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Void for Vagueness

by Carl E. Schneider

When law regulates a profession, where does it get its standards? Largely from the profession. Members of professions acquire esoteric and abstract knowledge through formal education and the experience of practice. They use professional judgment in applying this knowledge to their regulation of medicine's standard of care. Furthermore, physicians must be called as expert witnesses to guide juries in that work.

Even when lawmakers contemplated intensifying their regulation of medicine by creating the duty of informed consent, they could consult a literature to which doctors and medical ethicists contributed crucially. In some jurisdictions, even the scope of the duty is determined whether the doctor met medicine's standard of care. Furthermore, physicians lack this expertise, they adopt the esoteric and abstract knowledge acquired in practice. They use professional judgment in applying this knowledge to their regulation of medicine's standard of care. Furthermore, physicians must be called as expert witnesses to guide juries in that work.

Indeed, plaintiffs rarely bring informed consent actions (except as appendages to malpractice suits), rarely win them, and rarely obtain large verdicts.

In short, lawmakers have essentially established rules intended to hold medicine to its own standards and then mostly left the system to work unmostrusted. What lawmakers have not noticed, however, is that the status of informed consent in the medical literature has become parlous. Two developments particularly matter. First, a torrent of empirical evidence now suggests that informed consent does not work as intended: Doctors generally tell patients too little and patients generally understand too little for patients to make the choices that lawmakers had imagined.

Second (and relatedly?), the literature seems to be deserting the term "informed consent." And what instead? A comet shower of novel terms. "[T]here is now a profusion of competing models that attempt to convey subtle differences in the sharing of information and power between clinician and patient." A smattering of the latest models: "evidence-based patient choice," "informed decision-making," "informed medical decision-making," "informed treatment decision-making," "physician as perfect agent," "shared decision-making," "shared clinical decision-making," "shared medical decision-making," and "shared treatment decision-making." From this welter of multiplying, mystifying distinctions, one term has emerged most stoutly—"shared decision-making."

So, what is shared decision-making? Would that I knew. Or that anyone did. Makoul and Clayman heroically slogged through the literature and concluded that there is no shared definition of shared decision making. They identified 31 separate concepts used to explicate SDM, only two of which appeared in more than half of the conceptual definitions. In fact, "60% of articles that purport to focus on shared decision-making failed to include any conceptual definition at all."

As this suggests, many proponents of shared decision-making seem to regard its meaning as self-evident. And no doubt most people suppose that they understand the term. "Sharing" does the real rhetorical work here. Who doesn't understand sharing? Who could oppose it? Yet the skimpiest reflection reveals that the slogan is ambiguous unto incoherence.

For example, what makes a decision "shared"? It is logical, plausible, reasonable to say, as many advocates of shared decision-making seem to say, that anyone who helps shape a decision, helps give the decision meaning, helps give it effect, "shares" in it. But on this reading, virtually all consequential medical decisions are shared. The doctor must propose something; the patient must at least acquiesce; both have participated; they have shared the decision.

Or look at "sharing" from another angle. When doctors and patients talk, they develop a framework for their conversation and goals for their interaction. These often emerge implicitly, with neither party really grasping what is happening. Both parties shape the framework and assumptions: Patients initially state the issue in the case; doctors initially state the solution. These frameworks and assumptions can decisively shape the conversation and its conclusions. In this sense, again, almost every decision of any moment is "shared."

In the mess and murk of real life it is in fact often hard to say who "made" or even "participated in" a decision. A neurologist wants to do a lumbar puncture. Patient: "Will the results affect the choice of treatment?" Doctor: "No. . . . Let's wait on the LP. What happened?
The patient did not explicitly state a preference and perhaps had none. Or not a clear one. Or a firm one. What if the doctor had persisted? What would the patient have said? Why did the doctor desist? What decision was actually made, and who participated in what way? Was this a “shared” decision? I was the patient, and I can’t answer any of these questions.

