
Marc Ginsberg
John Marshall Law School, 9ginsberg@jmls.edu

Follow this and additional works at: http://repository.jmls.edu/facpubs

Part of the Health Law and Policy Commons, and the Medical Jurisprudence Commons

Recommended Citation

http://repository.jmls.edu/facpubs/662

This Article is brought to you for free and open access by The John Marshall Institutional Repository. It has been accepted for inclusion in Faculty Scholarship by an authorized administrator of The John Marshall Institutional Repository.
Beyond Canterbury: Can Medicine and Law Agree about Informed Consent? And Does It Matter?

Marc D. Ginsberg

For those of us whose scholarship focuses on medico-legal jurisprudence, the law of informed consent is a gift. It has been a fertile topic of discussion for decades, with no end in sight. Although it is not difficult to acknowledge that patient autonomy is at the core of informed consent, the doctrine is not static — it has evolved in scope and continues to engage courts in thought provoking analysis.

There is no doubt that the doctrine of informed consent is fundamental to the physician-patient relationship. My concern, and the purpose of this paper, is to consider that true informed consent is a lofty goal but, possibly, unattainable.

I noted in a previous paper that it would be unnecessary to expound in detail about the history of informed consent, and the same is true for the purposes of this paper. Nevertheless, a few points are worthy of mention. Informed consent is possibly, if not likely, of ancient origin. Certainly, the doctrine focuses on patient autonomy, about which the celebrated opinion of then Judge Cardozo in Schloendorff v. Society of New York Hospital stated:

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages."

This notion of patient self-determination is central to informed consent and, in theory, derives from information disclosed to the patient by the physician concerning the risks, benefits and complications of, and alternatives to, a recommended treatment or procedure. A physician who provided unconsented treatment could be liable in tort for a battery. A "consented to" treatment or procedure would not support a battery claim but consent obtained in the absence of a proper disclosure to the patient would support a medical negligence claim for lack of informed consent.

Basic to the physician-patient relationship is the standard of care. The standard of care is that care which a reasonably well qualified physician would provide to a patient under the same or similar circumstances. The standard of care then, is used to evaluate physician conduct, including the need to obtain a patient's informed consent.

There are two basic models of informed consent — the professional model and the reasonable patient...
The professional model focuses on the examination of the informed consent disclosure from the standpoint of the reasonable physician. This model of informed consent requires the use of expert testimony to prove that the physician failed to obtain informed consent. The reasonable patient model focuses on the physician’s disclosure from the standpoint of the patient—what information would a reasonable patient want to know before consenting to a proposed treatment or procedure.

**Canterbury v. Spence Shapes Informed Consent**

For almost 45 years, the opinion in *Canterbury v. Spence* has been central to the reasonable patient model of informed consent, linking the materiality of the risk to be disclosed to the patient’s decision to undertake a proposed treatment. *Canterbury,* however, provides another important insight into the law of informed consent, through its most compelling footnote 36, which states as follows:

> We discard the thought that the patient should ask for information before the physician is required to disclose. Caveat emptor is not the norm for the consumer of medical services. Duty to disclose is more than a call to speak merely on the patient’s request, or merely to answer the patient’s questions; it is a duty to volunteer, if necessary, the information the patient needs for intelligent decision. The patient may be ignorant, confused, overawed by the physician or frightened by the hospital, or even ashamed to inquire. [Citation Omitted] Perhaps relatively few patients could in any event identify the relevant questions in the absence of prior explanation by the physician. Physicians and hospitals have patients of widely divergent socio-economic backgrounds, and a rule which presumes a degree of sophistication which many members of society lack is likely to breed gross inequities.

This pronouncement teaches that informed consent requires a *disclosure,* not a dialogue or a conversation with the patient, not demanding significant, if any, patient engagement. Yet, if patient consent is truly to be “informed,” the doctrine of informed consent, if it is effective, requires patient understanding, suggesting something more than only a physician disclosure. Of course, neither *Canterbury* nor any other judicial pronouncement can guarantee or provide an enforcement mechanism for patient understanding. Therefore, the concept of informed consent seems strained at a basic level.

**Law vs. Medicine**

*Canterbury* creates another problem for medicine, relating to the establishment of the standard of care to which physicians should be held. The development of practice guidelines by physicians “set the de facto standard for medical practice and therefore influence clinical decisions about individual patients, [and] practice measures....” Yet, insofar as the development of informed consent is concerned, *Canterbury* teaches that the law of informed consent is too important to leave its imposition to the medical profession. The *Canterbury* court emphasized this point when stating:

> Respect for the patient’s right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves.

