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The Leapfrog Standards: Ready To Jump From Marketplace To Courtroom?

Using the tort system to enforce aspirational standards of care may inhibit achieving greater patient safety.

by Michelle M. Mello, David M. Studdert, and Troyen A. Brennan

ABSTRACT: The Leapfrog Group, a consortium of large employers, aims to use its collective purchasing power to motivate hospitals to implement particular measures designed to improve patient safety and the quality of care. While these criteria are meant to be purely aspirational, and while Leapfrog’s effort is praiseworthy, we caution that the articulation of these standards of care may have unintended legal consequences. Efforts by aggressive medical malpractice attorneys could rapidly transform Leapfrog’s standards from marketplace advantages for compliant hospitals to performance expectations required by law. This undesirable potential outcome compounds the importance of selecting these standards with the utmost care.

The Institute of Medicine’s reports on patient safety and quality improvement have sparked a flurry of activity in health policy by a range of stakeholders. Traditional regulators such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and Medicare Peer Review Organizations have developed new patient safety requirements. The federal Quality Interagency Coordination Task Force is attempting to synthesize a comprehensive federal approach to medical safety improvement. The nonprofit National Quality Forum is doing much the same, working with insurers, states, and the federal government. Finally, the Agency for Healthcare Research and Quality (AHRQ) is formulating expert evaluations of cost-effective safety practices.

Perhaps the most enterprising activity is that of the Leapfrog Group, a consortium of more than 100 large employers, to mobilize employers’ purchasing power to motivate health care institutions to improve patient safety. Founded by the Business Roundtable, the Leapfrog Group has announced the intention of steering the thirty-one million employees it represents toward health care institutions that...
have adopted specific safety measures. This is to be accomplished by giving consumers information about comparative institutional performance, selecting and deselecting providers from employer health plans, and manipulating employee cost-sharing levels.

To date, Leapfrog has identified three safety standards: computerized physician order entry (CPOE) of medication orders, referral of patients in need of certain high-risk procedures to hospitals that meet specific annual volume criteria, and round-the-clock coverage of surgical and medical intensive care units (ICUs) by intensivists. Leapfrog selected these measures based on their perceived potential to greatly reduce avoidable adverse events, their feasibility of implementation in the near term, their appeal to consumers, and their measurability.

Leapfrog’s approach attempts to expedite patient safety improvements by situating them in a marketplace context, rather than relying on regulators to introduce and enforce new requirements. Leapfrog points to General Motors’ experience with value purchasing of health plans as evidence that purchasers can effectively exploit “leverage points” to inspire providers to institute quality improvements.

We applaud this employer initiative but caution that it may have unintended consequences in an overlooked area: medical malpractice litigation. In many respects, the Leapfrog initiative is an effort to redefine the medical standard of care, nudging it upward from today’s standard. Although there is no suggestion from the Leapfrog Group or its proponents that the selected performance criteria are intended to constitute a legal standard of care, such critical revisions of medical standards can create grist for malpractice litigation. We argue that efforts by aggressive malpractice attorneys could rapidly transform Leapfrog’s safety standards from marketplace advantages for compliant hospitals to performance expectations required by law. This suggests that we must be very careful in the selection and articulation of such standards.

**Trends In Defining The Legal Standard Of Care**

**Waning role of professional custom.** A review of trends in the legal definition of the standard of care in medical malpractice cases illustrates how the Leapfrog criteria might be integrated into that standard. Medical malpractice, like other areas of tort law, is a matter of state law. The legal standard of care is set by state court judges (or, rarely, a state statute) and therefore may vary across states. Although it is important to recognize this variation, it is possible to make some observations about overall trends in malpractice law.

Historically, courts have defined the malpractice standard of care in a conservative fashion. In most other areas of tort law, the negligence standard involves a determination of whether the defendant deviated from “reasonable” conduct, as defined by a jury. In medical malpractice, negligence traditionally has been defined as a failure to conform to the standard of care that would customarily be expected of a
physician in the same specialty practicing in a similar community. The customary standard of care and the defendant’s breach of that standard are established through expert testimony.

Expert witnesses will often find independent grounds to support their opinions. Through their testimony, findings contained in textbooks, clinical practice guidelines, and peer-reviewed publications may be entered into evidence. But the expert’s testimony must confirm that the content of these publications indeed describes current customary practice.

