

The Impact Of Evidence-Based Medicine And Evolving Technology On The Standard Of Care In Emergency Medicine

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Abstract

Liability in a medical malpractice case is determined by assessing whether medical care meets the "standard of care". Generally, physicians are accustomed to a standard of care that reflects prevailing medical practice. Evidence-based medicine (EBM) provides an alternative standard, by encouraging physicians to apply current best evidence when caring for patients. In this paper, we explore the ramifications of an EBM-based standard of care. We propose that one important ramification may be "fast tracking" proposed medical innovation to the threshold of legal liability before general acceptance by the medical community. We anticipate that this will be problematic when the innovation requires time to implement -- such as when the acquisition of new skills must precede implementation of an evolving technology. Emergency physician-performed ultrasound guided central venous access represents such a technology. This paper explores the role of custom in medical malpractice litigation and the evolution of EBM. A hypothetical case involving emergency physician-performed ultrasound distinguishes a standard of care based on custom from a standard based on EBM.

Introduction

Physician liability in a medical malpractice case is determined by assessing whether medical care meets the “standard of care”. Generally, physicians are accustomed to a standard of care that reflects prevailing medical practice. Reliance on the medical community to define this customary standard for professional liability has led to allegations that physicians have been allowed to determine their own negligence standard in medical malpractice litigation. Some propose a more objective, measurable standard more palatable to a lay jury. This more judicial standard would be less reliant on a profession whose members often disagree on how to practice their profession.

Evidence-based medicine provides an alternative standard, by encouraging physicians to apply current best evidence when caring for patients. To accomplish this, EBM instructs physicians to rely on current scientific evidence, even before that evidence is regarded as the prevailing custom. In this paper, we explore the ramifications of an EBM-based standard of care. We propose that one important ramification may be “fast tracking” proposed medical innovation to the threshold of legal liability before general acceptance by the medical community. We anticipate that this will be problematic when the innovation requires time to implement—such as when the acquisition of new skills must precede implementation of an evolving technology. Emergency physician-performed ultrasound guided central venous access represents such a technology. This paper begins by examining the role of custom in medical malpractice litigation. Next, the evolution of EBM is discussed. Finally, a hypothetical case involving emergency physician-performed ultrasound is presented to exemplify how an emerging medical innovation might be viewed in light of an EBM-based standard of care.

Customary Practice Standard of Care

The Basic Framework

Medical malpractice is an area of negligence law. The tort of negligence contains four elements: duty, breach, causation, and damage. A plaintiff in a medical malpractice action must answer each question in the affirmative in order to prevail¹. Typically, to satisfy this burden, plaintiffs use expert witnesses to distinguish the medical care in question from care regarded as acceptable by practicing physicians similarly situated. The “standard of care” is the legal vernacular for acceptable care by which all other care is measured.

The Customary Standard of Care

Standards of care are derived from various sources including common law, state statutes, federal and state agencies, and professional ethics². In most areas of negligence law, these sources predominate in establishing a standard and manifest in the “jury's wisdom” or the “legislature's fiat”³. While the majority of negligence cases use a standard born out of reasonableness, medical malpractice cases rely on what is customary among physicians to establish the standard. Why has the legal community allowed physicians to dictate their own standard of care? Perhaps the most compelling theory rests in the highly technical nature of a medical malpractice case. Laymen, it is feared, may be unable to evaluate a physician's conduct, or determine what a reasonable person with specialized training and knowledge should have done under similar circumstances⁴. Furthermore, the adage that “medicine is an art, as well as a science” conveys the notion that physicians tailor the science of medicine to individual patients, weighing their individual health histories, behavior and other variables in a way only other physicians could appreciate and understand⁵.

Limitations of the Customary Standard

Before national standards for medical care were recognized by courts, the customary practice standard of care applied to physicians in close proximity to each other. This “locality rule” was intended to protect rural physicians from, having to be as advanced in training and resources as their urban counterparts⁶. In the past, the customary standard may have contributed, to the difficulty litigators had in eliciting experts to testify when both expert and defendant practiced in the same locality. Accusations of a conspiracy of silence arose when lawyers could find no one willing to testify against a neighboring physician⁷. Instead of addressing the negligence standard which relied so heavily on participation from the medical community, many jurisdictions addressed the problem by lifting the locality rule's geographic constraint.

