The Elusive Standard of Care

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In medical negligence cases, the forensic expert must explain to a trier of fact what a defendant physician should have done, or not done, in a specific set of circumstances and whether the physician's conduct constitutes a breach of duty. The parameters of the duty are delineated by the standard of care. Many facets of the standard of care have been well explored in the literature, but gaps remain in a complete understanding of this concept. We examine the standard of care, its origins, and who determines the prevailing standard, beginning with an overview of the historical roots of the standard of care and, using case law, tracing its evolution from the 19th century through the early 21st century. We then analyze the locality rule and consider local, state, and national standards of care. The locality rule requires a defendant physician to provide the same degree of skill and care that is required of a physician practicing in the same or similar community. This rule remains alive in some jurisdictions in the United States. Last, we address the relationship between the standard of care and clinical practice guidelines.

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A medical negligence case is the result of a clinical situation that has had an adverse outcome. The task of the forensic expert is to determine what actions a defendant physician should have taken and whether a breach of duty has occurred, in accordance with the parameters set forth by the standard of care. Thus, the forensic expert must both define the standard of care and opine whether it has been properly applied.[1]

Scholars have examined the standard of care and provided guidance for those involved in these forensic cases. For example, Recupero and Harms[2] studied whether psychiatrists treating outpatients agree about the standard of care for requesting records from a patient's past clinician. Rogers *et al.*[3] provided commentary on the differences between legal and clinical standards of care and offered suggestions on incorporating medicolegal aspects of standard of care in psychiatry residency curricula. Simon[4] wrote an editorial on standard-of-care testimony for *The Journal*.

Experiences with clinicians and a personal review of expert witness testimony suggest that a complete understanding of the standard of care is still elusive. What is a "standard of care"? From whence does it arise? Who determines the prevailing standard? Our aim is to examine these questions, beginning with an overview of the historical roots of the standard of care and using case law to trace its evolution from the 19th century through the 20th and early 21st centuries. We analyze the locality rule and consider local, state, and national standards of care. Finally, we address the relationship between the standard of care and concepts with which it is often conflated, such as best practices, expert opinions, and the now-pervasive clinical practice guidelines.

The Genesis of the Standard of Care

Through most of the first half of the 19th century, there was little scientific foundation for the practice of medicine. It was based largely on a received ancient wisdom, and bore practically no resemblance to the medicine of today.[5] Early American physicians, like their European counterparts, attempted to establish professional authority based on education, licensing, and membership in professional societies, but there was little legitimate basis for their claims.[6] This disjunction was brought into stark relief during Andrew Jackson's administration, which was marked by egalitarian, antielitist sentiments. Under Jackson, all state medical licensing laws were repealed, replaced by a "marketplace professionalism" in which anyone, trained or not, was free to offer their services in an unregulated marketplace.[5]

This situation began to change around the mid-19th century, as traditional medicine began to reas-

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sert its authority. The American Medical Association (AMA), founded in 1847, worked for reforms in medical education, standardization of medical practice, and reinstitution of licensing laws.[5] As well, medical authority began to be asserted on the basis of the legitimacy of practice and scientific breakthroughs in, for example, ether anesthesia (1846), introduction of antisepsis by Lister (1867), and immunology, including the development of vaccines (cholera, 1879; anthrax, 1881; and rabies, 1882). Medical doctors were the primary emissaries of these advances, and their growing competence began to bestow legitimate authority upon them.[7]

Through the first third of the 19th century, medical malpractice lawsuits were extremely rare.[8] These actions, originally derived from English jurisprudence, were comprised chiefly of common law writ proceedings. The middle third of the century, dubbed by Spiegel and Kavaler[8] as America's first medical malpractice crisis, coincided with this era of marketplace professionalism. During this period of unlicensed, unregulated practice, in which medical doctors ("regulars") openly competed both with members of their own profession and with their "irregular" counterparts (e.g., homeopaths, hydropaths, and botanists, among others), medical care was sometimes regarded by the courts as comprising a contract between individuals and malpractice as a breach of contract. Gradually, during the final third of the century, tort emerged as an independent branch of the law and, with it, the concept of medical negligence evolved as a genuine tort doctrine, conditioned on a policy determination that a standard of care had been breached.[9]

White[9] argued that the writ system collapsed of its own weight, devolving into an unwieldy classification system, chiefly because of the growing diversity of American law. Little academic attention has been paid to the reasons for the shift from contract to tort.[10] Certainly, both medical and legal factors were responsible. Mohr[5] asserted that the change was brought about, in large part, by the medical profession's efforts to achieve professional status and to distinguish medical care from ordinary commercial transactions. Medicine argued that contracts assumed equal footing between parties, and the increasing complexity of medicine created asymmetries in knowledge, risk evaluation, and bargaining power that made contract law unsuitable to the evolving nature of the physician–patient relationship.[5] As well, Atiyah[10] argued that medical misadventures, comprising unforeseen and accidental events, could not reasonably be accommodated by contract law.

