



Viewpoint

Developing Safe Harbors to Address Malpractice Liability and Wasteful Health Care Spending

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With national health care spending in the US expected to top \$7.2 trillion by 2031, the push to reduce health care resource utilization will only intensify in the coming years.¹ One important approach is curbing the expenditure of health care resources on unnecessary tests and procedures. Led by the American Board of Internal Medicine Foundation, the Choosing Wisely movement has attempted to curtail medical services with limited benefits relative to their costs.² By providing evidence-based guidelines, Choosing Wisely encourages clinicians and patients to avoid wasteful tests and procedures. However, these guidelines overlook a key factor that may drive the wasteful use of health care resources—malpractice liability. Without accompanying policy or legal changes, uptake of Choosing Wisely guidelines is low.³

Evidence suggests inpatient spending declines by about 5%, with no significant change in patient outcomes, when the threat of malpractice liability is removed.⁴ Current guidelines aimed at reducing waste do not account for the potential impact of medical liability and, therefore, may miss an opportunity to reduce spending without harming patients. We set out to explore the possibility of addressing malpractice liability while reducing low-value health care spending.

Specifically, we gathered legal and medical experts to create 3 separate safe harbors. In contrast to generic waste-reducing guidelines, which can target medical practices at various levels of specificity, safe harbors offer clinicians guidelines for delivering care in specific situations and, if followed appropriately, protect clinicians from liability. Effective safe harbors require 3 characteristics.⁵ They must (1) be announced in advance so clinicians know what is expected before they treat patients, (2) be narrowly conceived and highly targeted so juries and courts cannot second-guess the appropriateness of the clinicians' actions, and (3) carry the force of law and constitute the legal standard of care, not merely provide evidence of that standard.

One avenue to achieve force of law is adoption of safe harbors by quality improvement organizations (QIOs), which operate under federal law to monitor quality and cost in federal health care programs. The QIOs can protect clinicians from malpractice liability when clinicians practice nonnegligently in conformity with QIO-approved standards.⁵ Alternatively, state legislatures could implement safe harbors via statute or authorize state regulatory authorities to adopt safe harbors.

Properly implemented safe harbors can ensure clinicians that, if they competently follow the safe harbor, courts will have no latitude to determine their actions were negligent. Beyond simply offering guidance on how to avoid waste, safe harbors provide specific directions on what to do in specific situations and offer clinicians an avenue to avoid liability.⁵

Our goal was to create 3 proof-of-concept safe harbors for 3 of the most commonly seen conditions in emergency medicine departments: minor head injury, lower back pain, and uncomplicated headache. Research supporting those guidelines indicated that clinicians often order medical imaging for patients with these 3 conditions, even though imaging is not generally necessary for diagnosis, increases costs, and exposes patients to unnecessary radiation.⁶⁻⁸ Our safe harbors provide clinicians specific directions as to when they could avoid medical imaging among patients presenting with 1 of these 3 conditions.

We began the process of safe harbor development by convening medical experts to delineate specific clinical conditions for which a safe harbor would apply. For each of the 3 safe harbors, we

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included experts in emergency medicine and other specialists when relevant. For example, neurologists provided input on the safe harbors for minor head injury and uncomplicated headache.

The medical experts first developed inclusion and exclusion criteria to provide guidance on which patients fell within each safe harbor. Inclusion criteria included simple demographic factors, such as age of a patient; specific medical indicators, such as whether the patient's condition had worsened in the past 2 hours; and focused clinical judgment, such as whether patients could seek additional care if their condition did not improve within set time frames. With inclusion criteria set, the team of medical experts then developed exclusion criteria that would exclude some patients from each safe harbor who otherwise met inclusion criteria—typically those with signs and symptoms considered to be high risk by national guidelines and consensus statements.

The exclusion criteria ensured that patients who initially appeared to be candidates for each safe harbor underwent medical imaging consideration if certain indicators appeared in the patient's history or certain clinical conditions were present. For example, the safe harbor for low back pain excluded patients if they had recently undergone spinal surgery or their injury was caused by a dangerous mechanism (eg, ejection from a motor vehicle). Similarly, if clinical evaluation revealed saddle anesthesia, gait abnormality, or lower-extremity atrophy, patients presenting with low back pain were excluded from the safe harbor.

With the inclusion and exclusion criteria set, clinicians could determine specifically which patients fell within a given safe harbor and which did not. Unlike many guidelines that simply discourage the use of medical imaging for certain general conditions, the team of medical experts ensured that clinicians could evaluate individual patients using highly detailed criteria to determine whether their treatment fell within a given safe harbor. For patients falling within each safe harbor, the medical team provided written instructions that the patient need not undergo medical imaging. The team also provided written discharge instructions for clinicians to follow when treating eligible patients. For example, discharge instructions for uncomplicated headache recommend returning for further care if vomiting or confusion occurs or the patient develops a fever (temperature, $>38^{\circ}\text{C}$). The medical team also included with each safe harbor written documentation of medical evidence to support forgoing medical imaging for patients falling within the safe harbor.

Following the medical team's efforts, a team of legal experts reviewed each safe harbor to ensure that it was written with sufficient specificity that a court would support the safe harbor as the standard of care if malpractice litigation occurred. Specifically, the legal team, which included academic lawyers with expertise in the field and practicing lawyers who typically represent plaintiffs in medical liability actions and/or defend clinicians in those actions, reviewed each safe harbor for internal consistency, for sufficient specificity in the inclusion and exclusion criteria, and for sufficient specificity regarding instructions for clinicians. The legal team brought all questions and concerns to the medical team; all discrepancies and problems were resolved through dialogue between the 2 teams.

The final products of the teams' efforts were 3 safe harbors for minor head injury, lower back pain, and uncomplicated headache. These proposed safe harbors are available elsewhere.⁹ Each written safe harbor includes detailed inclusion and exclusion criteria. Each also provides detailed written discharge instructions for clinicians to use with patients falling within each safe harbor. Additionally, each safe harbor provides citations to relevant medical literature supporting omission of medical imaging for patients meeting the inclusion and exclusion criteria.

Going forward, we will deploy these safe harbors in an emergency department setting to evaluate their effects on practice patterns and patient outcomes and seek force-of-law protection based on evidence from this project. In this important first step, we have demonstrated the feasibility of developing safe harbors that account for the role of medical malpractice liability and go beyond generic guidelines discouraging the overuse of health care resources. This stage is a proof-of-concept exercise for which the impact will be reviewed and tested and that can serve as a prototype for other medical conditions and settings.

ARTICLE INFORMATION

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