Balancing law, ethics and reality in informed consent for surgery

AI Sarela¹, M Thomson²

¹Department of Upper GI Surgery, Leeds Teaching Hospitals NHS Trust & School of Law, University of Leeds

²School of Law, University of Leeds

ABSTRACT

Informed consent has different implications and requirements in law and bioethics, and some irreconcilable disputes with the reality of surgical practice in the National Health Service. This article explores and discusses various aspects of informed consent that are of critical importance for practising surgeons in all specialties.

KEYWORDS

Bioethics – Surgical Ethics – Law

Accepted 9 February 2014

CORRESPONDENCE TO

Abeezar Sarela, E: a.sarela@leeds.ac.uk

The notion that it is essential for a surgeon to obtain consent from a patient was decided first in an English law court in the mid-18th century (*Slater v Baker and Stapleton*).¹ Traditional medical practice paid scant attention to consent; historical codes of medical ethics enjoined beneficence and fostered a culture of silence in the surgeon–patient relationship. The concept of autonomy – the right to self-determination – and, with it, the requirement of consent in medical practice rose to prominence only in the 20th century, in parallel with contemporary social and political emphasis on human rights.

In a relatively short timespan, autonomy seemingly replaced beneficence as the dominant professional ethic in medicine.² In this environment, legally valid consent evolved from a requirement to simply obtain permission to an explicit duty to disclose information about risks and alternatives; the term ‘informed consent’ was coined in a landmark US judgement in 1957 (*Salgo v Leland Stanford Jr University Board of Trustees*).³

Legal decisions on claims of inadequate information disclosure have invoked predominantly the tort (a civil wrong that is compensated by monetary damages) of negligence; the tort of battery (unlawful touching) and criminal charges have been used sparingly.⁴ In line with actions in negligence, the ‘reasonable surgeon’ test (did the surgeon fail to disclose an issue that no body of his or her responsible peers would have failed to do?) has been applied extensively to determine liability. Such a model envisions adequate disclosure as an integral part of the surgeon’s duty of care and yet it generates a clear conflict with bioethics, for how can a professional practice standard reflect patient autonomy?

Subsequent jurisprudential debate led to the ‘prudent patient’ test (ie was the information disclosure adequate to

satisfy a hypothetical body of patients?). This latter test creates separate difficulties: first, it does not necessarily satisfy the specific informational requirement of an individual patient and, second, its abstract nature provides little practical guidance to surgeons.

There is little dispute that the ideal moral standard is subjective: information should be ‘tailored’ according to the individual patient’s knowledge base, values and preferences. Professional regulatory bodies, such as the General Medical Council,⁵ endorse the subjective standard, and it can be argued that such guidance mandates the practice of a ‘reasonable’ surgeon.⁶ In reality, a subjective standard not only creates enormous practical challenges but also may expose surgeons unfairly to the hindsight of dissatisfied patients. Indeed, some eminent bioethicists agree that it imposes unfairly burdensome and unachievable requirements.⁷ Generally, the legal requirement is what is reasonable to expect and not what is morally commendable. The most appropriate legal test (or hybrid) for adequacy of disclosure continues to be a subject of considerable jurisprudential debate.

The ethicolegal disquiet about adequacy of disclosure is compounded by confusion about the scope of informed consent and its relationship with shared decision making (SDM).⁸ The authors of the widely respected Georgetown model of bioethics envisage that informed consent comprises five distinct elements: the surgeon *discloses* material information, *recommends* a plan, and facilitates *understanding* so that the patient can *decide* in favour of a plan and *authorise* the surgeon to undertake the chosen plan.⁹ Informed consent is mandatory for all surgical intervention in competent patients. Only those who lack capacity can be treated without consent and such circumstances are covered by special provisions. In distinction, SDM is important

