MALPRACTICE, OUTCOMES, AND APPROPRIATENESS OF CARE

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I want to make the case that more and better research on the outcomes and appropriateness of medical care is necessary if we are to develop a more rational system for preventing, punishing, and compensating for medical malpractice. This case rests on several premises that I regard as matters of simple logic. However, because I find that my notions of logic are not always acceptable to others, I will begin by outlining these premises:

1. Malpractice claims and awards are only justified when inappropriate care is provided; a bad outcome of care is not a justification unless it is associated with inappropriate care.
2. Notwithstanding this point, malpractice claims are clearly related to outcomes of care. Patients presumably don't sue their doctors if they get the outcome they desire, even though the care might have been poor and they did well despite, rather than because of, the doctor's efforts.
3. A substantial proportion of the settlements of and court decisions on malpractice claims must almost inevitably confuse bad outcomes with inappropriate care because of the lack of definitive research on outcomes and appropriateness. I believe that this explains some of the unpredictability of the tort system.

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4. Without authoritative research on the distribution of outcomes that can be reasonably expected from a skillful medical care intervention, it is hard for the doctor to inform the patient about risks before the fact or to convince the court, after the fact, that a bad outcome is not a sign of malpractice.
5. Without authoritative research that establishes whether the care provided in a particular situation is appropriate, the doctor is poorly positioned to make the case that a patient's adverse outcome is just bad luck, not bad medicine.

I have no illusions that it is either straightforward or inexpensive to produce definitive research on the outcomes and appropriateness of medical care. However, without such research, it will not only be impossible to rationalize the medical malpractice system, it will also be impossible to make sound decisions about how to spend health care resources efficiently and effectively.

Before dealing with malpractice issues directly, I want to turn to some of the issues surrounding the determinations regarding when care is appropriate and when it is not.

First, there is far too little research on how particular medical interventions affect patient outcomes, that is, what constitutes appropriate care. The "gold standard" for this research is the randomized clinical trial--the RCT. However, it is all too rare to find definitive results from RCTs that establish appropriate indications for diagnostic and therapeutic interventions. The evidentiary bases for medical interventions are seldom found to rest on this gold standard. When they do rest on this firm foundation, they are often cast in narrow terms--not in terms that cover the range of situations faced by most practicing physicians. We clearly need to find more of this gold to back up standards of care.

Second, where the currency of medical practice is not based on this gold standard, what medicine regards as appropriate care appears to be determined by implicit consensus within the profession. However, there appears to be considerable resistance on the part of the profession to

treating consensus-building in a formal, professionally sanctioned manner. A common reaction is to treat these efforts with disdain, labeling them as "cookbook medicine."

Third, there are some noteworthy efforts to deal with consensus more formally, including the decade of experience with the NIH consensus development conferences, the American College of Physicians' Clinical Efficacy Assessment Program (CEAP),[1] and the research by some of my RAND and UCLA colleagues, which has been reported in recent months.[2-8] I would be the first to agree that these efforts can benefit from more refinement and validation and that other approaches should be tried. However, I am hard pressed to believe that these efforts at explicitly recording consensus are not superior to the haphazard implicit standards that a doctor obtains from his colleagues or from a hurried perusal of journal articles--or that a court can glean from testimony by experts chosen precisely for their polar viewpoints.

Fourth, formal consensus development efforts are not a substitute for research on outcomes of care; they should both rely on and complement RCTs and other, non-experimental research on outcomes. One has to wonder about the validity of consensus statements that are not founded in part on some more rigorous empirical work. Indeed, I am inclined to attribute some of the difficulty in reaching consensus--that is, the disagreement among experts on whether a procedure is appropriate in a particular situation--to the absence of better empirical studies.

Finally, research on outcomes of care is important, not just for the information it can provide the medical community, but also for the information it can provide to patients. Informed consent is regarded as both an ethical requirement and an important defense against malpractice. However, too often informed consent forms are designed less to inform the patient than to list all possible adverse occurrences--irrespective of their probability--to cover the provider in any eventuality. Both the doctor and the patient really need a balanced statement about the distribution of expected risks and benefits of an intervention under consideration. I believe that it is perfectly reasonable for one patient "to go for a long shot," and another to opt

for a conservative, non-interventionist strategy on the basis of the same information but different preferences for risk taking. I believe the doctor is asking for trouble if he makes these decisions for the patient, unless, of course, the patient explicitly opts out of the decision process. I am aware of the research that indicates patients do not necessarily process this kind of information well, but I think it is perilous for the doctor to assume that he is free from the same cognitive limitations.

