommend. Well-developed guidelines use formal decision rules or checklists to promote a systematic approach to arriving at recommendations and provide an explicit rationale for others to judge the process. Recommendations are often graded (eg, “A, B, C. . .”) to indicate the strength of the recommendations and the extent to which they are supported by scientific evidence.31

Writing the Guideline

Guideline documents are now often published in several formats, including a short version for busy clinicians that encapsulates the recommendations, a lengthier monograph that summarizes the scientific evidence and rationale, and a consumer version for patients. As noted above, the precise wording of the recommendations warrants special attention.22 Especially when the “best choice” for patients depends on personal preferences, guidelines often encourage shared decision-making with patients34 and may include “balance sheets.”39 The latter summarize the likely benefits and harms of available options, which the patient and clinician can review together to determine which choice is best for that individual.

Outside Review

To verify that the review of the scientific evidence and consideration of clinical issues is thorough, balanced, and accurate, it is important to have the draft document reviewed by content experts (researchers, experienced clinicians, government health agencies) and by appropriate methodologists (eg, biostatisticians, epidemiologists, decision analysts). Implementation and “buy in” of the guideline is facilitated by seeking input from relevant specialty societies and other organizations and agencies that can play an active role in promoting endorsement and implementation.
CONCLUSION

Even when guidelines define optimal medical care, studies consistently show that they are unlikely to be effective in changing practice behavior unless the production of the recommendations is coupled with effective implementation strategies.40,41 Of these, perhaps the most important is the active involvement of the local providers who will be responsible for implementing the guidelines. Other important tools include audit and feedback, reminder systems, “academic detailing,”42 and patient involvement. Evaluation studies are also necessary to determine whether the guidelines are being used and lead to improved outcomes.

The premise for this discussion has been that practice guidelines should advocate the best options for patients. Although everyone in the health-care system surely endorses this goal, private hospitals and health plans concerned about profit margins and government agencies struggling to finance Medicare and Medicaid must give greater weight to cost considerations than would individual patients and clinicians.43 This has created a lucrative market for the commercial vending of practice guidelines that trim costs, reduce in-hospital lengths of stay, and increase efficiency, sometimes at the expense of the patient. Private vendors and consulting firms have seized this opportunity by selling guidelines, in glossy promotional materials and computer software, to managed care organizations and hospital systems, which assume that they are buying protocols for high-quality care.44

As advocates for patients, physicians and physician organizations have a professional and social responsibility to insist that such practice guidelines, which are being implemented by health plans across the country on millions of enrollees, provide adequate disclosure of the process by which they were developed. The “black box” from which such guidelines are generated must be opened to determine the degree of science and uncertainty on which they are based. Only then can patients, providers, and payers know whether they are receiving, providing, or purchasing optimal care or whether, under the disguise of “quality” or “efficiency,” optimal health is being traded off in the interest of other agendas.

REFERENCES
10 Eisenberg JM. Doctors’ decisions and the cost of medical care: the reason for doctors’ practice patterns and ways to change them. Ann Arbor, Mich: Health Administration Press Perspectives, 1986
14 Woolf SH. Shared decision-making: the case for letting patients decide which choice is best. J Fam Pract 1997; 45:205-08
17 Enkin M, Hetherington J. Collecting the evidence systematically: ensuring that it is complete and up-to-date. Int J Technol Assess Health Care 1996; 12:276-70
20 Berwick DM. Harvesting knowledge from improvement. JAMA 1996; 275:877-78

170S

Disease Management of Pulmonary Infections
28 Oxman AD, Sackett DL, Guyatt GH. Users' guides to the medical literature: I. How to get started: Evidence-Based Medicine Working Group. JAMA 1993; 270:2093-95
29 Dickersin K, Scherer E, Lefebvre C. Identification of relevant studies for systematic reviews. BMJ 1994; 309: 1286-91
34 Thacker SB. Meta-analysis: a quantitative approach to research integration. JAMA 1988; 259:1685-89
40 NHS Centre for Reviews and Dissemination. Implementing clinical practice guidelines: can guidelines be used to improve clinical practice? Effective Health Care, No. 8. York: NHS Centre for Reviews and Dissemination, 1994
42 Soumerai SB, Avorn J. Principles of educational outreach ('academic detailing') to improve clinical decision making. JAMA 1990; 263:549-56