JAMA | Special Communication

A New Legal Standard for Medical Malpractice

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IMPORTANCE Patients in the US have persistent needs for safe, evidence-based care. Physicians in the US report fear of liability risk and the need to practice "defensive medicine." In 2024, the American Law Institute revised the legal standard for assessing medical negligence. Understanding the implications of this change is crucial for balancing patient safety, physician autonomy, and the legal system's role in health care.

OBSERVATIONS The updated standard from the American Law Institute shifts away from the traditional reliance on customary practice toward a more patient-centered concept of reasonable medical care. Although this revised standard still includes elements of prevailing medical practice, it defines reasonable care as the skill and knowledge regarded as competent among similar medical clinicians under comparable circumstances and acknowledges that, in some cases, juries can override customary practices if they fall short of contemporary standards. The restatement also embraces evidence-based practice guidelines, while leaving questions open about the variations in the quality of those guidelines. The restatement makes additional recommendations regarding informed consent and other aspects of physician-patient communication.

CONCLUSIONS AND RELEVANCE The new standard of care from the American Law Institute represents a shift away from strict reliance on medical custom and invites courts to incorporate evidence-based medicine into malpractice law. Although states may adopt the recommendations from the American Law Institute at different times and to varying degrees, the restatement offers health professionals and the organizations in which they practice an opportunity to reconsider how medical negligence will be assessed, and to focus more directly on promoting patient safety and improving care delivery. Nonetheless, physicians should recognize that, at least for now, many courts will continue to rely significantly on prevailing practice in assessing medical liability.

JAMA. doi:10.1001/jama.2025.0097
Published online February 26, 2025.

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Although the risk varies by medical specialty,[1] roughly one-third of physicians can expect to be sued at least once across the course of their careers.[2] Malpractice insurance gives physicians, especially those in larger practice settings, almost complete financial protection from court judgments and litigation costs.[3,4] Yet malpractice lawsuits carry additional consequences for physicians, including reporting requirements to boards of medicine, which can create public records, and potential limits on hospital privileges. Surveys show that these consequences are of concern to physicians,[5] and fear of liability can drive unproductive changes in practice patterns known as "defensive medicine."[6-8]

Research has also revealed frequent lapses in patient safety,[9] along with physicians failing to practice in accordance with the best scientific evidence,[10,11] and physicians acting on financial incentives that conflict with patient interests.[4,12] Tort liability should play a role in addressing these safety and quality concerns, in addition to compensating patients who were injured, but the evidence that current approaches to medical malpractice do so is mixed.[4] Even though medical liability can provide compensation to those injured, it has not consistently been shown to address concerns about care quality.[13-17]

On May 21, 2024, the American Law Institute (ALI) approved its first-ever restatement of the law of medical malpractice, including new standards for resolving malpractice claims. In this Special Communication, we describe the new legal standards and their significance for health professionals and organizations in 3 core areas: clinical care, communicating with patients, and the practice environment.

Restatement (Third) of Torts: Medical Malpractice

In the US, medical malpractice law arises primarily from the common law produced organically by judges as they decide individual cases,[18] although it can be supplemented by legislation (statutes) and occasionally by administrative regulations. Almost all malpractice law is state, not federal, law. Even though a finding of malpractice liability generally means that a physician was "negligent" in the provision of medical care (or in eliciting informed consent),[19] legal standards vary from state to state.

Founded in 1923, the ALI is an organization of judges, professors, and practicing attorneys that periodically synthesizes existing law in many domains and identifies important legal trends.

The ALI is the legal equivalent of the National Academy of Medicine and is a broadly constituted group of acknowledged leaders who bring an expert professional perspective to both what the law is and what the law should be, which for medical malpractice law includes regard for medical ethics and clinical performance as well as legal accountability.