In any event, the result was that, by the end of the 19th century, medical malpractice was firmly rooted in the principles of tort law. Whereas contract actions are evaluated based on agreed-upon outcomes, tort actions are evaluated by the integrity of processes.[11] The integrity of processes, in turn, are adjudged by the adherence to standards. To be liable for breaching standards of care, accepted standards must first be established.[11] Thus, the adoption of tort law required the establishment of standards by which medical care could be evaluated, standards that the AMA played a role in developing.[5] Although physicians would be protected from claims based on failure to achieve contracted outcomes, it left them vulnerable to whatever deficiencies in adherence to standards of care plaintiffs could demonstrate.[11] The medical establishment was willing to pay this price for its professional status.

The Locality Rule

As malpractice law evolved, courts began comparing a physician's practice to those of similarly situated professionals in their community. The applicable standard of care in medical malpractice lawsuits varies somewhat among jurisdictions in the United States. Expert witnesses should understand whether a locality rule applies in the jurisdiction of the case in which they have been retained. Black's Law Dictionary defines the locality rule as "a term in medical jurisprudence where the physicians of an area must maintain standards of practice."[12] The locality rule requires defendant physicians to provide the same degree of skill and care that is required of other physicians practicing in the same or similar community. It places a geographical dimension on the professional standard of care in medical negligence litigation.[13] The strictest form of the locality rule would require expert witnesses to practice in the same or a similar community of the case in which they are offering opinions.[14]

Once widely adopted in the United States, the locality rule was originally designed to protect rural physicians from having to uphold the same standard of care as that provided in the academic health science centers and modern clinics of the city.[15] It was believed that rural practitioners lacked the equipment of the urban health centers and did not benefit from the latest advances in science and practice that emanated from medical research conducted at urban

hospitals. There is controversy, however, because some critics have called extant locality rules "archaic, anachronistic, and in fact, insulting to modern medicine" (Ref. 13, p 324–5).

Landmark Cases

The origin of the locality rule is often attributed to *Small v. Howard*,[16] an 1880 opinion of the Supreme Judicial Court of Massachusetts that endured until overruled by the same court in 1968. This case is cited as the first appellate decision requiring the use of a locality rule. In *Small*, Dr. Howard was sued by a patient in Massachusetts for alleged "malpractice in dressing and caring for a wound upon the [patient's] wrist" (Ref. 13, p 322). Dr. Howard was a general practitioner in a country town with a population of 2,500. He was consulted by the plaintiff, Mr. Small, to treat a severe wound, a serious injury caused by glass, that required a considerable degree of surgical skill. The wrist wound "extended to the bone, severing all the arteries and tendons" (Ref. 13, p 328). In *Small*, the plaintiff proposed, and the trial court refused, an instruction suggesting "that the skill required of the defendant was merely the average skill of all practitioners, educated and uneducated, permanent and occasional, regulars and interlopers alike" (Ref. 13, p 329). The Supreme Judicial Court of Massachusetts rejected this form of instruction and offered the following, which is often credited as the origin of the locality rule:

> The defendant . . . being the practitioner in a small village . . . was bound to possess that skill only which physicians and surgeons of ordinary ability and skill, practi[c]ing in similar localities, with opportunities for no larger experience, ordinarily possess; and he was not bound to possess that high degree of art and skill possessed by eminent surgeons practi[c]ing in large cities, and making a specialty of the practice of surgery [Ref. 13, p 329].

In *Brune V. Belinkoff*,[17] the Supreme Judicial Court of Massachusetts overturned their prior ruling in *Small*. *Brune* was a malpractice case of Ms. Theresa Brune who sought to recover from the defendant because of alleged negligence in administering a spinal anesthetic. Ms. Brune delivered a baby in 1958 at St. Luke's Hospital in New Bedford, Massachusetts. During the delivery, Dr. Belinkoff, a specialist in anesthesiology practicing in New Bedford, administered a spinal anesthetic to the plaintiff containing 8 mg of pontocaine in 1 cc of a 10% solution of glucose. When Ms. Brune attempted to get out of bed 11 hours later, she slipped and fell on the floor. She subsequently complained of numbness and weakness in her left leg, which appeared to have persisted to the time of trial.

