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When triggered by the desire to reduce unwarranted variation in practice and provide patients with benchmark quality care, adherence to clinical guidelines can often improve patient safety. But turning guidelines into legal standards would be bad for both patients and doctors.

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An astonishing new article from *JAMA Internal Medicine* reveals that at least 150,000 people per year may be needlessly killed, rendered disabled, or otherwise harmed due to misdiagnoses in doctors' offices. Johns Hopkins, whose researchers authored this study, have been documenting epidemic levels of preventable medical errors in all sorts of new venues lately. Last year, it found that surgeons leave behind foreign objects, operate on the wrong site or even the wrong patient at least 4,000 times a year. In another study, it found:

> *As many as 40,500 critically ill patients in the United States may die annually when clinicians fail to diagnose hidden life-threatening conditions such as heart attack and stroke. The unexpectedly high frequency of deadly misdiagnosis in hospital intensive care units or ICUs was "surprising and alarming," said Dr. Bradford Winters, the lead author of the study.*

Does anyone really think the problem with health care quality today is that doctors are ordering -- and insurance companies are paying for -- too many tests? Yet incredibly, that's been the mantra of the medical lobbies for a number of number of years now. Their argument goes something like this:

> *That, in contravention of good medical judgment, the basic rules of Medicare (payment only for services that are medically necessary), threats of the potential for False Claim Act (prescribing, referring, where medically unnecessary), physicians will, as a group, act in ways which are possibly contrary to the interests of their patients, certainly contrary to reimbursement and related rules, under a theory that excessive or unnecessary prescribing and referring will insulate them from medical liability.*

This concept is called "defensive medicine." It was defined above by Dr. Fred Hyde, Clinical Professor in the Department of Health Policy and Management at Columbia University's Mailman School of Public Health, who also believes, by the way, that the entire argument is rubbish. And we would have to agree. Clearly, most physicians are not engaged in this practice. As one physician participating on a list serve about this topic recently explained:

> *As a physician, the first problem I face is what does it mean to say a test is "unnecessary." The term suggests that tests live in two categories, those that are helpful and those that are not, but in reality what we're really dealing with is a continuum of probability.*

While we wish doctors and hospitals had a better record preventing errors, clearly most physicians order tests and procedures because they are trying to be as accurate as possible. At least this is what they legally certify to Medicare and Medicaid. Perhaps some doctors do commit Medicare fraud, and clearly Medicare's "fee-for-service" medicine creates a perverse profit motive for providers to do too many tests and procedures. (See, e.g. here, here.) But it certainly is the lesson of history that even if you remove litigation as a factor, the extent of tests and procedures ordered will not necessarily change.

Unfortunately, this "defensive medicine" myth has gotten traction, but only for one real reason. It has helped lead to the passage of hundreds of state laws that insulate from liability negligent doctors and unsafe hospitals. Some laws have had devastating consequences for injured patients, as this recent *Texas Tribune* story illustrates. Indeed, the

health care industry benefits from more liability protections than virtually any other industry or profession in the nation, and the vast majority of preventable errors that physicians now commit never result in a claim at all. (The Johns Hopkins researchers put this likelihood at 1 percent.)

Incredibly, though, the medical lobbies want more.

So there's a "new" concept making the rounds. This new idea (actually a bad old idea, as explained below) is to provide immunity, or presumed immunity, to doctors who follow "clinical guidelines." Clinical guidelines would become the legal basis for deciding if patient harm was the result of negligence, essentially kicking the concept of individualized medicine out the door. Steven Brill talked about this in his recent *Time* magazine health care cover story. Citibank vice-chair Peter Orszag has been pushing the idea for a long time, and is now citing for support a Center for American Progress report, which our organization thoroughly debunked here. The goal is significant health care cost savings, even though, in over 30 years, medical malpractice premiums and claims have never been greater than 1% of our nation's health care costs and, as Dr. Hyde succinctly put it, "The costs, if any, of defensive medicine are trivial, in comparison to the cost of health care." In other words, it won't save money.

As I said, this is not a new idea. It was part of health care policy discussions in the 1990s. It was considered by President Clinton's White House Task Force on Health Care Reform. Several states even tried it out on an experimental basis. So what happened?

