

Summary

The Value of Clinical Practice Guidelines as Malpractice “Safe Harbors”

Timely Analysis of Immediate Health Policy Issues

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Guidelines hold promise for cutting wasteful defensiveness, but practical feasibility limits their reach. Their importance could grow if changes in payment rules or responsibilities changed provider or patient thinking about the desirability of additional procedures.

Why Are Clinical Guidelines Attractive as a Policy Reform?

Health care costs too much in the United States. One problem is overservice driven by physicians’ fear of lawsuit for failure to use all available modalities to diagnose or treat a patient, such as ordering advanced imaging or other tests. Physicians perceive great liability exposure for omissions or delays if a bad outcome occurs. Such fears promote “gold plating” of care—adding services that may look good at the time to a worried patient or to a jury or judge in a courtroom years later, but that have little or no clinical utility. Such defensive medicine seems to add a substantial, though often disputed, amount to health care expenditures.

Giving clinicians “safe harbor” protection from medical malpractice liability when they adhere to clinical practice guidelines could (a) encourage adherence to quality-promoting guidelines, as supported by recent legislation and Institute of Medicine reports, (b) cut the wasteful costs of defensiveness, and (c) potentially serve as a bipartisan compromise in the long-running, partisan battle over tort reform limits like caps on awards. A win-win-win.

How Can Guidelines Protect Providers?

Guidelines are already admissible in liability cases, to bolster one side’s expert in-person testimony or the other’s. But today’s plethora of often-conflicting guidelines undercuts the persuasiveness of any one guideline, so results are still governed by unpredictable jury decisions that foster defensive medicine. Going forward, better evidence and more authoritative guidelines could justify making them safe harbors. New laws would need to specify the standards to be met for a guideline to qualify for safe-harbor status, and also what legal effect that

status would have in litigation. For example, the Healthy Americans Act proposed in 2009 by Senator Ron Wyden (D-Ore.) called for guidelines to serve as “rebuttable presumptions” that care was not negligent. This standard means that a defendant could theoretically win without presenting any other evidence. In practice, in-person expert testimony is essential anyway, but the expert guideline might help sway a jury.

The word “safe” in “safe harbor” suggests stronger legislation, to make guidelines *conclusive* evidence of appropriate care. This would go farther than Senator Wyden’s bill or the 1990s’ state experiments with safe harbors. If safe harbors created an *irrebuttable* presumption, plaintiffs could not argue that the guidelines are wrong and that a jury should instead believe a different standard articulated by an expert witness.

What Recent Proposals Would Use Guidelines to Reform Medical Liability?

The safe-harbor concept has made it onto the short list of promising malpractice reforms that go beyond caps and other simple limits on traditional tort liability. For example, both bipartisan deficit reduction commissions of 2010 supported safe harbors for adherence to guidelines, along with other reforms. Moreover, the Obama administration has actively promoted experimentation with patient safety liability reforms, and funded the

What are Clinical Practice Guidelines?

According to the Institute of Medicine, “Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.” As an example, National Guideline Clearinghouse guideline NGC-8118 addresses “diagnosis and treatment of chest pain and acute coronary syndrome” (www.guideline.gov).

state of Oregon's guidelines and safe-harbor project, among other state efforts. The president's fiscal year 2012 budget proposed a new, larger round of grants for states to develop reforms, including safe harbors. No state currently has operational safe harbors, though they drew much interest in the late 1980s and early 1990s. Maine and three other states tried them to limited extents, after which they fell into disuse or were repudiated.

What Challenges Arise in Designing Safe-Harbor Protections?

Maine's experiment with safe harbors revealed a number of practical challenges. The state's 1990 legislation called on four specialty societies to create guidelines. Development took about three years, and only a limited number were ever created. The promulgated guidelines were also often vague, with many exceptions. Leaving such flexibility for responsible clinicians was not unusual; it simply reflected the state of the art at the time. The promulgated statutory guidelines were not used in many legal disputes, and it became clear that guidelines could be used not only as shields against liability but also as swords to establish liability. By the end of the decade, Maine's enabling legislation was repealed.

In short, while guidelines' potential is great, using guidelines as safe harbors will face challenges like the following:

Producing guidelines is hard and expensive. It may not be technically feasible to create enough relevant and reliable guidelines fast enough to alter clinical care any time soon.

