Consent: the law and ethical considerations

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Abstract

Morally, 'consent' allows an autonomous patient to determine what treatments he or she will accept or refuse. The law relating to medical consent protects such self-determination, and allows for treatment decisions to be made for patients who cannot decide for themselves. Consent is valid if it is given voluntarily by a competent patient and is based on the information provided to him or her. Information must be provided about what is to be done and why, and what the foreseeable risks and consequences of treatment are. Competent patients understand, remember and use the information provided to them to either consent to, or refuse, treatment. Patients without capacity are protected by the Mental Capacity Act 2005, which obliges medical treatment decisions made by third parties (doctors, defined proxies or the courts) to be both necessary and made in the patient's best interests, in the absence of a valid advance directive. Consent relating to children, pregnant women, the mentally ill, emergencies and teaching requires special consideration.

Keywords ethics; informed consent; legislation and jurisprudence; mental competency

The process of consent enables patients to indicate which treatments they are willing to accept from their anaesthetist.

Morally, this gives the autonomous, but vulnerable, patient a measure of protection from any perceived paternalism on the part of the anaesthetist. Society has continuously reinforced the importance of such protection through the development of common (judge-made) and statutory (government-made) laws relating to consent, such that an anaesthetist may be liable in battery or assault if (s)he administers a treatment to a patient without obtaining valid consent from the patient. Legal sanctions, including awards of damages and (in extreme cases) imprisonment, are used to ensure that patient autonomy is respected.

The text below is summarized in Table 1.

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Practical summary of the law relating to consent

- Consent should be obtained for any procedure which involves touching a patient or which carries a risk that might be significant to the patient
- Obtaining consent from a patient is not the same as having the patient sign a consent form
- Documentary evidence of consent provides important legal evidence, but not affirmation of valid consent
- The clinician providing treatment is responsible for obtaining consent from the patient
- Consent is legally valid if it is given voluntarily by an appropriately informed person, who has the requisite capacity to exercise an informed choice
- Competent patients understand and remember information given to them about the treatment, and use the information to decide whether or not to consent to treatment
- Information should be given about what treatment involves and why it is being given, in order to avoid committing a battery
- Information should be given about the risks and consequences of treatment, in order to defend actions in negligence
- A competent adult may refuse any and all treatment, even if it is life-saving
- Medical decision-making involving adults without capacity is now subject to regulation under the Mental Capacity Act 2005 (MCA)
- According to the MCA: adults (over the age of 16) are
 assumed to be competent, unless it is shown that they
 cannot understand, remember or use the information given
 to them; patients must be given a reasonable chance to
 demonstrate that they have capacity; the treatment of adults
 without capacity must be both necessary and in the patient's
 best interests
- According to the MCA: Lasting Powers of Attorney and courtappointed deputies can make treatment decisions in the best interests of an adult without capacity, but only Lasting Powers of Attorney can refuse life-saving treatment (if specifically authorized to do so by the patient)
- The MCA reaffirms the legal validity of advance decisions, provided they are made voluntarily by an appropriately informed adult, who specifies the circumstances under which the refusal of treatment should apply
- Under 16s may consent to treatment if they are deemed Gillick/Fraser competent. Refusals of treatment by anyone under 16 years old may be challenged in court
- Patients detained under certain sections of the Mental Health Act 1983 are not necessarily excluded from making medical treatment decisions

Table 1

Ethics

Patients and anaesthetists usually agree about proposed treatments. However, problems tend to occur when conflict arises, and patients reject anaesthetic advice about what is medically in their best interests (e.g. spinal anaesthesia for hip hemiarthroplasty in a patient with severe chest disease).

In these instances, proponents of patient autonomy – and indeed society as a whole – stress the prime importance of letting the autonomous patient decide, by asserting that only patients can really decide what is in their best interests overall, as opposed to merely being in their medical best interests.

It has been argued that all patients are never more than partially autonomous in a medical setting, as a result of their illness, treatment or dependency on treatment, and because they rely on the opinions of others when deciding about treatment. Furthermore, otherwise autonomous patients may waive their autonomy by asking the anaesthetist to decide for them, or by refusing to listen to any information about their treatment.