In other areas of tort law, courts have been willing to impose their own views of what constitutes reasonable behavior, in order to promote greater safety. The classic decision by Judge Learned Hand in The T.J. Hooper is an example of an activist court demanding greater use of technology—in that case, radio receiving equipment in tugboats—to reduce the likelihood of accidents. In contrast, courts in medical malpractice cases traditionally have been hesitant to require a higher standard of care than that to which physicians customarily adhere. The rationale is that cases of professional negligence involve judgments that judges and juries, who lack medical training, are not well qualified to make.

There are clear signs that this historical deference to medical custom is waning, however. Until relatively recently there were only a few instances of judicial departures from the custom rule. Although well publicized, these cases were generally viewed as aberrant. Perhaps the best-known such case is Helling v. Carey, a 1974 decision in which the Washington Supreme Court applied a standard of care based on reasonable prudence, rather than medical custom, to an ophthalmologist who did not administer an intraocular pressure test to a thirty-two-year-old woman who subsequently developed glaucoma. Despite credible expert testimony that ophthalmologists did not customarily perform this test in patients who were under age forty, the court found the defendant negligent. The court noted that because the pressure test was simple, inexpensive, effective, and risk-free, it was indefensible not to provide it to all patients.

The trend away from adherence to the custom rule has recently become much more pronounced. There are a mounting number of cases in which judges have used Helling-like reasoning to hold health care providers liable in negligence even when they did not depart from customary medical practice. Eleven states and the District of Columbia have now explicitly abandoned the custom standard and adopted a reasonableness test, and an additional nine have endorsed a reasonableness test without specifically addressing the role of custom. The drift away from customary standards is particularly evident in three areas: adoption of new technology, the evidentiary role played by clinical practice guidelines, and expansions in the doctrine of informed consent.

**Adoption of new technology.** In several cases, courts have forced the adoption of a specific technology by invoking the reasonableness standard. In Washington v. Washington Hospital Center, for example, a D.C. appellate court upheld a multimillion-
dollar negligence verdict against a hospital that did not employ end-tidal carbon dioxide monitors and continuous oximetry to reduce the risk of anoxic brain injury during general anesthesia. In 1987, at the time of the surgery at issue, the benefits of these technologies had been established, the American Association of Anesthesiology had issued guidelines that “encouraged” their use, and some of the nation’s leading academic medical centers had implemented them. However, there was no evidence that all or even most hospitals had yet adopted them. Notwithstanding the lack of an established custom, the court ruled that the use of the monitoring equipment was required under a standard of reasonable prudence.

This case illustrates how the shift from a custom-based to a reasonableness standard may have important implications for technology adoption: Hospitals that lag in adopting “best practices” may face legal consequences. The shift to a reasonableness standard thus presents some danger both for providers and, because new technologies tend to push up the cost of health care, for society as a whole. However, unlike the custom standard, the reasonableness standard entails an evaluation of the costs and benefits of the proposed safety-enhancing technology. Courts generally ground their analysis in a rudimentary formula articulated famously by Judge Hand more than fifty years ago: If the burden $B$ of the proposed safeguard is less than the probability $P$ of injury without the safeguard multiplied by the severity $L$ of the potential injury, then the defendant may reasonably be held liable for failing to adopt the safeguard. The implication for the Leapfrog standards is that courts testing their reasonableness may demand that plaintiffs show that the interventions are justified by a basic cost-benefit balancing.

**Clinical practice guidelines.** Departures from the custom-based standard of care are also evident in the types of evidence that courts allow plaintiffs to introduce to establish the standard of care. For instance, courts often admit clinical practice guidelines into evidence in connection with expert testimony about the standard of care without requiring a showing that the guidelines actually represent customary medical practice. Typically, plaintiffs must prove that the guidelines are “reliable” in that they are recognized as authoritative in the medical field, but this determination hinges more on what organization issued the guideline and the soundness of the process used to draft and update it than on whether most physicians comply with the guideline.

Indeed, courts have in some cases required adherence to authoritative guidelines even though an expert has testified that compliance with those guidelines is not universal. In *Kramer v. Milner* an Illinois appellate court considered the case of Lillian Kramer, who died of breast cancer at the age of seventy-four. Her cancer was detected through a screening mammogram in 1988. Her husband sued her previous primary care physician, who had not recommended a mammogram at any time between the date he began treating her in 1985 until she left his care in 1988. The plaintiff’s expert testified that the standard of care required an annual mammogram for all women over age fifty whose mother or sister had had breast
cancer, based on the recommendations of the American Cancer Society and the National Cancer Institute. (Kramer’s sister, also a patient of Milner’s, also had had breast cancer.) The plaintiff’s expert further testified that these guidelines enjoyed adherence by a strong majority of physicians, but the defense expert countered that the guidelines were only “signposts” to assist an internist in practice, enjoyed less than 50 percent adherence, and were not “clearly standards of practice” in 1985.