Keeping guidelines up-to-date is difficult. The speed of medical innovation may outpace the capacities

of existing researchers and guideline writers to periodically review and revise them.

Guidelines may be hard put to definitively indicate what care is to be given and what is not, which is needed to serve as an effective safe harbor. However, research seldom produces a bright line between indicated and non-indicated care. Gray areas may be created not only by imprecise scientific knowledge, but also by differences of opinion about, for example, how to value increments of additional knowledge gained by ever more elaborate testing.

Resistance to guidelines can be potent. Strong emotions were recently aroused by new preventive-service guidelines on the value of certain cancer screening tests. Such objections may be able to derail guidelines at any stage: the creation and promulgation of guidelines; the enactment of legislation to make them safe harbors; or jurors' interpretation and application of guidelines.

What Hurdles Will Affect the Application of Guidelines as Safe Harbors in Practice?

Guidelines tell practitioners what plan of care they should choose, so they protect against claimed errors of planning, not of execution.

Malpractice claims generally allege errors of execution, so even if guidelines work as intended, they will leave many lawsuits unaffected.

There will always be battles over whether a particular patient's case should be an exception to the general guideline. Guidelines themselves routinely contain exceptions to their general recommendations for special

subpopulations or people with particular medical histories.

Judicial rulings could prevent effective application of safe harbor rules. Plaintiffs can litigate the validity of safe harbors. Some courts might find safe harbors unconstitutional, just as caps on awards and other legislative limits on court-made tort doctrine have sometimes been invalidated.

Safe harbors cannot keep clinicians completely safe from having to appear in court. Although guidelines may discourage most suits and provide a solid defense to those brought, defendants may still have to go to court to assert that defense—which doctors detest having to do.

How Much Could Safe-Harbor Guidelines Reduce Medical Overspending?

Guidelines could somewhat reduce liability exposure and fear, but less than the strongest conventional limits. Caps, limits on time to bring suit, and the like apply *across the board*, to all cases. In contrast, guidelines target very specific circumstances—*only a fraction* of all claims.

Defensive medicine is partly caused by generalized fears, and hence may not be greatly affected by specific guidelines. One suggestive indicator of this phenomenon is that the level of legal fear reported by surveyed physicians tends to be similar across states, independent of their varying legal climates.

Even without defensive medicine, other strong pressures encourage overservice. Other influences come from medical practitioners, patients, and social culture, including the fear of bad publicity, professional perfectionism, and peer pressure. The

typical levels of fee-for-service insurance payment also encourage overutilization.

Concluding Discussion

Defensive overutilization is a real problem, and guidelines as legal safe harbors appear to offer a partial solution. But not all care is amenable to the creation of guidelines, and implementing guidelines as a safe-harbor liability defense faces challenges. By their nature, guidelines provide guidance on what typically constitutes the best care for an entire population. It is therefore hard to use a guideline to deny care to a particular patient, who can always argue that their case is an exception to the general rule. Accordingly, liability safe harbors are unlikely to contribute much in the near term to bending the curve of increasing medical spending.

Safe harbors seem most likely to be useful as adjuncts to more general interventions that target overutilization, whether driven by consumer education or incentives, provider risk-sharing, health plan controls, or government directives. Then, the legal protection offered by safe harbors could simply facilitate compliance with the other efforts. Such a multi-pronged initiative seems well suited to the multiple enablers of overservice. No single silver bullet can cure defensive overutilization because the tendency to gold-plate care is driven by many factors.

It is still important to press ahead with evidence-driven guidelines, in the interests of improving value in health care. Over time, the popular media might end up playing a larger role than legal reform in reducing defensive medicine and increasing adherence to guidelines. *Newsweek*, for example, recently sought to teach readers when to say “no” to more medicine.

Eventually, motivated and informed patients with a greater understanding of available medical options and their relative merits will probably help curb low-value services, especially if joined with other controls or incentives.

Improved appreciation for how added services add medical risks and other costs should help modify today’s expectations that more care is almost always better than less. This change should make patients and clinicians alike more likely to use guidelines. It should also alter how future judges and juries react to conflicting expert evidence and see the desirability of signaling to clinicians to leave no stone unturned when caring for patients. Such evolution in customary expectations lacks the quick-fix appeal of legislation, but seems likely to be more influential and sustainable.

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