



# Medicolegal Sidebar

## The Law and Social Values: Medical Uncertainty

Wendy Z. W. Teo BA(Cantab), BM BCh (Oxon), LL.M., Lawrence H. Brenner JD,  
B. Sonny Bal MD, JD, MBA

### Introduction

Informed consent and its application in clinical practice are of vital interest to surgeons because allegations of medical battery (that is, the intentional treatment of a patient without informed consent) can accompany medical malpractice lawsuits if the court perceives that there was an insufficient or defective informed consent [14]. Physicians are

trained to discuss informed consent with patients. This discussion should include documentation of the known risks, benefits, and alternatives to a proposed treatment or surgical intervention [3]. Complicating the full-disclosure requirement of the law is the increasing awareness that the exact benefits of many common operations and medical interventions are uncertain. In our technology- and information-driven world [1], patients have access to many sources of healthcare statistics that are outside the physician-patient interaction. As such, the focus of medical practice has moved away from a paternalistic view to one that is consultative—the physician presents options to the patient,

who then makes a choice [11]. In this model, the law offers little guidance about how to convey uncertainty during the informed-consent discussion.

### Questioning Basic Assumptions

While no one single study is dispositive in resolving the clinical effectiveness of a medical procedure, there are compelling and thoughtful arguments that question basic assumptions in US healthcare.

Authors Norton Hadler MD in *Worried Sick* [5], and David H. Newman MD in *Hippocrates' Shadow* [9] write about the lack of scientific support for many commonly accepted treatments in contemporary medicine. In *Hippocrates' Shadow*, Dr. Newman refers to certain medical practices as procedures that are believed to be effective simply because of cultural norms, rather than scientific proof. For example, commonly prescribed antidepressant medications may be no more effective than placebos, except in rare cases [7, 8]. Even a well-ingrained practice such as dental flossing may have no identifiable benefit for the maintenance or improvement of dental

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W. Z. W. Teo BA(Cantab), BM BCh (Oxon), LL.M., L. H. Brenner JD,  
B. S. Bal MD, JD, MBA  
BalBrenner/Orthopaedic Law Center,  
Chapel Hill, NC, USA

B. S. Bal MD, JD, MBA (✉)  
University of Missouri, 1100 Virginia  
Ave., Columbia, MO 65212, USA  
e-mail: balb@health.missouri.edu

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health [4]. He notes that our science is ultimately limited, and where there is an absence of evidence, the best we can do is make (what we believe to be) educated guesses. He writes: “In some cases, physicians don’t know the evidence that contradicts their practice, having blindly accepted the teachings of their predecessors. And in other cases, physicians are well aware of the evidence but obstinately refuse to reexamine their practice and themselves” [9].

In *Worried Sick*, Dr. Hadler questions the efficacy of many expensive, well-entrenched standards of care. According to Dr. Hadler, an underlying assumption in US healthcare policy is that everyone needs a large amount of expensive care, in doses that are determined by pharmaceutical companies and the medical establishment. A familiar orthopaedic example is knee arthroscopy degenerative meniscal tears; a multicenter, randomized, double-blind, sham-controlled study showed no benefit of surgery over placebo surgery [13].

Drs. Newman and Hadler advise consumers to view recommended medical treatments with skepticism, and to get information on their own to decide what healthcare is really necessary. Patients are encouraged to understand that there is uncertainty about the benefits of many medical treatments, despite the confident

recommendations of their doctors. The practical implications are that patients are more likely to seek information about their treatments outside the traditional physician-patient relationship. As such, the informed-consent process should anticipate a more engaged and questioning patient in contrast to the traditional deference shown to physicians in the past.

## The Courts

While the courts have never directly clarified the boundaries of complete disclosure during informed consent, some rulings have supported incomplete disclosure under limited circumstances. For example, a doctrine called “therapeutic privilege” allows a doctor to withhold information if full disclosure might psychologically harm the patient or cause a patient to forego an operation that is medically necessary. Therapeutic privilege was addressed in *Nishi v Hartwell*, a 1970 Hawaii Supreme Court ruling where the Court held that the primary duty of a physician is to do what is best for his patient, and in executing that duty, he/she can withhold information that might adversely affect the patient’s best interest [10]. Of note, subsequent legal decisions have diluted the therapeutic privilege exception considerably, adopting a much

narrower interpretation of it. Those subsequent rulings have increasingly supported a patient-centric approach, whereby full disclosure is required, even in the face of medical uncertainty. In other words, a physician cannot withhold information on the justification that other, reasonable physicians in a similar situation would also withhold that information for fear of upsetting the patient, or causing the patient to refuse necessary care. Rather, the legal standard has evolved to asking whether or not another reasonable patient in similar circumstances would desire disclosure of withheld information to formulate a decision about their healthcare.

The seminal case in informed consent is the 1972 ruling in *Canterbury v Spence* that required physicians to convey those risks that a reasonable person would consider material to deciding whether or not to undergo a medical procedure [3]. *Canterbury* makes the assumption that the physician obtaining informed consent has an accurate understanding of the benefits of the proposed treatment. In reality, while physicians may be aware of medical uncertainty in clinical practice, the communication during informed consent rarely addresses it. Audiotaped patient-physician discussions found that uncertainty was communicated only 5% of the time when obtaining informed consent [2].