Faced with this disagreement, the trial court did not instruct the jury to consider the guidelines as part of its determination of negligence. The jury found for the defendant. The appeals court overturned the verdict, holding that professional practice guidelines are an appropriate consideration in determining negligence even where there exists conflicting evidence about the appropriate medical standard of care.

It seems likely that the courts will continue to incorporate practice guidelines into standard-of-care determinations, despite evidence that most guidelines do not garner compliance by a strong majority of physicians. Up to now, the guidelines considered have usually been those promulgated by professional societies, but a plaintiff’s attorney might be able to persuade a court to consider the Leapfrog standards as well. So long as the plaintiff establishes the authoritativeness of the group that drafted the criteria and the process it used, the criteria might be considered as evidence of the standard of care even though most hospitals are not yet in compliance with them.

Informed consent. A century ago courts typically demanded that the expert testimony against a defendant physician in malpractice cases be drawn from the local area in which that physician practiced. Influenced by the nationalization of medicine through developments such as standardized board examinations, courts dismantled this “locality rule” in the mid-nineteenth century and embraced a national standard of care. At least one recent case suggests that that standard is now morphing into a new one, at least in the area of informed consent.

In Johnson v. Kokemoor the Supreme Court of Wisconsin considered the case of a patient who underwent a basal artery aneurysm clipping in Chippewa Falls, Wisconsin. The patient had no neurological problems before the operation but afterwards was a quadriplegic. The plaintiff claimed that the surgeon had overstated his experience performing this type of surgery and understated the risks. Additionally, the plaintiff’s experts testified that patients with basal aneurysms should be referred to tertiary care centers with appropriate neurological ICUs, microsurgical facilities, and more experienced surgeons, such as the Mayo Clinic, which was only ninety miles away. The most trenchant part of the plaintiff’s informed consent claim was her assertion that the circumstances created an obligation to offer a referral to a tertiary care center. The Supreme Court of Wisconsin agreed that the defendant had such an obligation, holding that “the plaintiff could not make an intelligent decision or give an informed consent without being made
“The Leapfrog standards are intended to improve patient safety, which is the quality issue that malpractice litigation targets.”

aware that surgery in a tertiary facility would have decreased the risk she faced.”23

This holding has potential implications for the Leapfrog standards. For example, under Kokemoor, a physician at a hospital without constant coverage by intensivists may have an obligation to tell high-risk surgical patients that they face better odds at a hospital that meets this Leapfrog criterion. In the absence of such a warning, the patient could bring suit against two targets: an ordinary malpractice claim against the hospital for not implementing the Leapfrog measure, and an informed-consent claim against the physician for not warning of the hospital’s “failure” in this regard.

Leapfrog Standards As Legal Standards Of Care

In some respects, the Leapfrog standards are readily integrated into a legal definition of the standard of care. They are intended to improve patient safety, which is exactly the quality issue that malpractice litigation targets. Additionally, the Leapfrog standards are clear, explicit, and measurable—it is easy to determine whether an institutional provider adheres to them. This clarity will appeal to a judge or jury, who otherwise could be confused by complicated medical testimony.

What would it mean, as a practical matter, for the Leapfrog standards to become the legal standard of care? A patient injured by a rare drug interaction while hospitalized could introduce expert testimony that this interaction, although rarely anticipated by practicing physicians, can be reliably identified and prevented by standard CPOE systems, as shown by Leapfrog’s research. To take another example, a patient injured by complications from esophageal surgery at a hospital that does fewer such surgeries than Leapfrog’s volume standard could argue that he should have been warned that he faced a greater risk of complications at the low-volume hospital than he would at a high-volume facility. Thus, hospitals could face tort liability for failing to adopt the Leapfrog measures. Additionally, hospitals that do adopt them could be held liable for implementing them in a negligent fashion—for example, installing a faulty CPOE system that fails to detect a known drug interaction. We do not explore the latter point in depth, but we note that with the adoption of new technologies comes new responsibilities.

