

RISK MANAGEMENT

Legal Risks of Clinical Practice Guidelines

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Well-crafted systemically developed clinical practice guidelines (CPGs) are intended to frame current medical knowledge in a manner that will assist health care providers in delivering high quality care. CPGs are being used in the malpractice arena to define a credible standard of care to measure the accused physician for an alleged problem addressed. This may occur despite a medical society's disclaimer that they are not intended, nor devised, for that purpose. It can be argued that CPGs may be used with greater effect by the plaintiff's bar for inculpatory evidence than by the defense as an exculpatory standard. Physicians should be aware of the legal use of CPGs and the associated risk management implications. Physicians who write guidelines for medical societies may wish to consider the potential future courtroom use of CPGs as they attempt to use evolving research to enhance patient care. A fine line may separate a "best practice" from acceptable quality care; the former may not be expected to occur in all patient care interactions. Suggestions embedded in a CPG rather than other publication may be legally interpreted incorrectly as a baseline standard of care expectation.

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INTRODUCTION AND BACKGROUND

The Institute of Medicine (IOM) defined Clinical Practice Guidelines (CPGs) as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (1). CPGs are essentially consensus statements created by various entities and experts, both public and private, to outline what may be appropriate treatment for a specific medical condition, symptom complex, or approach to disease prevention. Contemporary development of CPGs involves the use of evidence-based medicine (EBM) that proposes the model under which medical decisions and practice are based on the best available evidence.

"EBM acknowledges that intuition, unsystematic clinical experience, and pathophysiologic rationale are insufficient grounds for clinical decision making, and stresses the examination of evidence from clinical research." The EBM approach in developing CPGs involves a ranking of the quality of evidence (2). There are many problems with the EBM approach and this method of creating CPGs. A full discussion of this issue is beyond the scope of this article, but was recently addressed (3). For example, four major problems with practice guidelines include: (a) many guidelines are of low quality, (b) in many cases the primary literature is too incomplete to develop evidence-based guidelines, (c) most guidelines are developed for the "textbook" patient, and (d) guidelines are often developed without consideration of whether their implementation would be acceptable to patients, physicians, or health care systems (3, 4).

Once a CPG is published, physician compliance with the same becomes an issue. A recent study assessing the util-

ity of Web-based guidelines revealed that when CPGs were available online, readership was suboptimal and adherence to CPGs to manage deep vein thrombosis or upper gastrointestinal bleeding was not improved when offered in this format (5). Recently, Kane and Reddy surveyed 200 clinical gastroenterologists prior to and for 6 months after the American College of Gastroenterology published evidence-based guidelines for the management of osteoporosis in inflammatory bowel disease. They found a total of 35% of gastroenterologists read the guidelines while only 25% were comfortable in treating osteoporosis in this patient population (6).

Some nonmedical tort reformers have suggested that CPGs should be used as evidence of the standard of care in medical malpractice cases (7). Advocates of the use of CPGs in medical malpractice litigation believe they are better than vague tort standards, as discussed previously (8), and have suggested CPGs be given judicial notice as conclusive evidence of the legal standard of care, thereby supplanting expert testimony (9). The American Medical Association, among other entities, has opposed this approach, understanding some of the problems and limitations of CPGs (10, 11). The IOM discusses CPGs as one of the first steps in developing a safer health system (12). Superimposed is the medical malpractice crisis affecting medical practices whereby, among other problems, physicians are experiencing trouble finding and/or affording malpractice insurance (13).

The purpose of this article is to review the development, purpose, and current status of CPGs, and to then understand how they are currently used in malpractice litigation. The relationship between CPGs and the standard of care in medical

malpractice cases will briefly be discussed. We will conclude with suggestions that a gastroenterology practice may follow to improve patient safety and risk management, thereby limiting liability.

DEVELOPMENT AND PURPOSE OF CLINICAL PRACTICE GUIDELINES

CPGs have been involved in medical practice for over 50 years. Interest in the use of CPGs to improve medical practice disparities grew in the 1970s and 1980s after researchers identified wide variations in care for the same medical problem between different geographic regions within the United States (10, 14).

Promulgators in developing and disseminating CPGs fall into three categories: professional societies, government bodies, and payers (insurance companies). CPGs developed by professional medical societies are regarded as highly authoritative because of presumed lack of financial incentive, and their goal of providing top quality patient care utilizing medical literature and clinical expertise (9, 10). Medical professional societies aim to improve the quality of patient care and avoid medical injuries (15). These guidelines allow room for physicians to use medical judgment based on their individual patient.

While guidelines created by professional and governmental bodies are intended to educate physicians with the hope they will change practice behavior, guidelines created by health care payers are often used for utilization review and physician profiling purposes. In other words, guidelines developed by professional medical societies are focused on achieving defined medical outcomes while guidelines developed by payers are influenced by concerns over cost control (10). CPGs have also been criticized for providing reasons for insurers to deny benefit coverage, and for conflict of interest influences, by both specialty societies and the pharmaceutical industry in guideline development (16).