Some patients do not possess autonomy, because they do not have the capacity to think, decide and act on the basis of such thought, independently and without hindrance. Patients may be permanently or temporarily unconscious. Children, although capable of independent thought and deed, are not necessarily able to decide about treatment based on the information given to them. Patients with mental illness may transiently or permanently be unable to make a treatment decision. In these instances, a third party is called on to make a proxy decision about what treatment should be given (if any) in the patient's best interests. This process is necessarily paternalistic, but achieves the best outcome for the patient provided the decision-maker acts beneficently (i.e. optimizes patient benefit), non-maleficently (i.e. minimizes patient harm) and justly (i.e. authorizes treatment that they themselves would be happy to accept in similar circumstances).3

Law

The law relating to consent allows an individual to define and protect his or her own interests and to control bodily privacy. An anaesthetist may be liable in battery (usually a civil remedy but also a criminal charge in more serious cases) if (s)he administers treatment to a patient without his or her consent.

Obtaining a patient's consent is not the same as having the patient sign a consent form. A consent form does not prove that consent was obtained, although a written, countersigned document provides important evidence if consent is disputed in court.⁴ However, verbal or implied consent (e.g. when the patient holds out his or her arm for cannulation) can be equally valid.

Consent may be withdrawn at any point. Withdrawal of consent renders subsequent treatment unlawful.

Consent is valid if it is given **voluntarily** by an **appropriately informed** person, who has the requisite **capacity** to exercise an informed choice.

Consent must be voluntary

This may be affected by a wide range of perioperative influences, including family and religious considerations, the necessity and urgency of treatment, and the status of the patient with regards criminal or psychiatric detention.

In practice, this is rarely an issue in legal determinations of consent. The leading English case remains that of ReT, in which the Court of Appeal upheld the lower court's decision to allow the transfusion of blood to T, a critically ill Jehovah's Witness,

on the basis that the patient had been unduly persuaded by her mother to refuse transfusion on religious grounds.

The patient must be appropriately informed

The few studies that have assessed what information about their treatment patients would like to be given have been inconclusive, with some patients preferring simple descriptions of procedures and explanation about the main risks and benefits, and others requesting fuller or exhaustive information.

In order to defend an action in battery (defined for these purposes as the intentional touching, however slight, of another person without their consent), the anaesthetist has to be able to prove that (s)he supplied the patient with adequate information about both the **nature** and the **purpose** of the treatment given (i.e. what the treatment involves and why it is being recommended).

In order to succeed in a civil action in battery (which would actually be brought as a claim in clinical negligence), the patient has to prove that the anaesthetist failed to supply adequate information about the **risks** and **consequences** of the treatment given, and that the patient made the treatment decision based on that information.

Anaesthetists cannot withhold information about risk from patients for fear of scaring them into not having treatment, unless (very rarely) the court agrees that non-disclosure is appropriate, but it would be unreasonable to suggest that every single risk should be mentioned. A way to look at how much information should be given to the patient is to consider and discuss with the patient the significant risks of that procedure. The definition of 'significant risk' remains vague and can lead to considerable difficulties in quantifying risk, and consequently communicating risk to patients. Pragmatically, professional bodies suggest that a significant risk is one that occurs with a prevalence in excess of 1%. Another way to look at this is to consider minor but frequent risks (such as vomiting after general anaesthesia), rare but very serious risks (such as permanent nerve damage following spinal anaesthesia) or risks that might have particular relevance to the patient (e.g. vocal cord damage when intubating an opera singer).

The standard of care to apply when considering whether a patient has been properly warned of the anaesthetic risks of a procedure is whether a reasonable body of anaesthetists would warn the patient of that risk, and the decision not to mention a particular risk must be capable of withstanding logical analysis.

The patient must have capacity to consent or refuse treatment

The most significant recent change in the law relating to consent concerns whether a patient has the requisite capacity to make a valid treatment decision.

Previously, common law determined the legal position regarding capacity to consent, a doctor judging anyone over the age of 18 to have capacity if they could understand and remember the information given to them, and use it to make a decision about whether or not to have the treatment proposed. The decision made by the patient did not have to be sensible, rational or well considered. Capacity was a question of fact: either a patient had capacity (and could therefore consent to any treatment, or refuse any treatment even if refusal resulted in death) or the patient did

not have capacity, in which case treatment decisions were made by third parties provided that the treatment was necessary and in the patient's best interests.

The common law has been augmented by the Mental Capacity Act 2005 (MCA), in force since 1 October 2007, which aims to 'empower and protect people who cannot make decisions for themselves' by clarifying the law concerning decision-making by others on behalf of mentally incapacitated adults. In practice, the MCA is simply a statutory codification of the common law, with a few notable exceptions relating to proxy decision-makers, advance decisions ('living wills') and the conduct of research on adults without capacity.