Now, I want to discuss explicitly how the medical malpractice system might be improved by more and better research on outcomes and appropriateness of care. Of course, the purpose of this research would be to inform medical decisionmaking and to set standards. To begin, I want to acknowledge that the kind of standard setting I envisage would only be relevant to a certain class of medical malpractice problems--those in which the issue is whether it was or was not appropriate to take a specific action. This sort of standard setting would not be particularly relevant when the malpractice issue involves a careless act or an unskilled intervention.

The data I have seen on the sources of malpractice claims give only rough indications about the proportions of cases where the presence of standards might be relevant. My guess is that upwards of half of the cases could be decided more definitively or prevented if standards were promulgated. Of course, this depends a great deal on how physicians would respond to them. In any case, more analysis of some of the claims databases should permit a much better estimate of this number.

The first logical question that one might ask about setting standards relates to the degree of consensus that can be achieved with panels of experts. Let us accept for now that the formal empirical bases for setting standards are inadequate for the great majority of medical interventions. I think the research by my colleagues at RAND and UCLA is informative. Panels of nine expert physicians rated six medical and surgical procedures on a nine-point scale of appropriateness for a very detailed set of indications--ranging from about 200 to more than 1500, depending on the procedure.[2] Although the experts had little difficulty rating these procedures, their level of agreement was

somewhat disappointing--that is, the panelists at best agreed on a little more than half the indications. They clearly disagreed on as much as 30 percent of them.

Given this somewhat discouraging level of agreement among experts, one might next ask whether there is any hope that these sorts of seemingly equivocal standards might be relevant for preventing medical malpractice. Here the answer seems to be that such standards are more promising than the apparent lack of agreement would lead one to suspect. Review of a random set of medical records showed that the experts would have judged between 15 and 33 percent of the procedures to have been done for inappropriate indications.[5-8] Obviously, some of these inappropriate procedures were candidates for medical malpractice suits, and I would guess that many of the physicians who performed them would not have done so if they had had the benefit of ratings by the expert panels. Others almost surely would have taken pains to inform their patients of the potential risks. By the nature of their data, my colleagues could more easily identify actual cases of overuse than of underuse. However, their scales of appropriateness have broader applicability than might be readily apparent. For example, in cases where diagnostic procedures were judged inappropriate by the panels, I think there is protection for the doctor who is wrongly accused of sins of omission.

What about the more equivocal ratings--ones in which the panels were unsure or disagreed sharply among themselves? If I were a doctor performing procedures for these indications, I would be careful to explain this uncertainty to my patients. If I were a patient who was considering having such a procedure, I would see warning flags--particularly if there were significant iatrogenic risk.

If, as some assert, a significant proportion of malpractice claims occur because the patient has a bad outcome, despite appropriate treatment, I believe a determination by an expert panel that the intervention was done for an appropriate indication might prove to be an effective defense and a deterrent to frivolous claims. This, of course, assumes that the intervention was done proficiently.

A skeptic might well ask what real evidence there is--never mind the theory--that setting standards would ease the problems of malpractice. The best evidence I see is the fact that some insurers--for example, in Utah and Colorado--seem to be moving aggressively in that direction. They are issuing their insured physicians standards for care in areas that have historically had large numbers of claims. More important, they seem to be showing results in reducing both misadventures and claims.

I believe these standard-setting initiatives by malpractice insurers are a very good thing. However, I also think that there are some advantages to developing and promulgating these standards outside the medical malpractice community, as well as some economies to doing it more centrally. Moreover, I am somewhat concerned that there might be a bias within the medical malpractice community toward setting standards that err on the side of overuse. I am interested in a system of standards that protects the doctor who practices sound economical medicine, forgoing diagnostic interventions that have very low expected yield.

In summary, I think that developing better, more explicit standards of care is essential to developing a malpractice system that treats both the doctor and the patient more equitably. And I think that explicit standards are needed to ensure that our health care resources are used efficiently. I am not nearly so concerned about the risks of "cookbook medicine" as I am about a small, troublesome group of practitioners who serve up too many untested dishes, or about the much larger numbers of practitioners who perceive incentives to provide care that contains needlessly rich gourmet ingredients. Finally, I think that patients will not think less of doctors who consult a definitive cookbook to determine standards of care. Just as most of us who eat out have little desire to go back and help the chef prepare the meal, most of us who go to the doctor are not interested in directing our medical care. Nonetheless, we may find it encouraging that a group of expert chefs have specified a set of essential ingredients for a particular dish and reassuring that physicians who are acknowledged national experts have outlined standards of care.

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