Restatements from the ALI attempt to provide descriptive coherence across the 50 different state court systems and to help states clarify and improve their laws. Restatements are unique in US law because, although they are based on detailed analysis of state common law, they are produced as systematic sets of rules similar to the legal codes that predominate in Europe. Consequently, state supreme courts often refer directly to restatements in adopting (or, sometimes, rejecting) the approach from the ALI to a particular legal domain.

The process of crafting and approving the restatement of medical malpractice spanned several years and multiple rounds of drafting and revision led by 3 law professor reporters who were assisted by dozens of others in an advisory group. The restatement was ultimately approved by the council and full membership of the ALI.

The restatement of medical malpractice law accomplishes several goals. First, it captures and analyzes essentially all US law on medical malpractice,[20] including the common law made by courts in each state and judicial decisions applying and interpreting relevant state or federal legislation. Second, the restatement positions itself at the intersection of legal principle and real-world application, while attempting to avoid the interest group politics that have dominated "tort reform" in medicine since the 1970s, particularly during perceived crisis periods in the availability or affordability of liability insurance sold to physicians. Third, the restatement is expressed coherently with clear stepwise rules and carefully drafted comments that elaborate each rule to assist judges in applying it.

The Legal Standard of Care

The legal standard of care for medical liability can shape every aspect of dispute resolution—from clinicians assessing their financial exposure, to liability insurers evaluating malpractice claims, to judges overseeing the litigation process, and ultimately to a jury or arbitrator rendering a decision. Should a case reach trial, the judge instructs the jury regarding the standard of care it should use in its role as fact finder to decide the case. Although the vast majority of claims are dismissed or abandoned, or are resolved through a settlement between the parties, the likelihood of settlements occurring, their timing, and the monetary damages that may be agreed upon are driven by the litigants' perceptions of what a jury would do if the case were to reach trial.[21]

Since the mid-1800s, US courts have understood negligence to mean the failure to behave with "ordinary care" or "reasonable care."[22] Yet the subset of tort law comprising professional negligence recognized that a specialized approach is necessary when experts, such as physicians, are being held accountable by nonexperts, such as judges and juries.[23] The prior restatement of tort law, issued in 1965, explained: "[O]ne who undertakes to render services in the practice of a profession or trade is required to exercise the skill and knowledge normally possessed by members of that profession or trade in good standing in similar communities."[24] This standard also applied to other skilled professionals, including lawyers, accountants, and pharmacists.[24]

Accordingly, medical malpractice liability traditionally was based on whether a physician had followed the custom of the profession.[18,23] In contrast, tort law more generally has long rejected custom as determinative, with Judge Learned Hand writing in 1932 that an entire industry "may have unduly lagged in the adoption of new and available devices" because the interests of industry may not align with the interests of society.[25] Although agreement with or deviation from customary behavior can be helpful in assessing reasonableness, modern courts encourage jurors to consider other factors, including the risks and benefits of any precaution and community expectations. This approach, known as the "reasonable person" standard, is a fundamental feature of modern tort law nationwide. In medical malpractice cases, state courts have been gradually shifting from reliance on custom toward a reasonableness standard.[23,26]

Reasonable Care

The restatement from the ALI centers medical negligence on reasonable care rather than on customary care. It reads: "The standard of reasonable medical care is the care, skill, and knowledge regarded as competent among similar medical providers in the same or similar circumstances."[27] The restatement reassures physicians that its competency-based standard of reasonableness does not require above average or even average care. The comments accompanying the restatement observe that "those who have less than median or average skill may still be competent and qualified."[28] In other words, medical care need only be acceptable (above a minimum floor) to meet the standard.

