

Commentary: When Is a Practice Guideline Only a Guideline?

Howard Zonana, MD

Clinical Practice Guidelines (CPGs) have been promulgated by a variety of sources with differing goals: professional societies, state and federal governmental bodies, third-party payers such as insurers and HMOs, and hospitals. Compliance rates by practitioners are modest at best so that their use as standards of care for “usual and customary” practice is questionable. Some states are experimenting with the use of CPGs as a requirement for malpractice coverage.

J Am Acad Psychiatry Law 36:302–5, 2008

The possible uses of Clinical Practice Guidelines (CPGs) for malpractice litigation and the need for expert witnesses to be familiar with them as well as the rules of evidence relating to their use are the central themes of Dr. Recupero’s paper.¹ I have focused on the wide diversity of practice guidelines, many of which are clearly unsuitable as practice standards, and the need for caution both in interpreting them and in relying on them as the primary definers of standards of care.

The overall picture of CPGs is characterized by wide variation in the parties creating the guidelines, their goals, the intended purposes of the guidelines, the type of evidence on which the guidelines are based, the procedures through which the guidelines are developed, the scope of the guidelines, the specificity of the recommendations, and physicians’ perceived need to comply with the guidelines. A 1994 review estimated that more than 1600 different CPGs had been developed over the years.² Attorneys and legislatures proposing to use CPGs as the standard of care in medical malpractice cases, therefore, face a major challenge in selecting which guidelines will be applied in a particular case and why.

There seems to be general agreement in the literature that the impetus for the development of guidelines arose from studies that showed wide variations

in clinical practice in different parts of the country and even in different institutions within the same geographical area.³ Different frequencies of surgical procedures and medications for the same condition, and different lengths of hospital stay led the public and the profession to raise serious questions about the quality of care.⁴ For example, in Maine, the likelihood of a woman’s having a hysterectomy by the time she reached the age of 70 varied from 20 to 70 percent in different hospital markets. In Iowa, the likelihood that a man who reached the age of 85 would have had a prostatectomy varied from 15 to 60 percent in different areas. In Vermont, children who had undergone a tonsillectomy varied from 8 to 70 percent depending on geographic area.⁵

The implications were that either no one knew what really worked for the condition or that some knew and were correct and others were either ignorant or had other reasons for not using optimal treatments. The goal for medicine became to determine what works best and to encourage practitioners to adopt efficacious therapies.

Several different groups have become involved in developing and promulgating CPGs. Generally, they can be divided into four distinct categories: professional societies, governmental bodies, third-party payers such as HMOs and insurers, and hospitals.

Professional societies such as the American Medical Association (AMA), the American Psychiatric Association (APA), the American Academy of Psychiatry and the Law (AAPL), and over 50 other medical specialty associations have become involved in the

Dr. Zonana is Professor of Psychiatry, Yale University School of Medicine, Clinical Professor (Adjunct) of Law, Yale Law School, New Haven, CT, and Medical Director, AAPL. Address correspondence to: Howard Zonana, MD, Department of Psychiatry, Yale University School of Medicine, CMHC, 34 Park Street, Room 153, New Haven, CT 06519-1187. E-mail: howard.zonana@yale.edu

preparation of CPGs. These guidelines tend to be highly regarded, since they reflect physicians' reviews of the current literature and emphasize quality care for patients. They generally are written in a fashion that is broad and flexible, giving wide discretion to physicians in allowing them to use their clinical judgment across individual cases. They also often define a range of acceptable practices. The impetus for their development seems to come from an interest in improving the quality of care and education, reducing negative outcomes and injuries, and decreasing the need for defensive medical practices. They also are a response to guidelines developed by third-party payers, which are perceived as being primarily motivated by cost control and as threatening to physician autonomy.

Although guidelines by professional societies are generally highly regarded, Connecticut's Attorney General has challenged a recent guideline about the appropriate treatment of Lyme disease.⁶ He has notified the Infectious Diseases Society of America (IDSA) that he is investigating possible antitrust violations in connection with the development of the 2000 and 2006 Lyme disease guidelines. This rare move against a professional society and its practice guidelines appears to have been initiated on behalf of health care professionals and patient care advocates who disagree with the IDSA recommendation for limiting antibiotic therapy to 28 days. The opposition maintains that Lyme disease exists in a chronic form, and that long-term intravenous antibiotics (e.g., ceftriaxone) provide clinical benefit. The attorney general argued, in part, that conflicts of interest among panel members were not adequately reviewed and that members with opposing views were excluded from the panel. On May 1, 2008, the IDSA agreed to resolve the matter by having an external review of the guidelines. In the interim, the guideline remains in effect. The practical effect of the guideline is that insurers are refusing to pay for long-term antibiotic therapy.