This lack of trust in medicine by “the law” likely causes diminished respect for law by medicine.

A memorable, recent example of a court intruding in the realm of medicine and informed consent is *Jandre v. Wisconsin Injured Patients and Families Compensation Fund.* In *Jandre,* the Wisconsin Supreme Court interpreted an informed consent statute to require the disclosure of the differential diagnosis, discarded diagnoses and strategies to explore the potential range of diagnoses. Wisconsin physicians fought *Jandre* through the legislative process and successfully influenced an informed consent statutory amendment.

*Jandre* may also be an example of another basic conflict between law and medicine, also applicable to informed consent, pertaining to evidence and the resolution of disputes. It has been noted that:

> Courts and health care have historically viewed evidence in fundamentally disparate ways... The legal system is built on an adversarial model...
Disputes about facts are left to a jury or judge to decide, and the goal is to ensure fair process rather than fair outcomes or truth. Juxtaposed to this, empirical evidence in medicine seeks to define a single unimpeachable truth that can stand on its own. Moreover, medical evidence often focuses on populations, while at the court level, the evidence must be relevant to the single injured patient.27

The point here is that physicians may accuse the legal system of advising them how to practice medicine, based upon a private claim against an individual physician by an individual patient. This no less applies to the law of informed consent. Physicians may very well base their disclosures on their experiences with typical risks, benefits and complications of treatments and therapies and these experiences may not intersect with information a patient believes is material to a treatment decision. In a sense, informed consent involves some physician “crystal ball gazing” – predicting certain potential complications or poor outcomes possibly important to a given patient in order to build a defense to an informed consent claim in the event that complication or outcome occurs.

**Patient Participation and Understanding**

Should the law of informed consent contemplate patient participation in decision making as a necessary corollary of patient autonomy? The basic concept here is that a well-informed patient will be capable of making an informed decision about proposed treatment. However, it is not at all certain that patients uniformly desire to make treatment decisions.

The process of the "perfect treatment decision"28 has been described as follows:

In actual practice, the most reliable way to approach the ideal of the perfect treatment decision is through intense collaboration among health care professionals and with patients. A “perfect treatment decision” must be based on two elements: the most up-to-date scientific knowledge, which in its burgeoning complexity cannot possibly be mastered by individual physicians acting on their own; and the patient’s values in choosing among various treatment options with different mixes of benefits and risks, which cannot possibly be known by individual physicians unless they openly and honestly collaborate with their patients.29

Even if the perfect treatment decision is realistic, there is data suggesting that the preference of many patients is to defer to their “physicians to make treatment decisions rather than using a more collaborative process.”30 Expressed a bit differently, “for the majority of patients who are less educated, less well informed, and less able to marshal their arguments – a somewhat more directive or (without being pejorative) ‘paternalistic’ approach will be far more appropriate and gratefully received.”31 If this opinion is accurate, perhaps the law should contemplate a patient’s “consent,” informed or not. More on this point later, when patient health literacy is discussed.

Looking at the informed consent process, pursuant to Canterbury,32 the law, created by courts for physicians, contemplates a disclosure. The patient need neither engage nor participate in a discussion with the physician. It appears, however, that medicine views informed consent as a communicative process with patient involvement.33 For example, it has been suggested that “[t]he heart of informed consent, however, is a conversation between physician and patient about a proposed treatment, alternative treatments, non-treatment, and the risks and benefits of each of these options.”34

More specifically, consider the description of informed consent by the American College of Surgeons (ACS) on its patient education site:35

**Informed Consent**

Before having your operation, you will be asked to indicate that you understand the nature of the surgical procedure to be performed and that you give your permission for the operation.

This may appear to be a formality, but, in fact, this process should be taken very seriously. Before your operation, frankly discuss with your surgeon any questions or concerns that you have. Of course, not everyone wants to know all the specific details of the surgical procedure itself, but you should seek the answers to questions such as:

- What are the indications that have led your doctor to the opinion that an operation is necessary?
- What, if any, alternative treatments are available for your condition?
- What will be the likely result if you don’t have the operation?
- What are the basic procedures involved in the operation?
- What are the risks?
- How is the operation expected to improve your health or quality of life?
- Is hospitalization necessary and, if so, how long can you expect to be hospitalized?
What can you expect during your recovery period?
When can you expect to resume normal activities?
Are there likely to be residual effects from the operation?
Of course, your surgeon may volunteer much of this information... 

Why is the ACS encouraging patients to seek answers to questions which should be addressed in a mandatory disclosure calculated to obtain the patient’s informed consent to a surgical procedure? The Canterbury model does not suggest that the physician “may volunteer” information material to the patient — the physician must disclose the information.

