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Surgical consent

History of consent

The history of consent is the history of the balance of power between the patient and the surgeon. According to Plato,\(^1\) the need for consent depended on the status of the patient, from a slave it was unnecessary, but when treating a free man there was a duty to discuss the nature and proposed treatment of the condition and obtain his permission to undertake the treatment. When treating Kings and Emperors the balance of power was shifted so far towards the patient that not only was consent obtained verbally but the patient had to physically put the scalpel into the hand of the surgeon to indicate his free will for the surgical intervention.\(^2\)
The power of surgeons relative to their patients was perhaps highest during the Victorian era. Prominent surgeons such as Cooper and Liston were famous, wealthy, and had few social equals. The very act of having sought the help of such an eminent man was felt to be sufficient to allow him to do whatever he felt fit. Surgeons were paternalistic and in theory sought to decide what was good for their patient. Any communication that did take place was directed towards reassuring patients of a good outcome.

With the onset of the twentieth century there was a gradual recognition that consent, which had long been established in English common law as a defence against a charge of battery, was needed for surgical practice. This was perhaps most famously enunciated by Justice Cardoza who said in 1914 that ‘every adult human being of adult years in 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 a battery for which he is liable in damages’. He did not however, stipulate that there was any responsibility on behalf of the surgeon to ensure that the patient was informed.

The Second World War brought profound changes in doctor’s relationships with patients and to the practice and understanding on consent. In Europe and its empires the old-fashioned class system, whereby the masses were content to be ruled by a small elite, was swept away bringing a majority Labour government in the United Kingdom and independence for colonies. The common man and woman were determined to have their say in how they were governed and also in how they were medically cared for. The horrors divulged during the German Doctors’ Trials broke the spell that doctors were by dint of their profession good, and opened the door to a climate in which it was acceptable to challenge a doctor’s thinking and advice. The requirements for consent in medical research were codified at Nuremberg and were followed by the rapid realization that patients were entitled to the same rights when considering involvement in treatment. America now led the way with a number of important cases defining the legal requirements of informed consent.

In Salgo vs Leland Stanford Jr University Board of Trustees 1957 the court of appeal in California was asked to consider the case of Martin Salgo who in 1954 had suffered paralysis following a translumber aortogram. They ruled that the procedure had not been negligently done but that the doctor had negligently failed to inform the patient of the risks of the procedure and therefore did not have valid consent. Justice Bray, borrowing the words of a submission by the American College of Surgeons, said ‘A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed
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treatment.’ Having produced such clarity, Bray immediately opened up another debate on how much information should be disclosed to a patient.

Here the American and English courts diverged. American courts adopted the standard laid out in Canterbury vs Spence 1972 that required a disclosure of information if a reasonable person in the patient’s position would be likely to attached significance to the risk. In Sidaway vs Bethlam Royal Hospital Governors 1985 English courts adopted the Bolam standard for informed consent which allowed a defence that a surgeon was not required to inform patients of rare complications if a reasonable body of similar surgeons would not do so. While the Law defined the minimum requirements of informed consent, medical bodies and health organizations in many countries were issuing guidance on informed consent which attempted to define ideal practice. In the UK the General Medical Council consent guidance ‘Consent, patients and doctors making decisions together’ came into effect in June 2008. The guidance provided increasingly suggested that surgeons needed to provide the information required by the patient to make a decision. In this respect the practice recommended for obtaining consent followed the American legal position rather than that of Sidaway. This change in practice and change in the relationship between surgeon and patient was recognized in the United Kingdom Supreme Court in 2015. In a landmark judgement, Lord Reed and Lord Kerr after referring to the GMC consent guidance said “The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.”

**Information giving**

Information giving or sharing is a two-way process of mutual education between surgeon and patient. A surgeon may have detailed knowledge of a patient’s condition and the potential treatments but may know nothing of what is important in a patient’s life. An individual patient may know much or little of their condition and possible treatments and may have a limited or profound understanding of complex issues such as risk and probability. The process, whereby a surgeon comes to an understanding of a patient’s needs and wishes and the patient develops a depth of understanding about their condition, begins at the time of referral and develops through the process of consultation. This process of mutual education may not necessarily be achieved in one consultation and the process of consent may be spread over a number of consultations. Other healthcare professionals and other sources of information such as patient leaflets and on line resources may contribute to the process.