Federal and state governments have also become involved with professional society efforts to develop CPGs. In 1989, Congress created the Agency for Health Care Policy and Research (AHCPR), now renamed the Agency for Health Care Research and Quality (AHRQ), to enhance quality, appropriateness, and effectiveness of health care services, through the "development and periodic review and updating of . . . clinically relevant guidelines" (Ref.

7, p 307). Several states have also undertaken projects to develop CPGs as an effort to enhance statewide quality improvement goals as well as to reduce malpractice costs. In what has become identified as the Maine model, a statutory demonstration project was introduced in 1990. The statute limits the malpractice liability of physicians in four specialty areas— anesthesiology, emergency medicine, obstetrics and gynecology, and radiology—if they agree to follow the CPGs developed by the project. The state adopted 20 CPGs, and physicians can invoke the guidelines as an absolute affirmative defense against malpractice claims. Plaintiffs, on the other hand, were precluded from introducing CPGs as evidence at trial, whether or not the physician was participating in the demonstration project. The idea was not only to reduce liability costs but also, by offering a safe harbor, to encourage physicians to follow good clinical practice guidelines. The empirical evidence reported was not very salutary. Only a small percentage of physicians felt that CPGs had an effect on caesarian section rates, defensive medicine practices, or malpractice risk. CPG compliance was invoked in only one case as an affirmative defense.

Managed care organizations and health care insurers have developed their own guidelines for appropriate care. These guidelines are often used for physician profiling and utilization review. The latter determines whether a physician's treatment plan will be reimbursed. Profiling is used to see whether the physician's care is cost effective. Compliance is important, since the physician knows that the treatment plan will not be covered unless services are seen as being indicated by the practice guideline. Compliance may also be required as a condition, explicit or implicit, of a physician's participation in the HMO. These guidelines are generally not made fully public and are primarily used for cost containment.

Liability insurance carriers, interested in increasing profits by reducing liability costs, have become advocates of the promulgation and enforcement of specific clinical standards. For example, the Utah Medical Insurance Association and a Colorado insurer require compliance with their obstetrics guidelines as a condition of malpractice coverage. Other insurers may raise or lower rates, depending on the practitioner's willingness to comply with CPGs.

Hospitals are being encouraged to develop CPGs as a better way to improve care and to have better guidelines for peer review of staff performance.⁸ The argu-

ment is that peer review standards are so vague as to be meaningless. Since customary care can be variable, it does not provide a meaningful yardstick for review. As an example, many studies show that giving aspirin in the first 24 hours after a heart attack improves survival by 30 percent. In Massachusetts, hospitals provided the treatment 97 percent of the time. Arkansas hospitals provided it only 85 percent of the time. In most states, some hospitals provided it 100 percent of the time. Yet hospitals in the same community can vary from giving it 50 to 100 percent of the time. Suggestions are to make it a standard of care under a CPG, but also to allow for exceptions, which would then have to be documented.^{9,10}

In 2002, the Joint Commission on Accreditation of Health Care Organizations (JCAHO) implemented evidence-based standardized measures of performance in over 3000 accredited hospitals. The measures were designed to track the hospitals' performances over time and encourage improvement by providing feedback in the form of comparative reports. This newest iteration is now called evidence-based approaches in medicine (EBM). EBM has not been fully integrated into the legal malpractice litigation, which has been more focused on CPGs and traditional custom-based standards of care. EBM actually challenges the current legal malpractice reliance on how standards of care are assessed, by not relying on "usual and customary" practice as the standard.¹¹

It may be possible to determine what works best and also which treatment approaches are cost effective and which are not. But challenging questions remain. As treatments have involved more costly medications and highly expensive treatment protocols, the ability to pay for these treatments raises concern not only for insurers but also for physicians who both strive to provide optimal treatment and fear the liability consequences if they do not. Thus, if a new treatment becomes available that improves survival by five percent but is 10 times more expensive, a practice guideline will not resolve the difficult choice.