Today, the customary standard may account in part for the inertia evident in the way physicians incorporate proven medical innovation into their daily practice. Generally, the customary standard provides a safe haven for physicians who align themselves with the status quo regardless of whether or not this affiliation reflects the latest medical information. In doing so, the current standard may dissuade physicians from employing the latest medical advances⁸. Critics of the customary standard believe that physicians employing old or outdated techniques may feel immunized against liability as long as the profession still predominantly uses those techniques⁹. As a result, custom may contribute to the tremendous delay between discovery of effective therapies and their routine use¹⁰.

Courts deliberating medical malpractice cases have strayed from the customary practice standard with increasing frequency. The patriarchal case exemplifying a court's use of an alternative standard of care analysis may be *Helling v Carey*. In *Helling*, the Supreme Court of Washington supplanted a customary standard with a judicial risk/benefit analysis¹¹. The court concluded that an ophthalmologist was negligent for not employing a simple glaucoma test in a patient under forty despite the fact that it was not customary in 1974 to do so.

Currently, one quarter of states reject conclusive deference to medical custom¹². Nearly half of all jurisdictions employ some degree of reasonableness to their medical negligence calculus¹³. Scholars have acknowledged the shift towards a reasonable physician standard resembling the negligence standard used for nonprofessionals¹⁴. Others have described a “best-judgment” analysis holding defendants liable if the court concludes the defendant's conduct did not employ the “best judgment” regardless of whether or not the physician's conduct comported with prevailing custom¹⁵.

Evidence-Based Medicine

It remains unclear if EBM represents a resurrected methodology or *is* the progeny of modern medical thinking. The same ideological principles that serve as the foundation of EBM were criticized during their development in the nineteenth and early twentieth centuries¹⁶. Those seeking the origin of EBM will hardly find consensus on the topic; they will find a wide range of theories with which to align themselves. While some find traces of the movement's origin in ancient Greek philosophy¹⁷, others trace its roots to ancient Chinese medicine¹⁸. Most, however, consider the current version of EBM to be influenced to some degree by the recent work of a select few: Archie Cochrane's efforts to summarize pertinent innovations of clinical disciplines; Alvan Feinstein's delineation of the principles of quantitative clinical reasoning; David Sackett's innovation in teaching critical thinking—all were pivotal and have been credited with the latest rendition of EBM¹⁹.

Many definitions attempt to distill the essence of EBM, but perhaps the most successful is given in David Sackett's book, *Evidence Based Medicine: How to Practice and Teach EBM*. Dr. Sackett describes EBM as “the integration of best research evidence with clinical expertise and patient values”²⁰. Other definitions of EBM that have populated the literature over the last ten years offer some variation of this central message of merging best research with individual circumstance.

Practitioners of EBM achieve this level of integration by performing five critical steps. Physicians must first convert their need for information into an answerable question. They must then know how to track down the best evidence addressing that question. Once this information is in hand, physicians must have the skill to appraise the evidence critically, as well as to assess its impact on and applicability to a given situation. The fourth task is to integrate that appraisal with the physician's expertise and the uniqueness of the patient at hand. Finally, physicians must evaluate their performance²¹.

EBM has changed the way clinicians and researchers report, disseminate and use medical innovations; it advocates structured abstracts²² and “summarizing studies of high relevance and methodological quality”²³. To this end, *practitioners of EBM have spawned* collaborative international databases such as the *Cochrane Library* and *Clinical Evidence* that house systematic reviews of contemporary medical literature as well as medical texts dedicated to the tenets of evidence-based decision making²⁴. Teaching institutions no longer debate whether or not to teach EBM; the question, rather, is how to

teach it²⁵. Currently, a considerable body of literature engages in the conversation on which method should be used to incorporate EBM into the armamentarium of fledgling doctors²⁶.

However, EBM has its limitations. First, not all that is published in medical journals should be considered compelling medical evidence. For some time physicians have recognized that there exists a significant amount of chaff surrounding medical literature's wheat. Second, few articles possess the scientific integrity necessary to resolve a clinical question definitively. In 2003, a review of the current literature was conducted to determine whether the results from urinary dipsticks were sufficient to exclude a diagnosis of urinary tract infection.²⁷ Out of the seventy-five articles addressing the topic, only two contained the right combination of statistics, sample size and design essential to evidence-based medicine. Third, the large randomized controlled trials relied on so heavily by evidence based disciples are not without limits. Out of 3000 such trials existing in the field of neonatology, many await "unbiased evaluation" before they can be considered evidence worthy of changing how clinicians practice their specialty²⁸.