There are a tremendous number of CPGs presently in existence due to the efforts of professional societies, government bodies, and health care payers. A 1994 review estimated about 1,600 different CPGs in existence (10, 17). As of late 2005, there were more than 200 CPGs related solely to the management of gastrointestinal disorders listed by the National Guideline Clearing House (<http://www.guideline.gov>) (3).

Despite the intended purpose of medical professional societies to improve the quality of patient care and avoid medical injuries through the development of CPGs, some tort reformers and attorneys have proposed using them as the standard of care in medical malpractice cases (18). This creates a problem for practicing physicians given the tremendous diversity of CPGs—in the parties creating them, their motivations, intended purposes, the type of evidence upon which guidelines are based, the procedures through which guidelines are developed, the scope of guidelines, the specificity of the rec-

ommendations, and physician compliance (10). CPGs that address the same clinical problem but have different applications, goals, and recommendations present a problem for the courts (10, 15). Plaintiff attorneys can inappropriately use CPGs as the standard of care that, if not followed, will provide the basis of a malpractice lawsuit (10, 19).

The fact that CPGs may help guide medical practice does not imply they should also guide the practice of medical malpractice law. A brief discussion of negligence and the standard of care are necessary to understand how CPGs relate to medical malpractice cases.

BASIC LEGAL LIABILITY CONCEPTS: NEGLIGENCE AND STANDARD OF CARE

A tort is defined as a civil wrong for which a remedy may be obtained, usually in the form of damages (20). The most common form of a malpractice action against a health care provider is the tort of “negligence.” The plaintiff’s attorney must prove four elements to be successful in a medical malpractice lawsuit: (a) that the provider has an obligation (duty) of care for the individual, (b) that the duty was violated (breach) by practice below the accepted standard of care, (c) that substandard practice caused the harm alleged (proximate cause), and (d) that the plaintiff suffers compensable harm (damages) (8, 21).

The physician’s duty is defined by the legal standard of care. Essentially, a physician must exercise that degree of care that would be exercised by a physician in good standing in the same medical specialty in like circumstances (10, 20). Establishing that the physician has violated the standard of care is often the most critical element of the lawsuit. Expert witness testimony is required to establish the current standard of care (21). With increasing frequency, respected CPGs have become a key element used to establish the current standard of care (21, 22).

ROLE OF CPGs IN MEDICAL MALPRACTICE

A full discussion of the use of CPGs in malpractice litigation is beyond the scope of this article. We will focus on the manner in which and how CPGs are being used in malpractice litigation, and their effect on the same.

In order for a CPG to be used in a lawsuit, it has to be entered into evidence under requirements set out in the Federal Rules of Evidence or the applicable state and local evidence rules (23). The authenticity of a CPG requires expert testimony that the CPG is an accurate representation of what it purports. As a general rule, given the satisfaction of procedural requirements, courts have been increasingly willing to allow CPGs into evidence as learned treatises and to allow expert testimony regarding the same as the standard of care (24). The majority of state law allows CPGs to be used as a tool for the expert witness (25).

There is minimal empirical evidence on the use of CPGs in medical malpractice litigation. It is difficult to get insurer permission to study open and closed malpractice claims thereby limiting research in this field (26, 27). Investigators from the Harvard School of Public Health studied this difficult question by undertaking a two-part study to better document and address the use of CPGs in malpractice litigation. They reviewed a total of 259 litigation records at two professional liability companies, opened in 1990–1992, to investigate the use of CPGs by plaintiff and defendant attorneys. They then surveyed 578 attorneys who litigate these types of cases to assess their views on the role of CPGs from an inculpatory and exculpatory standpoint (27).

Realizing that the Harvard study deals with data that are over 15 years old, and that the number of medical malpractice cases has risen at an astounding rate over this period of time (13), the study showed an increasing rate of use of CPGs in this type of litigation. Almost 50% of plaintiff attorneys queried reported having at least one case per year in which CPGs played a role. Thirty-one percent responded that CPGs influenced their decision to file a medical malpractice case. Sixteen percent of attorneys said CPGs had influenced them to take more than two cases (24, 27). Attorneys reported that once a suit was initiated, CPGs were likely to be used for inculpatory purposes, as opposed to exculpatory. The only plaintiff attorney factor associated with increased use of guidelines was a practice in which more than 50% of the business was in medical malpractice. The insurance companies reported a 3:1 ratio of inculpatory *versus* exculpatory use of a CPG in their insurance claims reviewed. The authors felt that they likely underestimated the use of guidelines in their study given the constraints in gathering data of this nature (27).

CPGs also have an impact on the filing of medical malpractice cases. Approximately 30% of plaintiff attorneys admitted that CPGs influenced their decision to file a medical malpractice case, while 25% noted that CPGs influenced their decision at least once in the year to turn down a case. Twenty-seven percent of the surveyed attorneys indicated CPGs influenced their decision to settle a case. Twenty-two percent believed that a CPG influenced the trier of fact in the case put into suit (24, 27).