Persuading the courts. Courts might flatly rebuff plaintiffs’ attempts to introduce the Leapfrog standards into evidence, on the basis that they do not represent medical custom. However, there are at least three avenues through which plaintiffs’ attorneys might succeed in persuading courts to admit the standards as evidence of the standard of care. The first is via the informed consent angle. Along the lines of Kokemoor, the court could reason that a patient cannot give truly informed consent without knowing that her risk might be lower at a Leapfrog-
compliant hospital. This argument is potentially persuasive in both custom-based and reasonable-prudence jurisdictions.

The second avenue is through a *Helling*-type argument that the relevant Leapfrog standard is so imperative that for a hospital not to implement it is not justifiable. This argument may be quite effective in states that use a reasonableness test but less so in states with a custom standard. A defendant might protest that *Helling*-type reasoning is inappropriate as regards the Leapfrog standards because unlike the glaucoma test at issue in *Helling*, the Leapfrog measures are not simple or inexpensive to provide. However, modern analyses under the reasonable-prudence standard, such as the *Washington* opinion, do not appear excessively concerned with absolute costs but tend to focus more on the effectiveness or cost-effectiveness of the measure in question.

The third avenue is to draw on precedent concerning the admissibility and evidentiary weight of clinical practice guidelines. The plaintiff’s attorney could argue that the Leapfrog criteria are a type of guideline that should be considered as evidence of the legal standard of care, just as other kinds of guidelines are. The Leapfrog standards do resemble clinical practice guidelines in terms of the process of research and deliberation that underpins them. They diverge from some guidelines in that Leapfrog does not claim that its criteria represent current medical custom, but some guidelines are intended as best practices rather than minimum “quality baselines.”24 Both clinical practice guidelines and the Leapfrog criteria would be more difficult to get admitted into evidence in jurisdictions that use custom as the legal standard of care than in jurisdictions that have moved to the reasonable-prudence standard.

### The role of causation.

It is important to keep in mind that a plaintiff must do more than simply persuade the trier of fact that a given Leapfrog criterion represents the legal standard of care; he must show that his injury was causally related to the defendant’s failure to adhere to a Leapfrog standard.25 This may be challenging, since acts of omission are not mechanistically linked to effects in the way that acts of commission are. However, as discussed earlier, a plaintiff might be able to present compelling evidence in the form of expert testimony that if a CPOE system or round-the-clock intensivist coverage had been in place, the problem that caused injury would have been detected before harm was done.

### Reason for concern?

Is there any reason for concern over the potential use of Leapfrog criteria in malpractice litigation? The threat of greater liability would likely boost hospitals’ incentives to devote resources and energy toward meeting the Leapfrog standards. The answer thus depends in part upon our confidence in the Leapfrog criteria as reasonable standards and partly upon our judgment about the appropriateness of using legal sanctions (as opposed to just economic leverage points) to induce compliance with them. A closer view of the standards gives some cause for disquiet on both fronts.
Leapfrog Standards Revisited

We turn first to the question of whether the three recommended interventions are reasonable standards. Some consumer groups, as well as hospitals, have voiced doubts and concerns about the standards.26 One’s assessment of their reasonableness may hinge on whether the standards are viewed as aspirational best practices (as the Leapfrog Group intended) or as the legally required standard of care. In both cases, a minimum requirement is a solid body of evidence in support of the standards as tools for promoting patient safety. But we should require especially convincing evidence when the law steps in to demand universal compliance with the standard. Moreover, we also ought to be concerned with the feasibility and costs of implementing the standard when compliance will be legally enforced.

- **CPOE implementation.** One concern surrounding CPOE is implementation costs, which range between $1.5 million and $25 million, depending on the institution.27 Although CPOE might reduce care costs by preventing adverse drug events and their associated increases in hospital lengths-of-stay, hospitals that are paid on a per diem basis will be financially hurt, rather than helped, by this cost savings.28

Clearly, benefits accrue from the implementation of CPOE systems.29 The face validity of dose-checking and drug-to-drug interaction monitoring cannot be denied.30 However, the only existing quantifications of the impact of CPOE on drug errors are studies from two hospitals, the Brigham and Women’s Hospital (Boston) and the LDS Hospital (Salt Lake City).31 As compelling as these case studies are, many might wish to see additional positive trials before an intervention that carries such high costs is widely adopted.

- **Referral to high-volume providers.** Other issues surface in examining the case for evidence-based referral of patients in need of certain surgeries (percutaneous transluminal coronary angioplasty; coronary artery bypass graft, or CABG; carotid endarterectomy; resection of a nonruptured abdominal aortic aneurysm; and esophagectomy for malignancy) to high-volume hospitals. The medical literature suggests that such hospitals have lower rates of mortality in some surgical operations and invasive procedures as well as shorter lengths-of-stay for complicated procedures.32 Many high-volume surgical and invasive cardiology services use standardized processes that promote highly coordinated clinical teamwork. High-volume facilities also have the needed structures to address quality issues in a timely and coordinated manner, thus ensuring oversight and consistency.