Other limitations exist. Estimates based on current rates of publication indicate that it would take reviewers a decade to produce the necessary number of *Cochrane* reviews required to summarize existing evidence²⁹. Also, to practice EBM one must have evidence. Many questions in medicine are without the preferred randomized controlled clinical trials needed to support or refute an intervention³⁰. Other problems are linked to the worthiness of unpublished data, homogenization of populations studied, and the supposition that only randomized studies lead to valid scientific knowledge³¹.

Evidence-Based Medicine as the Standard of Care

The issue of when a medical innovation becomes standard therapy is not new in cases of medical malpractice. Not long ago, courts used a customary care standard to help define when computerized axial tomography (CAT) scans³² and pulse oximetry became standard technologies³³. While courts continue to hear cases involving new technologies, they are also becoming familiar with the concept of EBM. In 2004, EBM was used to persuade the Supreme Court of Wyoming to enter into evidence a theory citing trauma as an etiology for fibromyalgia³⁴. Similarly, a trial court in the Commonwealth of Virginia heard EBM introduced as the standard of care in a defense against a claim of medical malpractice³⁵. It is foreseeable that the issue of when a medical innovation rises to the level of standard of care therapy will soon be viewed in light of an EBM-based standard of care.

Testing the evidence-based standard

The need for physicians to acquire new skills has been one factor cited in determining how quickly new innovations are adopted into clinical practice³⁶. The use of emergency physician-performed ultrasound for procedural guidance represents a recent technology with evidence for improved patient care that has yet to be adopted by the majority of practicing emergency physicians. This technology will be considered in light of customary and evidence-based standards of care.

Emergency Physician-Performed Ultrasound

Ultrasound is a modality used for both diagnosis and procedural guidance. In the past, ultrasound in the United States has been primarily performed by radiologists, with emergency physicians and other clinicians obtaining needed studies in consultation with one of these specialists. However, as ultrasound equipment has become smaller, better, and less costly it has been increasingly adopted for use by clinical physicians at the bedside.

Emergency physician-performed ultrasound was first described in the literature in the 1980's^{37, 38, 39} and has become widely used in teaching programs. In 1997 approximately 50% of residencies provided training in bedside ultrasound. By 2002 over 92% provided such training with the remainder reporting plans to implement training programs^{40, 41, 42}. The American College of Emergency Physicians (ACEP) has issued a policy statement regarding ultrasound stating that "bedside ultrasound evaluation, including examination, interpretation, and equipment, should be immediately available 24 hours a day for ED patients", and that "emergency ultrasound procedures are standard emergency physician skills"⁴³. However, penetration into the community setting has been slow. The longitudinal survey by the American Board of Emergency Medicine found that in 2001 only 21% of board certified emergency physicians "personally perform bedside emergency ultrasound"⁴⁴.

Hypothetical Case

An obese fifty year-old woman presenting to the ED with fever, hypoxia, and dehydration is found to have severe pneumonia. After several attempts at peripheral intravenous catheter placement by the nursing staff the only access obtained is a 24-gauge catheter in the wrist. Although the patient has been stabilized somewhat on oxygen and is slowly receiving antibiotics, the admitting physician requests that the emergency physician obtain central venous access prior to transfer to the intensive care unit. Informed consent is obtained for the central line. Despite availability of ultrasound in the ED the physician performs landmark-guided access to the internal jugular vein. After several attempts access is obtained and portable chest radiograph appears to show the line in good position. The patient is sent to the intensive care unit. The following morning the patient is found to be aphasic and hemiplegic on the side contralateral to the central line. It is discovered that the line was placed in the carotid artery with resultant thromboembolic stroke. The line is removed and replaced on the opposite side. The

patient makes a partial recovery but significant deficits remain. The patient sues the doctor for failing to use ultrasound guidance to obtain central access.