I argue that, at the present time, an increase in the use of clinical practice guidelines as the definition of the standard of care in medical malpractice cases, especially psychiatry, would be undesirable, whether used in an inculpatory or exculpatory fashion. CPGs do not represent the customary practice in a great many instances, and compliance by most practitio-

ners is probably quite low. A meta-analysis of 23 compliance studies published from 1980 to 1991 determined that the average compliance rate across 143 sets of guidelines was only 54.5 percent.¹² In another study, 64 percent of physicians complied with a CPG on chest pain, a result that led the authors to conclude that it was a successfully implemented guideline.¹³ It certainly will add to confusion about what the law requires of physicians when attempting to decide what will be seen as appropriate care. Many CPGs are either silent or vague about the status of the guideline as a standard of care. Many, like the APA, try to state more definitively that their CPGs are guidelines only. Guidelines may not be uniform and leave wide room for physician discretion, especially for psychiatric disorders.

Allowing physicians to use guidelines while prohibiting plaintiffs from introducing them would seem to require strong justifications that are not present. The need to protect the profession from frivolous lawsuits does not constitute a substantive justification for the disparity. It also forces physicians to comply with guidelines, which changes the status of the guidelines from recommendations to requirements. That some states and insurers have already moved in that direction is evidence of that effect.

This is not to conclude that CPGs are not an effective way to improve the quality of care. They help to provide more uniform practice when there are good evidence-based data. Being good for practice does not imply that they should guide medical malpractice law. They may, however, have some place in adding support for an expert's testimony. But because of the problems described earlier they should not be used to replace expert testimony in defining the standard of care in a specific litigation. This interaction permits the retention of customary care as the relevant standard and allows the expert to review the specific case to ascertain whether the guideline for the typical case fits the individual case under consideration. There may also be some guidelines that are clearly accepted as a standard of care, such as no sexual relationships being permitted between a physician and patient (rarely is anything absolute; e.g., writing a prescription for one's spouse is not that unusual and yet it legally creates a physician-patient relationship).

Clinical practice guidelines are still in a relatively early stage of development. Their use in malpractice

litigation requires caution until and unless CPGs are developed in a fashion that distinguishes between guidelines that represent the only acceptable approach to a particular problem (i.e., defining a practice standard) and those that offer one suggestion among many. Appropriate use in malpractice litigation also requires acceptable procedures to promulgate and disseminate guidelines to insure that physicians have been informed of the standards.

References

1. Recupero P: Clinical practice guidelines as learned treatises: understanding their use as evidence in the courtroom. *J Am Acad Psychiatry Law* 36:290–301, 2008
2. Ayres JD: The use and abuse of medical practice guidelines. *J Legal Med* 15:421–43, 1994
3. Wennberg J, Barnes BA, Zubkoff M: Professional uncertainty and the problem of supplier-induced demand. *Soc Sci Med* 16:811–17, 1982
4. Chassin M, Brook RH, Park RE, *et al*: Variations in the use of medical and surgical services by the medicare population. *N Engl J Med* 314:285–90, 1986
5. Wennberg JE: Dealing with medical practice variations: a proposal for action. *Health Affairs* 3:6–32, 1984
6. Attorney General's Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees To Reassess Guidelines, Install Independent Arbiter. Connecticut Attorney General's Office Press Release, May 1, 2008. Available at <http://www.ct.gov/AG/cwp/view.asp?a=2795&q=414284>. Accessed July 22, 2008
7. Merz S: Clinical practice guidelines: policy issues and legal implications. *Joint Commis J Qual Improv* 19:306–7, 1993
8. Van Tassel K: Hospital peer review standards and due process: moving from tort doctrine toward contract principles based on clinical practice guidelines. *Seton Hall Law Rev* 36:1179–256, 2006
9. Jha AJ, Li Z, Orav EJ, *et al*: Care in US hospitals: the Hospital Quality Alliance Program. *N Engl J Med* 353:265–74, 2005
10. Fessenden F: Quick, what do you do for a heart attack? *The New York Times*, July 31, 2005. Available at http://www.nytimes.com/2005/07/31/nyregion/nyregionspecial2/31wehosp.html?_r=1&oref=slogin. Accessed July 22, 2008
11. Williams C: Evidence based medicine in the law beyond clinical practice guidelines: what effect will EBM have on the standard of care? *Washington & Lee Law Rev* 61:479–533, 2004
12. Grilli R, Lomas J: Evaluating the message: the relationship between compliance rate and the subject of a practice guideline. *Med Care* 32:202–3, 1994
13. Ellrodt AG, Conner L, Riedinger M, *et al*: Measuring and improving physician compliance with clinical practice guidelines: a controlled interventional trial. *Ann Intern Med* 122:277–82, 1995