Eight physicians provided testimony, much of which was related to the plaintiff's condition. There was ample evidence that her condition resulted from an excessive dosage of pontocaine. Others testified that it was an appropriate dose and a customary dose for New Bedford vaginal deliveries.[17]

The Supreme Judicial Court of Massachusetts offered:

> A general medical practitioner is to be held to the standard of care and skill of the average qualified practitioner, and a medical specialist is to be held to the standard of care and skill of the average practitioner of the specialty, taking into account with respect to either the general practitioner or the specialist the advances in the profession and the medical resources available to him [Ref. 17, p 798].

Thus, a specialist should be held to the standard of care and skill of the average member of the profession practicing the specialty, taking into account the advances in the profession.

The last case we review redefined the standard of care but was heard in a different jurisdiction than the previously two described cases. In *Hall v. Hilbun*,[18] Terry Hall was admitted to the hospital in Mississippi in May 1978 complaining of abdominal pain. Dr. Hilbun, a general surgeon, was consulted and performed surgery for a small bowel obstruction. Mr. Hall had provided adequate consent, and surgery was performed with apparent success. However, Mr. Hall later died in the hospital of respiratory failure.

Two areas of fault suggested were Dr. Hilbun's failure to make inquiry regarding his patient's postoperative course before retiring on the night of May 20 and his alleged failure to give appropriate postoperative instructions to the hospital nursing staff. The plaintiff called Dr. S. O. Hoerr, a retired surgeon from Cleveland, Ohio, as an expert witness. Through that testimony, the plaintiff sought to establish that there is a national standard of surgical practice and surgical care of patients in the United States to which all surgeons, including Dr. Hilbun, are obligated to adhere. Dr. Hoerr conceded that he did not know for a fact the standard of professional skill, including surgical skills and postoperative care, practiced by general surgeons in Pascagoula, Mississippi, but that he did know what the standard should have been. The Mississippi Supreme Court provided the following:

> [G]iven the circumstances of each patient, each physician has a duty to use his or her knowledge and therewith treat through maximum reasonable medical recovery, each patient, with such reasonable diligence, skill, competence and prudence as are practiced by minimally competent physicians in the same specialty or general field of practice throughout the United States, who have available to them the same general facilities, services, equipment and options [Ref. 18, p 873].

Emergence of Professional Standards

The locality rule was established before the standardization of medical training and certification, which, critics argue, obviated the need for a locality rule. The Liaison Committee on Medical Education (LCME) is recognized by the U.S. Department of Education as the reliable authority for the accreditation of medical education programs leading to a Doctor of Medicine degree.[19] The LCME was founded at a 1942 meeting of the Association of American Medical Colleges and the AMA.[20] The accreditation of allopathic medical schools in the United States is granted by the LCME through compliance with national standards. The locality rule is now difficult to justify, as medical education has become more standardized, and modern technology provides rural physicians with the same access to information for patient care as is available to urban ones.

The Accreditation Council for Graduate Medical Education (ACGME) was founded in 1981 and accredits all U.S. clinical residency and fellowship programs.[21] The ACGME accredits organizations that provide continuing medical education that has a national focus. Medical board certification examinations, administered by the member boards of the American Board of Medical Specialties since its founding in 1933, are national in scope. Although medical school training, medical licensing requirements, and board certification requirements are based on national standards, some states continue to rely on local practice standards to determine the applicable standard of care in medical malpractice lawsuits.

Toward a National Standard of Care

Although *Brune* overturned *Small* and there is an established national basis to the training and certification of medical education, the locality rule remains alive in the United States. Lewis and colleagues[22] delineated which states had established different standards of care. At the time of that publication in 2007, 21 states maintained a version of the locality rule, in which physicians are judged by the standard of care in their locality; 29 states followed a national standard. Of the 21 states that followed a version of the locality rule, 3 followed a statewide standard, 2 the same-community standard, 11 the same- or similar-community standard, and 5 the similar-community standard for general practitioners and a national standard for specialists. These counts were updated in 2014 (M. H. Lewis, personal communication, July 6, 2015); 45 states are now believed to follow a national standard, whereas only 5 states (Arizona, Arkansas, Idaho, New York, and Pennsylvania), still follow a version of the locality rule. Notably, medical schools operate in all states that adhere to the locality rule except Idaho.