The Harvard study therefore suggested that CPGs have an impact on the type of cases filed and their outcomes. By making it easier to determine whether the facts of a particular case indicate a deviation from the standard of care, and to prove that issue during a trial, CPGs may actually encourage more plaintiff attorneys to file malpractice cases against physicians (10).

Some tort reformers advocate carving out a greater role for CPGs in malpractice litigation by legislative initiatives. It has been suggested that these initiatives should obligate physicians and patients to agree to be contractually bound by a set of CPGs that would define the standard of care or that courts take judicial notice of CPGs as conclusive evidence of the standard of care (10, 28). Others have suggested that

CPGs be incorporated into the medical staff by-laws so that physicians may be held accountable for their use under the hospital peer-review process (28).

HYPOTHETICAL SITUATION: QUALITY MEASURES FOR COLONOSCOPY

Interest by medical societies and the public in ensuring that colonoscopy is performed with sufficient quality to fulfill its promise of colorectal cancer prevention makes this a topic suitable for a hypothetical evolving guideline development. As committee members review and suggest measures, perhaps topics might include training/credentialing, withdrawal time, polyp find rate, cecal intubation rate, and complication rates. Suppose the committee wishes to select polyp find rates as a guideline parameter.

From a medical legal point of view, gastroenterologists nationwide could be held to the numbers set by that committee. Are the data sufficient, and what cut points should be selected? Should gastroenterologists practicing reasonable and competent medicine be expected to meet those standards? What was the level of certainty that went into writing the guideline by the committee members? Are we presently certain that all gastroenterologists who perform a quality exam of their patients, that may have a different mix of age, ethnicity, and symptoms, among other variables, from the few published studies to date, will attain certain thresholds of polyp find rate?

From the medical society view, if a combined society guideline endorses the polyp find rate as a measure, then in the courtroom, the gastroenterologist could be required to show his or her individual polyp find rate, and may be assumed to have performed poor quality examinations merely because this polyp find rate is below the guideline threshold. No evidence or information as to the controversies surrounding the adaptation of the polyp find rate guideline, the strength of the limited literature relating this parameter to quality of colonoscopy examination, or other issues the committee struggled with and/or discussed would likely succeed as defense.

From a practitioner point of view, consider the implications of not attaining the polyp find rate, if possible, set by this select expert committee and endorsed by your major medical societies. If you were challenged to defend a cancer found 3 yr after the colonoscopy, defenses might include the possibility of fast-growing cancers, the malignancy developed submucosally and therefore was not seen endoluminally, and that despite the performance of a quality colonoscopy, no test is perfect. However, if the plaintiff convinces an unsophisticated jury that your polyp find rate was below the standard set by gastrointestinal societies for an alleged competent exam, you may have the uphill battle of explaining why guideline polyp find rate data were not scientifically sound, or applicable to your case, and that the colonoscopy you performed was excellent.

SUMMARY AND CONCLUSIONS

Based on our brief review of the issues associated with CPGs and their use in medical malpractice litigation, the practicing physician should consider the following when deciding whether or not to use the same:

1. CPGs are intended to assist the physician in decisions about appropriate health care for specific clinical circumstances.
2. The EBM approach to establishing CPGs increases objectivity in their development, but does not imply CPG recommendations are absolute and without problems.
3. Physician compliance with CPGs in general is low but will increase over time as professional organizations work on educating physicians on the role of CPGs in patient care.
4. CPGs should be used selectively. They do not apply to every patient. Each patient is unique so it is necessary to factor in the patient's competing medical problems and medications, general health and well-being, and values.
5. Consider the source of a CPG before implementing the recommendations.
6. There are over 1,600 CPGs available with more than 200 relating to gastroenterology alone.
7. CPGs developed by professional medical organizations are probably the least biased and most accurate in their recommendations.
8. CPGs are available through the National Guideline Clearing House at <http://www.guideline.gov>, in addition to our professional organizations.
9. The precedent exists for the use of CPGs in medical malpractice litigation.
10. CPGs do not represent the standard of care.
11. CPGs are affecting medical malpractice settlements.
12. Despite the purpose of CPGs from a medical standpoint and their limitations including low compliance rates and the problems associated with EBM, attorneys and tort reformers are pushing to use them to establish a standard of care and hold physicians accountable for failing to implement CPGs in patient care.
13. The development of CPGs and the EBM approach is a science that has to evolve.
14. Be aware of what you are treating and why.

Gastroenterology, and medicine in general, is committed to providing the best quality of care to patients. Patient safety and best outcomes are issues at the forefront for medicine, payers, and government. CPGs will become more important and affect the practice of medicine in the future on many levels. Given the use of CPGs in medical malpractice litigation and the current medical malpractice crisis, practicing physicians must communicate and cooperate with their national organizations in developing and implementing CPGs in patient care where appropriate. Physicians should decide whether or not to follow a CPG, and to what degree, based on the in-

dividual patient and the clinical situation of that particular case. CPGs should clearly state their limitations based on the available research so as not to be confused with any standard of practice, and subsequently misrepresented by nonmedical entities. This article has offered an understanding in addition to some suggestions to providers in gastroenterology to lessen liability exposure when dealing with CPGs.

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