The research that justifies implementing the Leapfrog standards for referral to high-volume providers as a matter of public policy, however, is relatively thin. John Birkmeyer and colleagues’ recent analysis of Medicare patients undergoing fourteen procedures in low- and high-volume hospitals found that mortality decreased as volume increased for all of the procedures but that the magnitude of the decrease varied widely among procedures.33 Notably, of the four Leapfrog-recommended procedures examined (CABG, carotid endarterectomy, abdominal aortic aneurysm repair, and esophagectomy), a large (15 percent) difference in
mortality between patients in very-low-volume and very-high-volume hospitals was observed only for esophagectomy. Much smaller differences (0.3–3.4 percent) were found for the other procedures. While this study provides fairly strong overall evidence for the volume-mortality relationship in surgery, it does not provide good support for Leapfrog's choice of these specific procedures over others.34

Birkmeyer and colleagues' earlier analysis for the Leapfrog Group, which served as a basis for that decision, relies heavily on work by Adams Dudley and colleagues that calculates the potential number of deaths averted if a sizable proportion of cases were moved from low- and medium-volume to high-volume hospitals.35 Dudley in turn relies on a large literature on the relationship between volume and outcomes in surgery but notes that most of the studies are observational and based on administrative data. Birkmeyer and colleagues' 2002 study, although impressive in its scope and findings, shares this limitation.36 Ideally, before major health policy changes are undertaken that might result in the wholesale displacement of large groups of patients, with potentially serious financial implications for low- and medium-volume hospitals, we would like to see higher levels of evidence in the form of controlled trials.37 However, such trials do not appear to be possible.38

Importantly, Birkmeyer's estimate of the mortality savings associated with evidence-based referral is based on shifting cases from 80 percent of the urban hospitals that now perform them to high-volume hospitals.39 Marketwide moves of this magnitude are simply not feasible now because of the limited capacity of the few hospitals that meet the Leapfrog criterion.40 In addition, most high-volume hospitals are teaching hospitals, where the costs of care are higher than at community hospitals.41 These marginal costs likely are not counterbalanced by length-of-stay reductions or other efficiencies that might arise from using high-volume hospitals. Nor are a variety of unintended consequences of widespread implementation of evidence-based referrals factored into the cost estimates. Such implementation might result in large-scale disruptions for patients and physicians, have profound implications for surgical graduate medical education, and prevent the transfer of the benchmark practices from high-volume institutions to medium- and low-volume hospitals and surgeons.42

**Round-the-clock intensivists.** Similar questions arise in examining the case for use of intensivists. The Leapfrog Group estimates that 53,000 lives would be saved if full-time intensivists were available around the clock on site in medical and surgical ICUs. It is difficult to square this estimate with data from two large chart-based studies of medical injury suggesting that 44,000–98,000 preventable deaths per year occur across all areas of hospital care.43 Review of the literature underlying the Leapfrog Group's estimates provides insight into the disparity between these figures. Birkmeyer and colleagues were appropriately conservative in developing their estimate of lives saved, but the estimates were again based on a series of studies, many of which have methodological problems including confounding and lack of
statistical significance. The Leapfrog Group’s projections of savings from deaths averted should be assessed in this context.

Although the financial upside of averting deaths may not be as high as the Leapfrog Group estimates, the business case for hospitals’ implementing round-the-clock intensivists is relatively good. According to Leapfrog estimates, the cost of intensivists themselves would be between $150,000 and $500,000 annually, depending on the size of the ICU. Several studies suggest that the presence of intensivists reduces ICU and overall length-of-stay and may reduce inappropriate ICU admissions. Physician workforce experts, however, report that there simply are not enough intensivists available to staff critical care units around the clock for all U.S. hospitals. This will be a major source of frustration for hospitals that are asked by courts to meet the Leapfrog standards.