Looking at the informed consent process, pursuant to Canterbury, the law, created by courts for physicians, contemplates a disclosure. The patient need neither engage nor participate in a discussion with the physician. It appears, however, that medicine views informed consent as a communicative process with patient involvement. For example, it has been suggested that “[t]he heart of informed consent, however, is a conversation between physician and patient about a proposed treatment, alternative treatments, nontreatment, and the risks and benefits of each of these options.”

The American College of Obstetricians and Gynecologists (ACOG) has published a Committee Opinion on informed consent which provides, in relevant part, as follows:

5. Informed consent should be looked on as a process rather than a signature on a form. This process includes a mutual sharing of information over time between the clinician and the patient to facilitate the patient’s autonomy in the process of making ongoing choices.

There is no question that a consent form signed by a patient is not informed consent. At best, the signed consent form is evidence of informed consent. But, again, the idea that informed consent necessarily involves a sharing of information between physician and patient, in the nature of a dialogue, is simply not the legal model of informed consent, which requires a disclosure.

Not to be overlooked is the “informed” component of informed consent. Implicit (if not explicit) in the doctrine of informed consent is patient understanding of the physician’s required disclosure. Is this a realistic expectation? I have previously written that:

Health literacy has been defined ‘as the capacity to acquire, understand and use information in ways which promote and maintain good health’ and as ‘the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.’

As of 2004, it was estimated that “nearly half of all American adults (90 million people) have difficulty understanding and acting on health information.” This statistic must have implications for the doctrine of informed consent. Simply put, it is likely that many adult patients will not comprehend the required informed consent disclosure. The disclosure is required to recognize patient autonomy. Yet, if many patients are unable to understand the disclosure, consent will not be “informed” and autonomy will not be served.

Conclusion
I am hopeful that this paper has demonstrated the stress and conflicts inherent in the doctrine of informed consent. The law, not physicians, creates the rules for informed consent. Canterbury requires a one-way disclosure from physician to patient, typically describing the proposed treatment, its risks, benefits, complications and alternatives (including no treatment at all). Significant and influential medical associations (ACS, ACOG) suggest that informed consent is a process involving patient participation. Often, patients prefer to allow their physicians to make the treatment decisions for them; perhaps because they sought the advice from their physi-
cians due to their professional expertise or, perhaps because health literacy statistics reveal that many patients simply lack the wherewithal to participate in an informed consent process and to understand health related information. Therefore, it may be fair to urge that the law, medicine and patients do not share the same values and are not of one mind regarding informed consent.

The scope of informed consent has evolved since Canterbury and courts have considered topics for disclosure likely not contemplated at that time, including factors personal to the physician and the differential diagnosis. Quite recently, the Supreme Court of New Jersey determined that the doctrine of informed consent did not require a physician to disclose the lack of professional liability insurance coverage to cover a potential loss. These are interesting topics but they divert our attention from a considerable issue — whether the doctrine of informed consent is realistic and productive due to conflicts among the interests of the law, physicians and patients. If these interests do not intersect, the goal of informed consent may not be realized.

Acknowledgments
The author thanks his wife, Janice, for her inspiration and support. The author also thanks his former research assistant, Ms. Tyler Duff, JMLS Library Research Fellow, Mr. Andrew Scott, and his current research assistant, Ms. Kerby Kniss, for their assistance in research, proofreading, and citation checking.

References


3. Ginsberg I, supra note 1, at 18.


7. Id., at 93.


9. Id., at 122.

10. Id. § 3-2, at 76-77.

11. Id. § 3-10, at 123-124.


13. Id., at 786-87.

14. 464 F.2d 772.

15. Id. at 783, n.36.


18. 464 F.2d 772.


20. 464 F.2d 772.

21. Id.

22. Id., at 784 (emphasis added).


24. 813 N.W. 2d 627 (Wis. 2012).


26. 813 N.W. 2d 627 (Wis. 2012).


29. Id., at 1185.


32. 464 F.2d 772.

33. C. Grady, "Enduring and Emerging Challenges of Informed Consent," New England Journal of Medicine 372, no. 22 (2015): 855-62, at 856 ("Informed consent is a process of communication between the health care provider ... the patient ... that ultimately culminates in the authorization or refusal of a specific intervention.").


36. *Id.* (emphasis added).

37. 464 F.2d 772.

38. *Informed Consent*, supra note 35.


40. *Id.*


44. 464 F.2d 772.

45. *Id.*

46. See Ginsberg I, supra note 1; Ginsberg II, supra note 4.

47. Jarrell, 123 A.3d at 1022.