A national standard of care presupposes that rural physicians will have the same training, and exercise the same level of judgment and diligence, as urban practitioners. It does not require that rural physicians have the same available medical facilities. For example, if the community does not have facilities for emergency surgery, physicians cannot be found negligent for failing to perform this surgery within the amount of time that might constitute the standard in a well-equipped urban hospital. Because there would still be differences in available resources, physicians practicing under a national standard would need to alert patients to the lack of necessary facilities or resources, should they exist. Advances in modern medicine and the ease of access to those advances regardless of practice location give further support for the eradication of the last vestiges of the locality rule in United States.

Clinical Practice Guidelines

In the 1970s and 1980s, the literature regarding health care costs, common practices, and outcomes surged.[23–26] Research demonstrated that medicine was practiced differently depending on location. For example, patients in Miami spent twice as much time in the hospital and intensive care units as similar patients in Minneapolis.[26,27] In addition, costs for comparable populations differed markedly across the United States. Gawande[24] reported that, in 2006, the average Medicare enrollee in McAllen, Texas, received approximately $15,000 per year in medical services, twice as much as comparable patients in the nearby and sociodemographically similar El Paso. Such disparities represent, in part, local differences in medical culture, including the degree to which communities practice defensively, especially if the science is unclear.

Because of these marked health care delivery inconsistencies, the United States Congress heeded the call for improvements in 1989 by creating the Agency for Healthcare Quality and Research, now called the Agency for Healthcare Research and Quality (AHRQ).[28] This agency was charged with creating specialty-specific clinical practice guidelines to align the fragmented practice of medicine in America. The AHRQ defined practice guidelines as "systematically developed statements [to] assist health care practitioners and patients to make decisions about appropriate health care for specific clinical circumstances."[29]

Professional medical societies, state governments, liability insurers, and health insurance companies followed suit and created their own guidelines. The AHRQ hoped that practice guidelines would result in a more uniform practice of medicine. In addition, the guidelines would provide a host of other benefits, including effective dissemination of research findings into clinical practice, promotion of patient safety, and reduction in the rising cost of health care.[30,31] With regard to health care costs, the goal was to reduce the practice of both defensive and offensive medicine. The latter refers to reducing the frequency of unnecessary interventions performed by physicians purely for financial gain. In establishing these guidelines, the intent was not to establish the standard of care. In fact, each American Psychiatric Association (APA) practice guideline clearly defines the proper use of the guide. For example, the APA Practice Guidelines for the Psychiatric Evaluation of Adults states:

> The American Psychiatric Association Practice Guidelines are not intended to serve or be construed as a "standard of medical care." Judgments concerning clinical care depend on the clinical circumstances and data available for an individual patient and are subject to change as scientific knowledge and technology advance and practice patterns evolve [Ref. 32, p 799].

Nonetheless, many states hoped that, through the creation of these guidelines, adherent practitioners could be shielded from frivolous litigation, eventually reducing the practice of defensive medicine.[26] Most notably, Maine promised in the 1990s that strict adherence to practice guidelines would shield practitioners as an affirmative defense to medical malpractice. However, this one-way street would not allow plaintiffs to use nonadherence to the guidelines as evidence in a malpractice case. Despite similar programs and intents in Florida, Minnesota, and Vermont, none of the state programs was successful, nor did they control costs. Furthermore, Florida and Minnesota failed to issue practice guidelines.[30]

As of April 2017, there were 8,228 individual guideline summaries for all medical specialties according to the AHRQ.[33] Of those, there were 229 individual guideline summaries for psychiatry and psychology. With this surfeit of guidelines, it is easy to conclude that, at best, many provide redundant information and, at worst, they provide conflicting information, thus undermining their primary intent. These guidelines have at least four significant pitfalls that limit their usefulness in unifying the practice of medicine and providing a concise summary of appropriate medical care for a specific clinical circumstance. More have been explicated by Recupero.[28]

First, many guidelines quickly become outdated because of new research and practices. After approximately six years, only half of all practice guidelines on the AHRQ website were valid.[34] Replacing a guideline costs an average of $350,000. The rapid expiration of guidelines requires large expenditures of time and money that can hamper effective dissemination of concise recommendations.

Second, many of the guidelines conflict with each other, even when created contemporaneously. Saddichha and Chaturvedi[35] highlighted how some preeminent psychiatric institutions' guidelines differ from one another. For example, in the management of schizophrenia, the duration of treatment and recommended psychosocial interventions differed significantly. These clashes confuse patients and may cause clinicians to ignore the weight of the recommendations.

