Virtual Mentor
American Medical Association Journal of Ethics
February 2014, Volume 16, Number 2: 120-123.

HEALTH LAW

Lack of Standardized Informed Consent Practices and Medical Malpractice

Richard Weinmeyer, JD, MPhil

The promise of efficient and appropriate health care has never seemed brighter. Telemedicine is providing needed access to medical services to patients in remote locations, research in genetics and genomics is teaching us more about human physiology and making personalized medicine possible, injuries and illnesses that were disabling or lethal in the not-too-distant past are now preventable and treatable. One might think that these advancements would contribute to a minimal standard of care for most medical conditions regardless of where a patient lives and seeks treatment. But, as the current research on variations in medical care demonstrates, such thoughts are false [1]. For example, a patient living in Baltimore, Maryland, is five times more likely to undergo a lower-extremity bypass for peripheral arterial disease of the leg than one living in Temple, Texas, while a patient with prostate cancer is three times more likely to be treated with a radical prostatectomy if he lives in Salt Lake City, Utah, than if he lives in San Francisco, California [2]. Whether it is the underuse of care, the overuse of care, or the inappropriate use of medical resources, national standards for health care are elusive.

Unwarranted variations in medicine not only have implications for physicians, patients, and payers but also have an impact on the law and the way courts and agencies regulate the conduct of physicians and health care institutions. When there is no consistent standard of care with which to assess the behavior of agents in health care, the law faces the formidable challenge of bringing about a fair and just result. This article looks at one particular topic in health law that is affected by variations in care: informed consent and medical malpractice. This is by no means the only legal matter that is tested by unpredictable practices in health care, but this example provides insight into how the law is attempting to adapt to fickle standards of care.

Measuring a Standard of Care

Variations in medical care can play a tremendous role in legal proceedings given that "the law attributes normative significance to the medical standard of care" [3]. Courts make determinations on whether or not a physician is liable for the injuries sustained by a patient during or following a medical intervention based, in part, on whether the physician deviated from the standard of care [4]. In order to ascertain exactly what the standard of care should be, courts rely heavily on the testimony of medical experts who possess the appropriate knowledge, education or training, skills, or experience to testify about the standard under scrutiny [4].

Two Standards for Informed Consent

The manner in which informed consent is achieved depends on the way the physician and the patient share information and how the patient ultimately makes her decision

to undergo or forgo a procedure. Just exactly how this deliberative process is undertaken can be the precise question before a jury in a medical malpractice case. In general, there are two kinds of informed consent in the United States: the physician-based standard and the patient-based standard [5]. Approximately half of the states in the country follow the physician-based standard [6], which is defined in reference to the actions of *other* physicians [7]. Within these jurisdictions, a physician "has a duty in the exercise of ordinary care to inform a patient of the dangers of, possible negative consequences of, and alternatives to a proposed medical treatment or procedure" [8] with the same "degree of skill and diligence exercised by a reasonably prudent practitioner in the same field of practice or specialty" in that same state [9]. The patient-based standard, on the other hand, which has been adopted in 23 states and the District of Columbia [10], requires a physician to disclose any material risk to the patient, meaning the physician believes a reasonable person in the patient's position "would be likely to attach significance to the risk...in deciding whether or not to forego [sic] the proposed therapy" [11]. In order to support a claim of medical malpractice, a patient has to prove that (1) the physician failed to meet the applicable standard, (2) the patient would have decided not to undergo the procedure had the standard been met, and, (3) overall, the physician's failure was the proximate cause of the patient's injuries [12].

Is There Really a Single Standard?

When unwarranted variations in care plague medicine, determining whether the appropriate standard for informed consent has been met can prove problematic. While state legislatures and courts have adopted and applied a particular type of informed consent law, a single standard of care typically does not exist for most treatments, and researchers have demonstrated that standards vary substantially by region [13]. These variations are not random, but reveal differing patterns of practice: in some areas, physicians become specialized in certain treatments and then regularly recommend those treatments to patients suffering from particular conditions, while, in other areas, treatment decisions may be constrained by hospital or clinic management [14]. Furthermore, studies indicate that similar patients are not treated similarly; patient preferences and the supply of physicians fail to account for variations in care [15], and physician culture varies by location.

With respect to informed consent, the ambiguity around just what the standard of care is makes it difficult for courts to determine when a physician's informed consent practices have fallen outside the range of reasonable options. As Feldman-Stewart and colleagues have found, physicians often do not reach a consensus on the quantity nor the content of information that should be disclosed to patients, and this holds true even among physicians living in the same geographic region and working in the same specialty [16]. Such a conclusion is problematic for states that abide by the physician-based standard. And, in terms of the patient-based standard, patients frequently disagree about what risks they consider to be "material" for a particular treatment option [17], and physicians tend to be quite poor at predicting patient preferences [18]. The legal theory behind informed consent laws, it seems, differs considerably from the reality of medical practice.