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This lack of communication was particularly true in discussions for decisions of high complexity; only 0.5% of such decisions were fully informed [2].

## Informed Consent and Uncertainty

The true benefits of a medical intervention are complicated by the placebo effect (patient improvement following treatment with an intervention that has no demonstrable therapeutic efficacy) especially if the provider believes in the proposed treatment and the patient trusts the provider. To be clear, knowingly administering a placebo, or performing sham surgery to achieve a placebo benefit has serious legal and ethical implications, and is not endorsed.

Patient improvement after medical interventions that lack evidence-based proof may have other explanations as well. Physician demeanor and confidence in the recommended treatment may be important because of patient reassurance that the doctor trusts the treatment, and has had good experience with it [9]. Another explanation for patient improvement is the Hawthorne effect, which refers to the alteration of behavior by subjects in a study because of their awareness of being observed [12]. Clearly, patient recovery after surgery is related to a

number of complex variables, in addition to the objective, scientifically proven merits of the operation itself.

## Discussion

Several communication strategies can help a clinician express medical uncertainty to a patient during informed consent. These strategies include recommending other sources of information such as professional websites, and encouraging questions related to all aspects of the patient's healthcare [6]. During informed consent, a physician should be open-minded, sympathetic, and when presenting alternatives, should explain his/her own treatment preferences, values, and goals [6]. Communication skills and training are central in this model. Indeed, an orthopaedic surgeon's ability to convey his/her beliefs about the benefits of a procedure accurately may require skills that equal—or even exceed—the technical expertise required for successful surgery.

The law recognizes that the practice of medicine has been (and always will be) complicated by uncertainty. In dealing with the unproven scientific benefits of medical procedures, one approach that can balance the competing values of full disclosure versus achieving the most patient benefit is

for the surgeon to express his/her opinion and experiences about the benefits of the intervention. In treating a meniscal tear in a mildly degenerative knee joint, for example, a surgeon can convey that in his/her experience, arthroscopy is one effective option toward pain relief, but it adds the risk of a minor operation. Other alternatives include anti-inflammatory medication, rest, injections, and/or physical therapy—all of which avoid surgery. There is no evidence that surgery has any benefit over the non-surgical treatments [13].

Medical practice, regardless of specialty, is an art and a science. Statistical comparisons of the efficacy of an operation to scientifically appropriate controls cannot tell the whole story. Whether improvements after surgery are derived from the surgeon-patient relationship, measurable outcomes, or other imprecise variables, the procedure itself is related to how the surgeon views the benefits of the recommended intervention, and how effectively he/she communicates those beliefs to the patient.

## References

1. Bal BS, Brenner LH. Medicolegal sidebar: Informed consent in the information age. *Clin Orthop Relat Res.* 2015;473:2757–2761.
2. Braddock CH, Edwards KA, Hasenberg NM, Laidley TL, Levinson W.

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- Informed decision making in outpatient practice: time to get back to basics. *JAMA*. 1999;282:2313–2320.
3. *Canterbury v Spence*, 464 F.2d 772 (1972).
  4. Donn J. Medical benefits of dental floss unproven. *Associated Press*. Available at: <http://bigstory.ap.org/article/f7e66079d9ba4b4985d7af350619a9e3/medical-benefits-dental-floss-unproven>. Accessed Sept. 9, 2016.
  5. Hadler N. *Worried Sick: A Prescription for Health in an Overtreated America*. Chapel Hill, NC: University of North Carolina Press; 2008.
  6. Hewson MG, Kindy PJ, Van Kirk J, Gennis VA, Day RP. Strategies for managing uncertainty and complexity. *J Gen Intern Med*. 1996;11:1481–1485.
  7. Kirsch I. *The Emperor's New Drugs: Exploding the Antidepressant Myth*. New York, NY: Basic Books; 2010.
  8. Kirsch I, Deacon BJ, Huedo-Medina TB, Scoboria A, Moore TJ, Johnson BT. Initial severity and antidepressant benefits: a meta-analysis of data submitted to the Food and Drug Administration. *PLoS Med*. 2008;5:e45.
  9. Newman D. *Hippocrates' Shadow: Secrets from the House of Medicine*. New York, NY: Scribner; 2008.
  10. *Nishi v. Hartwell*, 473 P.2d 116 (1970).
  11. Paterick TJ, Carson GV, Allen MC, Paterick TE. General considerations for physicians. *Mayo Clin Proc*. 2008;83:313–319.
  12. Payer L. *Medicine and Culture*. New York, NY: Holt Paperbacks; 1996.
  13. Sihvonen R, Paavola M, Malmivaara A, Itälä A, Joukainen A, Nurmi H, Kalske J, Järvinen TL; Finnish Degenerative Meniscal Lesion Study (FIDELITY) Group. Arthroscopic partial meniscectomy versus sham surgery for a degenerative meniscal tear. *N Engl J Med*. 2013;369:2515–24.
  14. Weathington PE, Freije PB. I'm getting sued for WHAT? Available at: <http://www.aaos.org/AAOSNow/2008/Jan/managing/managing9/?ssopc=1>. Accessed October 11, 2016.