Third, many of the guidelines lacked the requisite scientific evidence to support their recommendations. One study found that 90 percent of guidelines failed to describe formal methods of how guideline authors reconcile scientific evidence with expert opinion, and more than 25 percent of guidelines failed to cite any references.[36] Furthermore, some guidelines note that relevant older literature was explicitly excluded from the guidelines for practical purposes, to streamline literature review. For example, the authors of the APA's Major Depressive Disorder practice guideline acknowledged that the recommendations emphasize newer treatments, minimizing helpful information regarding tricyclic antidepressants and monoamine oxidase inhibitors.[37] To mitigate these omissions, the authors encouraged readers to consult older versions of the practice guidelines. However, these older versions are not available on the website.

Finally, guidelines established by private health insurance companies, liability insurers, and the pharmaceutical industry, groups without fiduciary responsibilities to patients, may be biased. Guidelines created by these entities should be considered with skepticism because of inherent conflicts. Nor are guidelines that are issued by professional medical societies immune from bias, as many authors have significant relationships with industry. Choudhry and colleagues[38] discovered that only seven percent of guideline authors believed that their own relationship with the pharmaceutical industry influenced their recommendations. Yet, of that same group of authors, 19 percent believed that their coauthors' recommendations were influenced by pharmaceutical relationships.

Notwithstanding these many pitfalls, the question remains of whether physicians adhere to their specialty's practice guidelines with the goal of unifying and improving the practice of medicine. Even with free online access to over 8,200 individual guidelines, the behavior of physicians has not measurably changed.[30] More than half of the physicians surveyed did not know that guidelines existed online. Even those aware of the guidelines objected to following them for various reasons, including an aversion to practicing "cookbook" medicine, the wish to adhere to non–evidence-based recommendations, and the perception that guidelines represented a threat to their practice autonomy.[39]

Even though the creation of practice guidelines was not intended to set the standard of care, artful attorneys have found that these widely published standards, despite their many pitfalls, could be persuasive to juries in malpractice litigation, especially those guidelines created by professional medical societies. The Federal Rules of Evidence[40] and landmark cases of *Reilly v. Pinkus*[41] and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[42] paved the way for entering medical treatises as evidence. Plaintiff attorneys attempt to use CPGs as a "sword," or as inculpatory evidence. Defense attorneys attempt to use CPGs as a "shield," or as exculpatory evidence.[43] Although malpractice cases rarely make it to trial,[44] the cases that do may involve use of CPGs as evidence on either side of the courtroom.

Hyams and colleagues[43] assessed how often and how successfully CPGs were used as evidence in malpractice cases. In a computerized search of U.S. courts from 1980 through 1994, there were 37 instances in which CPGs were used as either a shield or sword, whether successful or not. CPGs were used successfully in 28 cases, 22 times by plaintiffs, and 6 times by the defense. Generally, when CPGs were used successfully, the guidelines originated from strong, evidence-based sources, such as the APA, American College of Obstetrics and Gynecology, American Heart Association, AMA, American Academy of Pediatrics, and the American Society of Anesthesiologists. However, nine times the guidelines were used unsuccessfully: seven times by plaintiffs and twice by the defense. In those instances, the guidelines originated principally from liability carriers or federal institutions, not professional medical societies, likely contributing to their failure to persuade. It should be noted that these outcomes hinged on the verdict at trial and CPGs were just one part of the larger body of evidence. In addition, because of the age of that study, the findings may be limited; it is unclear if this pattern of CPG use in the courtroom persists today.

Discussion

This historical review of the development of the standard of care reminds mental health experts that despite case law and the national standards of medical training and certification, the locality rule remains alive in some jurisdictions of the United States. The distinction between a generalist and a specialist still prevails. For example, a family medicine practitioner in the rural southern United States will not be expected to possess the same knowledge of viruses as an infectious disease specialist at an academic institution in a major city in the southeast.

When retained in medical malpractice cases, the expert must remember that the standard of care may vary among jurisdictions in the United States. Practice guidelines, although intended to unify and improve the practice of medicine, often fail to provide sufficient clarity because of age, conflicting recommendations, various levels of evidential support, and underutilization by practitioners. In many cases, the standard of care is determined *de novo* and is a moving target. This is one reason why static documents, guidelines, and algorithms are not quite coextensive with the requirements of the legal system. Furthermore, learned medical treatises do not constitute evidence *per se*. Rather, they are elements of the experts' opinions that may be introduced into evidence at trial.

Expert witnesses must carefully consider whether to use CPGs in reports or testimony, for example in personal-injury cases. Newer technologies and data analytics, including standards built into the elec-

tronic health record, may also shape the modern standard of care. Future research should examine the current use of practice guidelines and emerging technologies as evidence in malpractice cases.

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