Attending to the Variability of Informed Consent

Because these variations in health care delivery standards make it difficult to assess conformity with informed consent laws, scholars have proposed solutions that would establish more appropriate legal standards. Perhaps the most persuasive of these proposals is that of King and Moulton, who argue that states should move towards a shared decision-making standard for informed consent because this framework incorporates evidence-based medicine and requires both the physician and the patient to share information and jointly participate in the decision-making process [19]. Under this type of system, the physician would "share with the patient all relevant risks and information on all treatment alternatives and the patient [would share] with the physician all relevant personal information that might make one treatment or side effect more or less tolerable than others" [20]. This model of informed consent, they suggest, would preserve patients' individual autonomy by giving them greater access to the information they need in considering the options before them [19], while also improving physicians' ability to advise their patients on treatment choices [21]. Despite the promise this legal revision would bring, King and Moulton acknowledge that an overhaul of informed consent law would require considerable resources and present implementation hurdles for both the US health care and legal systems; however, surmounting these obstacles may well be worth it for better protecting the decisions made by patients and physicians in the provision of care [22].

Conclusion

The study of variations in health care delivery reveals that a multitude of care options are offered to patients across the country, and this variety in care may not be compatible with existing legal standards. The ways in which informed consent is obtained in hospitals and clinics, for example, may no longer comport with what the law requires to shield physicians from liability. Solutions to this medicine-law mismatch surely exist in some melding of evidence-based medicine with legal theory, but the measured evolution of the law means that standardized informed consent may very well be an unattainable standard of care for many for the time being.

References

1. The Dartmouth Institute for Health Policy and Clinical Practice. *The Dartmouth Atlas of Health Care.* http://www.dartmouthatlas.org/. Accessed December 6, 2013.
2. Arora A, True A. What kind of physician will you be? Variation in health care and its importance for residency training. The Dartmouth Institute for Health Policy and Clinical Practice. http://www.dartmouthatlas.org/downloads/reports/Residency_report_103012.pdf. Accessed December 6, 2013.
3. Wennberg JE, Peters PG. Unwarranted variations in the quality of health care: can the law help medicine provide a remedy/remedies? *Wake Forest L Rev*. 2002;37:932.
4. Schwartz VE, Kelly K, Partlett DF. *Prosser, Wade, and Schwartz's Torts*. 12th ed. New York, NY: Thomson Reuters; 2010:195-197.
5. King JS, Moulton BW. Rethinking informed consent: the case for shared medical decision-making. *Am J Law Med*. 2006;32(4):440-445.

6. King, Moulton, 441.
7. *Tashman v Gibbs*, 556 SE2d 772, 777 (Va 2002).
8. *Tashman*, 777 (citing *Rizzo v Schiller*, 445 SE2d 153, 155 (Va 1994)).
9. *Tashman*, 777 (citing *Bryan v Burt*, 486 SE2d 536, 539 (Va 1997); *Pierce v Caday*, 422 SE2d 371, 374 (Va 1992); *Raines v Lutz*, 341 SE2d 194, 196 (Va 1986)).
10. King, Moulton, 445.
11. *Canterbury v Spence*, 464 F2d 772, 787 (DC Cir 1972).
12. *Scott v Bradford*, 606 P2d 544, 559 (Okla 1979).
13. Wennberg, Peters, 925.
14. Wennberg JE, Cooper MM, Birkmeyer JD, et al. *The Dartmouth Atlas of Health Care* [1998]. http://www.dartmouthatlas.org/downloads/atlases/98Atlas.pdf. Accessed December 11, 2013.
15. Wennberg JE. Variation in the use of medical services among regions and selected academic medical centers: is more better? *Commonwealth Fund Rep*. 2005;8:6-8.
16. Feldman-Stewart D, Brundage MD, McConnell BA, MacKillop WJ. Practical issues in assisting shared decision-making. *Health Expectations*. 2000;3:49.
17. Bogardus ST Jr, Holmboe E, Jekel JF. Perils pitfalls, and possibilities in talking about medical risk. *JAMA*. 1999; 281(11):1039.
18. Teno JM, Hakim RB, Knaus WA, et al. Preference for cardiopulmonary resuscitation: physician-patient agreement and hospital resource use. *J Gen Intern Med*. 1995;10(4):180.
19. King, Moulton, 463.
20. King, Moulton, 431.
21. King, Moulton, 472.
22. King, Moulton, 491-492.

Richard Weinmeyer, JD, MPhil, is a senior research associate for the American Medical Association Council on Ethical and Judicial Affairs. Mr. Weinmeyer received his law degree from the University of Minnesota, where he completed a concentration in health law and bioethics and served as editor in chief for volume 31 of the journal *Law and Inequality: A Journal of Theory and Practice*. He obtained his master's degree in sociology from Cambridge University and is completing a second master's in bioethics from the University of Minnesota Center for Bioethics. Previously, Mr. Weinmeyer served as a project coordinator at the University of Minnesota Division of Epidemiology and Community Health. His research interests are in public health law, bioethics, and biomedical research regulation.

Related in VM

A Resource-Based Locality Rule, February 2014

The Role of Practice Guidelines in Medical Malpractice Litigation, January 2011