The restatement lists circumstances that may be relevant in determining reasonable medical care, including "the state of medical knowledge and the treatment options available at the time," with the commentary acknowledging the importance of "prevailing professional practices" (ie, custom).[29] The restatement takes account of the "resources available to the provider in the particular location or practice setting" in assessing the reasonableness of care, but it no longer factors in deference to the practice habits of physicians within any given locality or community.[27]

Physicians have, at times, been slow to adapt to changes in medical science, relying instead on habits from their own, possibly decades-old training, which may reproduce structural inequities.[30,31] Much of what is learned in medical school and training will change during practice.[32] Examples include (1) cardiac stenting may be no better than medical management for stable coronary artery disease,[33] (2) use of low-dose aspirin to prevent cardiac arrest may be harmful for many patients,[34] (3) many older adults are prescribed medications on the Beers list that may harm their health,[35] (4) many cancer treatments do not serve patient interests,[36,37] and (5) opioids are far riskier than commonly believed 20 years ago.[38,39] Although the restatement from the ALI will allow physicians to point to "prevailing professional practices,"[29] it will also allow injured plaintiffs to point to the best scientific evidence and argue that a reasonable physician would have practiced accordingly.

Evidence-Based Medicine and Practice Guidelines

The focus of the restatement on reasonable care is a meaningful move toward infusing current medical science into malpractice law, and parallels recent changes by the World Medical Association to the physician's pledge in its Declaration of Geneva to practice not only with "conscience and dignity" but also "in accordance with good medical practice." The American Medical Association principles of medical ethics similarly provide that "a physician shall continue to study, apply, and advance scientific knowledge,"[40] implying that evidence-based practice is a hallmark of competent care.

Younger generations of physicians may find the historic emphasis on custom odd, and may welcome an evidence-based approach instead.[40] As Eddy explains,[41] "Medical decision making has gone through a fundamental change in the last 40 years. Simply put, the foundation for decision making has shifted away from subjective judgments and reliance on authorities toward a formal analysis of evidence....Now, before recommending a treatment, physicians ask: what's the evidence?" Sometimes this means refusing patient requests for unproven risky care.[42]

In a well-known pair of articles published several years ago,[43,44] a physician described being held liable for following guidelines on prostate-specific antigen testing for prostate cancer, while the plaintiff's lawyer disparaged evidence-based medicine as substandard care. Such a situation is unlikely under the restatement from the ALI, which explicitly incorporates practice guidelines offered as evidence in malpractice cases, assuming that a court finds that the guidelines are relevant and authoritative.

Guidelines vary in quality, with most being issued by prestigious bodies that rigorously weigh evidence and police conflicts of interest, but some may be driven by particular agendas or financial motivations.[45-47] Accordingly, it will be important for courts to carefully scrutinize whether a particular guideline is in fact authoritative. Factors to consider include whether (1) the organization that issued the guideline has appropriate expertise and integrity, (2) the organization speaks with authority for a relevant portion of the medical community, (3) the organization issued the guideline after a period of careful deliberation, and (4) the guideline was designed to guide medical care in the best interests of patients. Courts should follow established scientific guidance on adjudicating levels of evidence when assisting jurors in interpreting guidelines, which in turn should do the same.[48]

The approach of the restatement does not provide an absolute safe harbor for practice that is in adherence to national guidelines, which is a reform that some legislatures have debated,[49,50] but the restatement encourages judges and juries to regard such a fact as exculpatory. Significantly, the receptivity to practice guidelines in the restatement is explicitly limited to defending malpractice claims.[51] The restatement identifies adherence to appropriate guidelines as sufficient evidence that the standard of care has been met, but nonadherence to guidelines remains insufficient to establish negligence. This asymmetrical provision, which has little support in case law, but nonetheless was endorsed by the ALI, may help blunt incentives for defensive medicine and reassure physicians that following best evidence that conflicts with guidelines, which can become outdated, will not be held against them in court.[51] Nonetheless, under the restatement, plaintiffs will still be able to introduce expert testimony that refers to guidelines as evidence of negligence, and defendants will almost universally need expert witnesses to defend their care as well, setting up a typical battle of the experts.[52]

Communicating Honestly and Openly

Several parts of the restatement also modernize legal aspects of physician-patient communication, while still recognizing and accommodating variation in state law. When determining the meaning of reasonable care in clinical context, for example, the restatement includes, among relevant factors, "any representations the provider made to the patient or public about the provider's level of care, skill, knowledge, experience, or scope of practice."[27] This would also hold a hospital or health care facility legally accountable if harm resulted from inadequately qualified or poorly equipped health professionals when a high standard of quality or safety had been promised.