mainly in situations of low medical certainty or absence of professional consensus, where a choice has to be made between two or more medically valid alternatives.¹⁰ On the other hand, in situations of high medical certainty, where there is only one, definite, best course of action, the surgeon–patient discussion may have an educational component but there is little scope for SDM. Nonetheless, informed consent remains vital and must involve adequate disclosure about the proposed operation. The patient may reject the recommendation and the surgeon is bound to respect (but cannot necessarily be expected to share) the patient's decision. Conceptually, the scope of informed consent hinges on risk: informed consent becomes more demanding with an increase in the risks of an intervention whereas SDM becomes more demanding with an increase in choice of available alternatives. Decision making aids can enhance SDM.¹¹ In contrast, standardised information (eg mass produced leaflets or complex forms) does little to increase the ethical or legal validity of the consent.

Tort law is weighted ostensibly in favour of the surgeon because, in order to succeed, the patient must prove not only that he or she sustained harm owing to the materialisation of a negligently undisclosed risk but also that he or she would have declined the intervention if the information disclosure had been adequate. The latter inquiry is almost invariably speculative and rests on adjudication of credibility. Established legal doctrine therefore clearly separates infringement of autonomy from actual causation of physical harm. While seemingly unfair, such demarcation is entirely coherent with the law of torts.⁴ Nevertheless, the dominance that professional ethics currently gives to autonomy, sometimes at the expense of other values, has intruded on the judiciary. In a notable decision (*Chester v Afshar*) that has generated much controversy, the House of Lords upheld a claim on the strength of violation of the right to self-determination.¹² Viewed from a historical vantage, such change in the perception of informed consent is not surprising and the evolution is likely to continue.

So far, the primary focus of litigation has been the non-disclosure of risks that have materialised subsequently. The failure to offer valid alternatives, where it is then

argued that this has resulted in a diminished likelihood of recovery or benefit (so called 'loss of chance' actions), has been litigated rarely and somewhat unsatisfactorily. With increasing public policy emphasis on patient choice and informed decision making, deprivation of the liberty to choose and loss of opportunity are imminently burgeoning legal contentions.

It is a common conception that the purpose of informed consent is to embed autonomy and that law is the protective vehicle. In reality, autonomy must contend with the competing ethics of non-maleficence (as distinct from beneficence) as well as distributive justice (notably, in publicly funded healthcare) and informed consent has to reconcile different imperatives.¹³ Having edged back from paternalism, it is now time for a renewed effort to construct a robust, practically workable model of informed consent.

References

1. Faden RR, Beauchamp TL. *A History and Theory of Informed Consent*. New York: Oxford University Press; 1986. pp116–117.
2. Faden RR, Beauchamp TL. *A History and Theory of Informed Consent*. New York: Oxford University Press; 1986. pp53–101.
3. Faden RR, Beauchamp TL. *A History and Theory of Informed Consent*. New York: Oxford University Press; 1986. pp125–129.
4. Jackson E. *Medical Law*. 2nd edn. Oxford: Oxford University Press; 2010. pp166–214.
5. General Medical Council. *Consent: Patients and Doctors Making Decisions Together*. London: GMC; 2008.
6. Fovargue S, Miola J. One step forward, two steps back? The GMC, the common law and 'informed' consent. *J Med Ethics* 2010; **36**: 494–497.
7. Manson NC, O'Neill O. *Rethinking Informed Consent in Bioethics*. Cambridge: Cambridge University Press; 2007. pp68–96.
8. Katz SJ, Hawley S. The value of sharing treatment decision making with patients: expecting too much? *JAMA* 2013; **310**: 1,559–1,560.
9. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 7th edn. Oxford: Oxford University Press; 2013. pp120–125.
10. Whitney SN, McGuire AL, McCullough LB. A typology of shared decision making, informed consent, and simple consent. *Ann Intern Med* 2004; **140**: 54–59.
11. An introduction to patient decision aids. *BMJ* 2013; **347**: f4147.
12. *Chester v Afshar* [2004] UKHL 41.
13. O'Neill O. Some limits of informed consent. *J Med Ethics* 2003; **29**: 4–7.