Using Tort Law As A Leverage Point

In our assessment, developments in medical malpractice law suggest that the Leapfrog standards could be readily integrated into plaintiffs’ cases and that a few large judgments in cases that centered on the Leapfrog criteria would motivate hospitals to aggressively pursue Leapfrog implementation. The potential for diffusion of the Leapfrog standards into malpractice litigation ultimately will depend to some extent on hospitals’ adoption of them. Some have suggested that because the number of patients accounted for by the Leapfrog employers is small in proportion to most hospitals’ total market, few hospitals will feel compelled to comply with the Leapfrog standards. In jurisdictions where the standard of care remains custom-based, plaintiffs will only be able to argue persuasively that Leapfrog should be considered the legal standard of care if a majority of hospitals have implemented the standards. In reasonable-prudence jurisdictions, however, the key issue will be the reasonableness of the standards (including, one would hope, a consideration of their cost), rather than the extent of their adoption.

A close review of the Leapfrog standards leaves us with serious reservations about whether these standards are ready to be enforced by malpractice litigation. In addition to questions about the efficacy and feasibility of the standards themselves, there are broader questions about whether the tort system should be used to drive quality improvement in this way.

Will providers under siege by the legal system buy into new safety standards? Many states are in the midst of a new “malpractice crisis,” with malpractice litigation rates, the size of settlements associated with such suits, and malpractice insurance premiums all increasing at alarming rates. An environment in which providers feel under siege by the legal system may be a fertile climate for effectively
wielding the tort law as a leverage point, but it does not promote the kind of genuine “buy-in” to new safety standards that the patient safety movement seeks. In the long run, it may be counterproductive.

Is investment in CPOE the best use of resources? We are also concerned that courts that consider the Leapfrog criteria may not make the best decisions with regard to cost-effective prevention of medical injuries. If Leapfrog is correct, and CPOE, round-the-clock intensivist coverage, and use of high-volume hospitals for surgery are the three most effective innovations to prevent medical injuries and can also be implemented without undue burden to hospitals, then perhaps it is reasonable to pursue the implementations of these measures through tort litigation. However, if we are not convinced that is the case, then this tactic may be inappropriate. Given existing evidence, it is not clear that all safety-minded hospitals would opt for the investment in CPOE over other safety-enhancing mechanisms. Yet the impetus for Leapfrog, multiplied by tort pressures, will likely force the decision to implement that specific measure. This carries an opportunity cost, consuming money and effort that could be dedicated to implementing other measures that may have a bigger impact on medical injury at a particular hospital.

Can the tort system regulate medical quality efficiently? Finally, there are the familiar concerns about the dysfunctional nature of the tort system as a mechanism for regulating medical quality. Because of the small degree of overlap between who is injured by medical negligence and who files a malpractice claim, as well as the large administrative costs of adversarial litigation, the system is not an efficient compensation mechanism. The evidence that the system is effective in deterring medical negligence is limited, reflecting the small fraction of instances of negligent injury that result in claims and the fact that physician liability insurance premiums are not experience-rated. The law’s traditional reliance on custom to set the standard of care has meant that cost-effectiveness considerations have been largely disregarded, leading to standards that may not reflect socially optimal policy choices. Further, a large body of research suggests that juries often do not faithfully perform their assigned task of applying the legal standard of care, frequently misunderstanding instructions, permitting a range of other factors to influence their decisions, and erring in their negligence determinations relative to what experts would decide. All of these general doubts about the functionality of the tort system bear on the degree of discomfort we should experience at the prospect of using tort liability to enforce the Leapfrog standards.

The Leapfrog Group could reduce the risk that its standards will fuel litigation by explicitly emphasizing that the standards are aspirational—a tactic that some promulgators of clinical practice guidelines have employed. However, courts may well disregard such disclaimers and instead focus narrowly on questions of custom and reasonableness. Leapfrog might also wish to publicize the fact that not all hospitals will be able to comply with its standards.
and take steps to identify the types of hospitals for which the standards are and are not within reach. This strategy would help hospitals ranked near the bottom in terms of resources but would penalize those at the top, which would have an even more difficult time defending a decision not to implement the standards. Because the potential legal implications of safety standards such as Leapfrog’s are uncertain, groups that are considering adopting particular standards should ensure that these are the most efficacious and cost-effective choices. The journey from marketplace to courtroom for these standards is not long and looks set to become even shorter.

NOTES
13. 60 F.2d 737 (2d Cir. 1932).
15. 519 P.2d 981 (Wa. 1974).
22. 545 N.W. 2d 495 (Wis. 1996).
23. Ibid.
33. Birkmeyer et al., “Hospital Volume and Surgical Mortality.”
42. Epstein, “Volume and Outcome”; and J. Daley, “Invited Commentary: Quality of Care and the Vol-


45. Ibid.