With respect to physician-patient communication after unanticipated harm occurs, the restatement makes clear that admissions by physicians of having provided substandard care can establish liability without the need for additional expert testimony, but only if those "statements are sufficiently detailed and direct."[53] The restatement thereby attempts to balance ethical desires to speak with candor, to express regret for a bad outcome, and to restore a trusting treatment relationship with the right to legal redress for negligence, which depends on whether the care actually delivered met the legal standard.[53-55]

The restatement also furthers sound medical practice with respect to informed consent. The ethics of informed consent have always had a greater real-world effect than any legal liability associated with failing to obtain it. The reason is that plaintiffs generally cannot prevail unless they prove that, had risks been completely disclosed, similarly situated patients would have chosen not to undergo treatment.[56] The restatement improves on this situation by recognizing that patients today often have choices among different treatment approaches rather than just the right to refuse treatment altogether. To recover damages for lack of informed consent under the standard in the restatement, patients must prove only that they would have chosen an alternative treatment course and that it would have been reasonable for them to do so.

The restatement assigns legal accountability for obtaining informed consent to the medical clinician who is "principally responsible" for the patient's care, but it recognizes that communication tasks in modern health care organizations may be delegated to others by the legally accountable clinician. The restatement also places an explicit legal obligation on physicians to answer patient questions truthfully, including about the physician's own skill, experience, financial interests, and circumstances, even if affirmative disclosures are not required.[57-59]

Improving the Medical Practice Environment

Recent trends toward physician employment accentuate the need for health care organizations to act responsibly and accountably. In addition to clarifying the legal obligations of physicians, the restatement should have a salutary effect on how hospitals and other

health care facilities structure their practice environments and risk management activities. For example, the standard of reasonable care in the restatement aligns with decades of experience at the University of Michigan and other leading health systems that no longer take a deny and defend approach to malpractice claims.[60] Studies of leading health systems have shown that being honest with patients regarding errors, conducting root cause analyses, supporting caregivers, and, when care has been "unreasonable," offering fair compensation for injury can improve patient and staff well-being without increasing malpractice-related costs.[60-65]

Increasing numbers of hospitals are embracing comprehensive strategies for patient, family, and caregiver engagement to prevent and respond to medical harm through so-called communication and resolution programs.[66] This approach is endorsed by multiple physician professional societies, including the American Medical Association.[67] In combination with these clinician-led efforts, the approach of the restatement to legal obligation may help shift the risk management process away from the courtroom and toward the bedside—emphasizing safe medical care and support for patients and caregivers[68] over seeking adversarial advantage through legal technicalities or partisan testimony. Closer alignment between malpractice law and present-day medical ethics, which the restatement invites, may also assist physicians in persuading their institutional employers and financial managers (who now shoulder the majority of malpractice-related costs) to improve the practice environment to facilitate safe, evidence-based, and compassionate care.

Conclusions

The new standard of care from the ALI represents a shift away from strict reliance on medical custom and invites courts to incorporate evidence-based medicine into malpractice law. Although states may adopt the recommendations from the ALI at different times and to varying degrees, the restatement offers health professionals and the organizations in which they practice an opportunity to reconsider how medical negligence will be assessed, and to focus more directly on promoting patient safety and improving care delivery. Nonetheless, physicians should recognize that, at least for now, many courts will continue to rely significantly on prevailing practice in assessing medical liability.

ARTICLE INFORMATION

Accepted for Publication: January 6, 2025.

Published Online: February 26, 2025. doi:10.1001/jama.2025.0097

Conflict of Interest Disclosures: Drs Robertson and Sage reported serving as unpaid advisers to the American Law Institute medical malpractice project. No other disclosures were reported.

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