The Evidence for Ultrasound-Guided Central Venous Access

In 2001, under its “Evidence-Based Practice Program”, the Agency for Healthcare Research and Quality (AHRQ) published *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*⁴⁵. This was largely in response to the Institute of Medicine's 1999 report that estimated between 44,000 and 98,000 deaths per year occurred in the United States as a result of medical errors⁴⁶. The AHRQ publication detailed ways to decrease medical errors with a specific chapter devoted to ultrasound-guided central venous access, noting that patients “with one or more risk factors, (eg. critically ill patients on positive pressure ventilation with generalized edema and coagulopathy), may reap the greatest benefit”⁴⁷. In an addendum to the report patient safety practices were rated by strength of evidence into one of five categories, from “*lowest impact and/or strength of evidence*” to “*greatest strength of evidence regarding their impact and effectiveness*”. Use of ultrasound guidance to decrease morbidity from central venous catheterization was placed in the highest category, reflecting the greatest strength of evidence⁴⁸. It should also be noted that among the eleven recommendations with greatest strength of evidence, ultrasound guidance for central venous access was one of two with an implementation cost/complexity that was rated as “high”.

In addition to evidence from the AHRQ, the ACEP policy statement specifically states that “the use of ultrasound imaging by emergency physicians is appropriate in clinical situations...and procedures that would benefit from the assistance of ultrasound.”

Application of an Evidence Based Standard

Under a customary standard of care physicians are expected to possess the same degree of professional skill or knowledge when compared to similarly situated physicians. This would mean that it would be standard of care only when it is customary for physicians to use ultrasound guidance for central access, regardless of any published evidence or recommendations. Alternatively, if the recommendations described above were considered the requisite evidence of an evidence-based standard, physicians would be held to that level of care regardless of whether or not other physicians had yet incorporated those recommendations into their practices.

Implementing New Technology

Courts may expect teaching hospitals to lead the way in incorporating ultrasound -guided central venous access into routine practice. In 1987 an otherwise healthy 36 year-old woman underwent elective tubal ligation under general anesthesia at a teaching hospital in the District of Columbia. She was intubated by a nurse anesthetist working under the

guidance of an anesthesiologist. The surgeon noted that the patient's blood was unusually dark, indicating hypoxia, and shortly after this the patient's heart rate dropped precipitously. An esophageal intubation was recognized and the patient was resuscitated, however she suffered irreversible anoxic brain injury. The family sued, with one of the major contentions being that end tidal carbon dioxide monitoring was not provided, which would have allowed earlier recognition of the failed intubation.

Despite the fact that a minority of hospitals were routinely using end-tidal carbon dioxide monitoring in 1987 the courts found in favor of the family, with the decision upheld on appeal. The Court's rationale was that end-tidal carbon dioxide monitoring was an "emerging standard of care" and that a teaching hospital such as the Washington Hospital Center should be held to this standard⁴⁹. In addition, the decision cited policy statements by the American Society of Anesthesiologists encouraging the use of monitors as well as the "Standards for Patient Monitoring During Anesthesia at Harvard Medical School" published one year previously.

Individual ability will also affect the timing of when ultrasound is incorporated into a physician's practice. Ultrasound is a modality requiring proficiency in both cognitive (indication and interpretation) and psychomotor (hands on) skill. It has been suggested that training in both image acquisition and image interpretation must be provided through curricula that include didactic lectures, demonstrations, and technical skill laboratories^{50, 51}. Ultrasound is not only a learned specialty, but one that requires maintenance of skills and familiarity with technology. While many emergency physicians currently emerging from training programs are well versed in the use of ultrasound, others with earlier training may be less acquainted with it. Should these groups of physicians be held to a different standard? While a customary standard may wait until this practice is widely adopted, an evidence-based standard has no provision for the acquisition of skills necessary to adopt some new innovations.

Conclusion

It remains to be seen how a standard of care based on EBM will affect physicians and the practice of medicine. One alternative depicted in the hypothetical case demonstrates how EBM may increase the pressure on physicians to adopt novel medical innovations in order to comply with the more judicial standard of care EBM would provide. One outcome may be that EBM may serve to hasten the implementation of proven medical innovations into routine practice. Alternatively, EBM may prove too inflexible a standard in certain circumstances, such as when the acquisition of new skills must precede the implementation of a new innovation. A customary standard of care may persist if the burden on physicians to incorporate new innovations under an EBM standard proves to be too great. It is not our intent to persuade physicians to choose ultrasound guidance over landmark-guided central line placement. However, readers should be aware that personal injury web sites sponsored by plaintiff attorneys, such as <http://www.injuryboard.com>, provides information regarding the benefits of ultrasound-guided central venous access while offering to assist its readers in finding a

personal injury attorney. Physicians should appreciate this aspect of EBM and understand how a standard of care based on “best-evidence” can affect their practice.

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