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The Role of Practice Guidelines in Medical Malpractice Litigation

Timothy K. Mackey, MAS, and Bryan A. Liang, MD, JD, PhD

Clinical Practice Guidelines (CPGs) play a dual role in medical malpractice claims. They can be used in litigation by an accused physician as a defense (exculpatory evidence) and by patients alleging a breach of the standard of care (inculpatory evidence). Establishing a breach in the standard of care is key in litigating medical malpractice claims under the negligence standard, in which a defendant physician attempts to assert that he or she has complied with the standard of care and a plaintiff conversely contends the acceptable standard was not met [1]. Studies have shown that CPGs have an impact on the outcomes of these cases [2].

Though CPGs may provide physicians with needed guidelines and consensus on care based on clinical evidence, the use of such guidelines in medical malpractice litigation is largely dependent upon state evidentiary practices and rulings [3]. Further, although CPGs may promote and standardize use of efficient and evidence-based clinical treatment, they may also limit physician autonomy and impose inflexible or unrealistic standards on clinical practice [4]. A brief examination of the juridical and legislative history of CPGs will show that these considerations need to be taken into account in medical tort reform efforts.

Learned Treatises Doctrine

The legal employment of CPGs is rooted in the early use of medical treatises in U.S. jurisprudence. In the 1923 case *Frye v. United States* [5], the court established that the admissibility of scientific evidence required “general acceptance” in the scientific community, leading to the possible use of medical treatises under this condition of admissibility.

As medical treatises became more accepted as evidence, much ambiguity arose regarding both what would qualify as admissible “scientific” evidence and, perhaps more importantly, how such treatises could be specifically used [1]. In 1949, the U.S. Supreme Court provided some guidance, holding in *Reilly v. Pinkus* that the applicability of medical treatises specifically extended to cross-examination or the impeachment of expert witnesses [1]. In 1975, the Federal Rules of Evidence were instituted and then adopted by many state courts, further expanding the scope of treatise use and allowing expert witnesses to employ them as direct substantive evidence supporting their testimony [1].

Finally, in 2000, the Federal Rules of Evidence, specifically Rule 702, were further revised. This revision set forth requirements that expert testimony be based upon

“reliable principles and methods” related to the clinical intervention at issue, in order to be construed as scientific knowledge and thus admissible [1]. This progression of the learned treatise doctrine opened the door for the use of CPGs as admissible evidence as a “learned treatise,” which allows consideration and admission of CPGs as a “reliable authority” for use in expert testimony [6].

The Evolution of Clinical Practice Guidelines

CPGs originated as a means of improving the quality of care by attempting to bridge wide regional variation in clinical practice, balancing overuse and underuse of medical services, and providing a medium for communicating outcomes-based and cost-effective clinical practices to physicians [6].

CPGs have proliferated rapidly; they are used by many organizations involved in health care, including the federal and state government, professional medical societies, managed care groups, the insurance industry, other health care payors, and peer-review organizations [2]. They are also key to the U.S. government’s efforts to enhance the quality of clinical care, judging by the Agency for Healthcare Research and Quality (AHRQ) investment in the development and dissemination of CPGs [7].

What we are learning, however, is that, in addition to varying in scope and quality, many CPGs (such as those created for utilization review by payors or those promulgated by specialty societies, which may conflict with other specialty societies’ standards) are designed to meet the needs of the drafting organization, rather than defining a specific, applicable standard of care for every case. This has complicated the adoption of CPGs in establishing the standard of care in particular cases [6].

The Growing Costs of Medical Malpractice

Medical malpractice adds both directly and indirectly to the cost of health care [6]. Direct costs include insurance premiums, expenses for damages, litigation fees, and indirect costs including the practice of “defensive medicine,” i.e., when physicians provide unnecessary tests and procedures in an effort to limit their liability [6].

It has been estimated, for example, that 10 percent of medical services cost is linked to medical malpractice litigation and defensive medicine practices; a study conducted by the Department of Human and Health Services estimated the direct cost of medical malpractice at 2 percent of health care spending [8]. A more recent study estimates the annual cost of medical liability and defensive medicine was \$55.6 billion in 2008 [9]. To alleviate concerns about the cost of malpractice cases and payments, some medical malpractice tort reform efforts have led to pilot projects in which CPGs are used as standardized tools in assessing liability [1].

Trends and Variations

The scope and admissibility of testimony that relies on CPGs to define the standard of care or establish expert witnesses’ credibility varies state to state. Increasingly, when considering testimony supported by CPGs, courts look to such factors as the type of case, the source of the guideline, the forum, the expert’s own

acknowledgment of its relevance and reliability, and whether the expert's testimony is itself reliable [1]. Courts have also exercised their own discretion concerning the quality, relevance, and reliability of CPGs, rejecting guidelines that they consider prejudicial or that failed tests of impartiality [1]. This includes materials that may represent individual financial conflict of interests or ghostwriting, which can invalidate the integrity of scientific materials [10].

Importantly, there is a growing trend of CPG admissibility as an affirmative defense in malpractice suits, reversing earlier challenges in many states. For example, a cardiologist examined a patient complaining of chest pain and ordered a chest x-ray, resting EKG, and an exercise treadmill EKG. The physician then concluded that the patient did not require hospital admission. The patient died at home 3 hours later from cardiopulmonary arrest. His widow filed suit for medical malpractice, claiming the cardiologist breached the standard of care [11].