To call this idea a flop would be generous. The Clinton Task Force said "no." None of the state laws were renewed. (See more in this fascinating new law review article by Case Western Reserve University School of Law professor Maxwell J. Mehlman.) And the people who killed the idea weren't attorneys, as Brill cynically and incorrectly suggests. It was doctors.

It is estimated that more than 1,400 sets of clinical practice guidelines exist today. While some standards, such as those in anesthesia, are "simple and clearly defined" and easily complied with, others, such as on obstetrical cases, are complicated and can be contradictory. As explained by Arnold J. Rosoff, Professor of Legal Studies and Health Care Systems at the Wharton School and Senior Fellow at the Leonard Davis Institute of Health Economics, University of Pennsylvania:

> *Achieving [guideline] unanimity would require designating some entity, presumably a governmental agency, as the sole arbiter of what is acceptable medical practice. That is practically and politically inconceivable ... Knowledgeable, respected professional groups can, and often do, come down on opposite sides on a particular treatment issue ... Accepting that there will almost certainly be multiple guidelines for many conditions, courts will have to engage in a process of deciding, when guidelines conflict on a material point, which one to treat as authoritative, or more authoritative.*

In other words, litigation could escalate.

In fact, as guidelines are written for "average patients" and cannot encompass the huge variation in how patients present, there may be good clinical reasons to vary from a guideline's recommendation for a patient. Even experts firmly committed to evidence-based medical practice recognize that there may be benefit to avoiding a "one size fits all" approach.

Again, notes Mehlman, quoting the former head of the AMA,

> *You cannot restrict physicians to one procedure or series of procedures for a specific condition ... No two patients are exactly alike and no two conditions are exactly alike. What we must do is provide physicians with parameters that give them the flexibility to utilize their own skills within an acceptable range of options.*

Now, some may say that guidelines today would be better, more "evidence-based" than they were in the 1990s. But whose evidence? Specialty medical societies? It is already generally recognized that conflicts of interest and specialty bias are inherent problems in the development of current guidelines. It would be fundamentally unfair for patients to have their cases judged by liability standards chosen by medical and specialty societies, especially since they are written with the knowledge that they will help exculpate fellow physicians. If medical societies are allowed to participate in writing guidelines they know will exempt their members from liability, conflicts of interest and bias will escalate.

How about guidelines written by the government, the main goal of which is cost-cutting? Noted the former head of the AMA in Mehlman's article, "Effectiveness, appropriateness, necessity -- to the federal government those are euphemisms for cost control and rationing." Saving money becomes the

goal rather than articulating appropriate standards of care. And because cost-cutting goals are non-safety-related, these kinds of guidelines could make patient safety worse. This article goes a step further and proposes that the government, i.e. politicians or bureaucrats, be granted divine authority to immunize a provider for anything it does. This is all so ironic, given how loudly the medical lobbies complain that the government should not be meddling in health care.

But what about using clinical trials to develop scientific, evidence-based guidelines? The same problems exist. As Mehlman notes,

> *Even if a guideline is based on a clinical trial that was conducted on the relevant patient population, the results of the trial may not hold true for specific patients. It is a truism of medicine that patients differ in how an illness affects them (assuming that they actually have the same illness) and in how they respond to treatments, based on factors such as their genetic makeup, the way their bodies function, and environmental conditions that researchers are only beginning to understand. Clinical trials often do not take this into consideration, and therefore nor would guidelines which were based upon them, with the result that recommendations in the guidelines would not necessarily comply with the standard of care for that patient. (footnotes omitted).*

Inevitably, guidelines would become stale or obsolete, and then what? Under this proposal, doctors will have little choice but to follow an outdated guideline just to get the benefit of the safe harbor provisions. In that case, the incentives work squarely against patient safety.

In sum, when triggered by the desire to reduce unwarranted variation in practice and provide patients with benchmark quality care rooted in science, adherence to clinical guidelines can improve patient safety in many situations. But turning guidelines into legal standards would be bad for both patients and doctors. For patients, allowing guidelines (particularly those developed by biased specialty societies or the cost-cutting government) to immunize a negligent physician or facility, is without any justification and is fundamentally unfair. For doctors, turning such guidelines into legal standards would restrict their ability to practice individualized medicine and has no business being part of important discussions about health care today.