In short, “shared decision-making” covers so much that it must mean too little. But “shared decision-making” is obscure in still another weighty way: Its relationship to informed consent is baffling. Does the former describe how the latter should work, or is it something fresh? Is it a response to the latter’s perceived failure or its perceived nobility? Does shared decision-making enhance the patient’s authority? Or the doctor’s? Most writing on the subject just ignores these basic questions. And there is authority for many interpretations.

For example, one defense of shared decision-making contends that “concern with patient participation in treatment decision-making has moved well beyond informed consent to include broader principles of patient autonomy, control, and patient challenge to physician authority.” On this view, shared decision-making continues the informed consent revolution. But how? I had always thought informed consent embodied broad principles of patient autonomy, control, and challenge to physician authority.

On the other hand, some writing on shared decision-making implies that doctors should share not only the decision, but also the authority to make it. Charles et al., for example, announce that doctors have a “legitimate investment in the treatment decision” and that doctors and patients should build a “consensus.” This is a far—and disquieting—cry from the usual understanding that patients are the principals and doctors only their agents.

Plainly proponents of shared decision-making need to give their term a much better considered and more precise construction. They need to realize that it has no inherent meaning, that it describes no natural phenomenon. It is a label applied to a prescription for the way doctors and patients should proceed. Until its proponents agree on the prescription, shared decision-making can only be a cipher.

But is agreement possible? Most enthusiasts for shared decision-making lump all decisions into one homogeneous category. However, medical decisions vary along so many axes that generalizations are doomed. Sometimes decisions rest on reliable evidence, sometimes not. Sometimes choices are few, sometimes many. Some decisions are weighty, some trivial. Some choices are complex, some simple. Some decisions are recurring, some unique. Some raise technical questions, some moral questions. Some choices are matters of taste, others of calculation. Some decisions must be rushed, some can be leisurely. Some decisions are made with a long-known doctor, some with a stranger. Some decisions are made with a trusted physician, some with a distrusted one. This list could be lengthily prolonged. The upshot is that decisions are so various that no single principle can well guide them all.

Not only do decisions vary, but so do doctors and patients, and in ways that dispositively affect how they can, and want to, and should make decisions. Doctors differ in specialty, experience, knowledge, insight, sympathy, tact, loquacity, lucidity, persuasiveness, confidence, patience, optimism, resourcefulness, trustworthiness, and so on and on. Patients differ—here’s the short list—in intelligence, literacy, numeracy, knowledge, wisdom, confidence, attentiveness, dispassion, judgment, insight, imagination, experience, anxiety, nerve, sanity, aggressiveness, suggestibility, deference, and so on and on. Perhaps most crucially, patients differ enormously in the way they want their medical decisions made. Worse, they want some kinds of decisions made differently from other kinds. Worse yet, patients’ preferences shift with advancing age and fluctuating health.

So suppose courts and legislatures concluded that informed consent has failed to achieve the purpose for which it was instituted. Suppose they concluded that “shared decision-making!” is medicine’s dernier cri. Could they follow their usual practice of adopting the profession’s standards as their own? No. A legal rule must be both predictable and administrable. The subjects of a rule must be able to discover what the law requires of them; the people who administer a rule must be able to comprehend it and apply it efficiently. Shared decision-making is so enigmatic that neither condition can be met. Nor, given the proliferating variety of medical decisions, can a definition that meets the two conditions be readily imagined.

Informed consent, in contrast, meets the two conditions (well, close enough for government work). It might be unclear in a given case exactly what the reasonable patient would want to know about a choice, but the principle that animates that standard is comprehensible to doctors, juries, and judges. Yet what use is a predictable and administrable standard that cannot produce its intended effects?

Thus we are brought back to the challenge of regulating professions. Lawmakers do not understand medicine’s work well enough to set standards for it. So medicine’s standard must be adopted. The long-standing principle—shared decision-making—is so inchoate that it is not even a paper mouse. And so . . .?