The trial court held for the physician based largely on guidelines created by the American College of Cardiology and American Heart Association that were introduced by the physician. The patient appealed; the appellate court affirmed the trial court. The appellate court found that the guidelines were recognized by a majority of experts as the standard of care for the profession. The court therefore concluded that CPGs were relevant and had authoritative power as substantive evidence in malpractice litigation [11].

Similarly, a plaintiff who was suffering from a partial blockage of her left common carotid artery underwent carotid endarterectomy and later suffered a stroke, resulting in permanent brain damage and disability. The plaintiff filed a malpractice suit, alleging that the physician had violated state informed consent law by not informing her of the availability of chelation therapy as an alternative treatment [12].

This case did not even go to trial. The lower court ruled in favor of the defendant's motion for summary judgment—a process in which the judge reviews materials and arguments for both sides and concludes there is no triable issue. The judge based the decision in part upon numerous guidelines introduced by the physician, including those issued by the American Medical Association, American Heart Association, American Academy of Family Physicians, American College of Cardiology, and American College of Physicians, all of which concluded that chelation therapy was not recognized as an acceptable treatment for coronary or other arterial atherosclerosis [12].

The patient appealed. In its ruling, the appellate court affirmed the lower court decision, permitting use of CPGs as a defense against plaintiff claims that physicians should use therapies not widely recognized by the medical community.

Malpractice Tort Reform

As the use of CPGs grows, tort reform incorporating them has been proposed in many forms. These include (1) the use of contracts by insurers to bind physicians and

patients to guidelines as a way of establishing the standard of care in the case of a future malpractice claim or a requirement for malpractice insurance or physician participation in managed care programs, (2) judicial notice, in which the court provides an impartial and court-appointed medical expert to establish the appropriate set of guidelines to be used as the standard of care in a case, and (3) using compliance with CPGs as an affirmative defense or safe harbor that can be used by physicians as exculpatory evidence [6].

The use of CPGs as exculpatory evidence has been given special scrutiny due to its use in the state of Maine as a statutory demonstration project in the 1990s [6]. Maine's Medical Liability Demonstration Project, undertaken to improve quality of care and reduce defensive medicine practices by encouraging compliance with CPGs, adopted 20 practice guidelines in four specialties (anesthesiology, emergency medicine, obstetrics and gynecology, and radiology) with the goal of reducing health care costs in areas burdened by costly malpractice claims [13]. Under the reform, physicians who adhere to these state adopted CPGs were provided an affirmative defense against medical malpractice claims, and the guidelines could not be introduced as inculpatory evidence [6].

Results, however, have not been encouraging. Studies that examined the impact of the project did not show significant reductions in defensive medicine practices or in malpractice claims, and the law's provisions had low utilization in court [6].

Furthermore, broader tort reform that provides such safe harbors may also cut the other way by interfering with clinical judgment. Mandated CPGs may unduly compel physicians to comply with such guidelines due to liability considerations even if they conflict with clinical judgment, potentially leading to adverse outcomes for patients [6].

Hence, the role of CPGs in malpractice tort reform may be limited. It has been argued that adherence to CPGs should not be the basis upon which liability is established, but instead should continue to be used only to support expert testimony [6].

Future Trends

The Patient Protection and Affordable Care Act passed by Congress in 2010 did not specifically address medical liability reform or the role of CPGs, but did authorize \$50 million for demonstration projects to test alternative medical liability systems [14]. However, limitations of the legislation and the proposed demonstration projects have been the subject of criticism [15]. Recently, Peter Orszag, the former director of the Office for Management and Budget, advocated for the adoption of safe harbors for physicians who follow evidence-based guidelines, particularly in the context of comparative effectiveness research [16]. Blue Cross and Blue Shield Association, one of the nation's largest insurers, has also called for the creation of safe harbors from medical malpractice claims for physicians who follow guidelines established

through comparative effectiveness research [17]. How such proposals will use CPGs in legal review of patient injury claims will be an important concern.

Conclusion

The use of CPGs in medical malpractice has evolved over several decades of case law, legal precedence, and rules and regulations and is the source of continued debate. Key in this discussion is the appropriate use of CPGs to establish impartial and scientifically sound support for expert testimony. Future reform will need to address the challenges of balancing the advantages and disadvantages of CPGs as authoritative sources in establishing the standard of care both by the clinician and in the courtroom.

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Timothy K. Mackey, MAS, is a senior research associate in the Institute of Health Law Studies at the California Western School of Law and a student in the joint doctoral program in global health at University of California San Diego and San Diego State University. He graduated from the joint master's degree program in health law at the University of California San Diego School of Medicine and California Western School of Law in 2009.

Bryan A. Liang, MD, JD, PhD, is the Shapiro Distinguished Professor of Health Law and executive director of the Institute of Health Law Studies at California Western School of Law and professor of anesthesiology and director at the University of California San Diego School of Medicine's San Diego Center for Patient Safety. Dr. Liang's work analyzes the interface between law, medicine, and economics, with special emphasis on patient safety and access, ethics, and health policy. He received his MD from Columbia University, his PhD from the University of Chicago, and his JD from Harvard Law School.

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