The MCA is founded on five basic principles, which imply three broad concepts.7 First, adults (now anyone over the age of 16) must be assumed to be competent to make decisions about their treatment, unless they are obviously unable to make a decision when they are required to do so, such that they cannot understand, remember or use the information given to them. Second, patients must be given a reasonable chance to demonstrate that they have capacity, for example through the use of interpreters, non-verbal communication aids and possible deferment of treatment until a patient regains consciousness or sobriety. The MCA restates that competent patients can make unwise decisions. Finally, the treatment of adults without capacity must be both necessary and in the patient's best interests. It remains the responsibility of the treating doctor to decide what constitutes the patient's best interests, and the doctor must be prepared to defend that decision in court. 'Best interests' is more than just 'medical best interests', and reasonable steps have to be taken to find out from the patient's relatives and friends what the patient might have wanted in the circumstances that arise.

Three new actors are empowered by the MCA to assist decision-making on behalf of an adult without capacity. The donees of a Lasting Power of Attorney (LPA) are appointed by competent adult patients in the anticipation of a future loss of competence. LPAs must be registered at the Office of the Public Guardian, and can make treatment decisions on behalf of an adult patient when that patient lacks capacity, including end-of-life treatment withdrawal decisions if specifically authorized by the patient to do so. Any decision made must be in the patient's best interests.

Court-appointed deputies (CADs) are appointees of the Court of Protection who can make treatment decisions (but **not** end-of-life decisions) on behalf of an adult without capacity in the absence of a LPA, provided they do so in the patient's best interests.

Independent mental capacity advocates (IMCAs) are appointed by the Secretary of State for Health (effectively) to support an adult without either capacity or any representative, by informing decision-makers about the person's wishes, feelings, beliefs and values. IMCAs **cannot** make decisions themselves about medical treatment on behalf of an adult without capacity.

Advance decisions ('living wills')

The MCA affirms the common law with regard advance decisions, namely that they are legally valid if made voluntarily by an appropriately informed adult with capacity. An advance decision must specify which treatments are refused (patients may not demand treatments which doctors consider to be not in their best interests) and the circumstances in which refusal is intended. A LPA may

supersede an advance decision. The refusal of blood by an adult Jehovah's Witness should be treated as an advance decision.⁸

Children

Patients under the age of 16 fall outside the remit of the MCA, and consent issues are decided in common law. Under the Family Law Reform Act 1969, children under the age of 16 in England and Wales are assumed to lack capacity unless they can prove otherwise. A *Gillick (Fraser)* competent child is one under the age of 16 who can understand, remember and use the information provided to them to make a decision about treatment, the child's competence being a question of fact. When the consequences of a decision puts the child's life at risk, a very high level of understanding is required by the court, and the court may well overrule a child's otherwise valid refusal of potentially life-saving medical treatment.

Proxy consent may be provided for incompetent children by parents (usually), temporary carers, local authorities or the courts, provided the consent is given in the best interests of the child. Each parent can consent, but the courts may limit the power of one parent to refuse treatment that is in the best interests of the child if there is disagreement between parents, or overrule both parents' refusals if appropriate.

Mental illness and the Mental Health Act 2007

Mental illness may impair a patient's capacity to provide valid consent or refusal for an anaesthetic intervention. However, a person receiving treatment for mental illness should not be assumed to be incapable of providing valid consent for, or refusal of, treatment.

The Mental Health Act 1983, recently amended by the Mental Health Act 2007, deals with issues of consent and non-consensual treatment for those with a defined mental illness (among many other things). Generally, the consent of a patient is not required for any medical treatment for the mental disorder from which the patient is suffering. Importantly, a refusal of electroconvulsive therapy by a patient deemed to have capacity is now valid under the 2007 Act, excepting emergencies when, as is the case with emergencies in general (and additional procedures required during anaesthesia), treatment may be given if it is immediately necessary to save the patient's life or prevent a serious deterioration in his or her condition.

Pregnancy

Pregnant women are no less autonomous that non-pregnant women. The pain and distress of pregnancy **may** completely erode capacity, but doctors must be satisfied 'that such factors are operating to such a degree that the ability to decide is absent' before declaring that a labouring woman lacks capacity.

Birth plans should be treated as advanced directives. An advance directive may be overruled by the patient herself ('Give me an epidural!'), providing the anaesthetist considers that she is competent to make that decision (i.e. as described above, having given appropriate information about the risks and benefits of epidural anaesthesia under the circumstances arising).

Teaching

Medical students (or other trainees) should obtain consent from patients before examining them (including examinations performed under anaesthesia), explaining their identity as students rather than qualified medical professionals. Similarly, consent must be obtained prior to taking photographs or video recordings of the patient. Consent must also be obtained before retaining tissue for teaching purposes.

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FURTHER READING

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