The General Medical Council in its guidance to doctors in the UK has indicated that they have an overriding duty to give information to the patients about:

(a) The diagnosis and prognosis.
(b) Any uncertainties about the diagnosis or prognosis, including options for further investigations.
(c) Options for treating or managing the condition, including the option not to treat.
(d) The purpose of any proposed investigation or treatment and what it will involve.
(e) The potential benefits, risks and burdens, and the likelihood of success for each option; this should include information, if available, about whether the benefits or risks are affected by which organization or doctor is chosen to provide care.
(f) Whether a proposed investigation or treatment is part of a research programme or is an innovative treatment designed specifically for their benefit.
(g) The people who will be mainly responsible for and involved in their care, what their roles are, and to what extent students may be involved.
(h) Their right to refuse to take part in teaching or research.
(i) Their right to seek a second opinion.
(j) Any bills they will have to pay.
(k) Any conflicts of interest that you, or your organization, may have.
(l) Any treatments that you believe have greater potential benefit for the patient than those you or your organization can offer.7

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It is important that the information given to patients is individual to that patient. Any assessment of risk may be informed by a surgeon’s overall success rate for that procedure but must also take into account any additional risk stemming from the patient’s own individual characteristics and co-morbidities. It is important that a surgeon confirms that a patient has retained and understood the information given.
Level of risk discussed

The likelihood of a particular adverse event occurring as a result of an intervention may vary from certainty (i.e. a probability of one) to an infinitesimally small chance (i.e. a probability of 0.0000001 or less). For example, a patient undergoing a sapheno-femoral ligation, stripping of the long saphenous vein and multiple avulsions for extensive varicose veins will certainly experience some bruising but is most unlikely to suffer an arterial injury resulting in limb loss. A surgeon seeking consent from a patient would certainly explain about postoperative bruising but should he/she discuss the minute risk of an arterial injury? Prior to 2015 the legal position in the USA was slightly different from that in the UK. In the USA the standard adopted is that the surgeon should explain a risk that a reasonable patient would wish to consider however remote that risk may be. In the United Kingdom a surgeon was only required to explain risks that a reasonable surgeon would explain and it had been suggested that a risk of less than 1% need not be discussed.

Both positions have their problems particularly where patient’s understanding of the quantification of risk may be limited. In the USA there is a danger that a patient may be confronted with a long list of terrible possible complications such that the patient may decline to undergo a potentially life-saving procedure that they would otherwise have agreed to. In the UK there is a risk that a surgeon may not explain a rare complication to a patient that unbeknown to the surgeon is of crucial importance to the patient in deciding whether or not to undergo the treatment. In practice the legal positions define the minimum defensible standards and surgeons on both side of the Atlantic aim to apply best practice to provide patients with as much information as they need to develop sufficient understanding of the proposed treatment in order to make an informed decision. This includes exploring with patients the complications that are important to them and their understanding of risk.

It is important to recognize that individual patients may have very different thresholds for accepting particular complications; to one patient a colostomy may be a minor inconvenience whereas to another it may be completely unacceptable. It is also important to recognize that many patients find different levels of risk hard to understand. Some patients will understand risk in terms of numerical chance, whereas others will have a better understanding if risk is described in comparative terms such as the risk of travelling 100 miles in a car.

Capacity

If a patient is to give informed consent they must have ‘capacity’ to do so. ‘Capacity’ is the ability of a patient to reach a clear understanding of their condition, the proposed treatment, and the risks and side effects involved. They should also be able to make and communicate a decision as to whether they wish to consent or refuse the medical care proposed. If a patient is unable to reach this clear understanding or to make or
communicate a decision they may be said to lack ‘capacity’. ‘Capacity’ is therefore procedure specific and a patient may only be said to lack ‘capacity’ once every effort has been made to obtain informed consent. A patient cannot be said to lack ‘capacity’ simply because they make an unwise decision, nor can they be said to lack ‘capacity’ simply because they are detained for reason of their mental health. Surgeons must be prepared to spend the necessary time and to use all possible methods of communicating with patients to allow a patient to give informed consent.

When patients lack ‘capacity’

The management of patients who lack ‘capacity’ differs between jurisdictions. In England and Wales the Mental Capacity Act of 2005 includes provision for advanced directives to refuse treatment, lasting powers of attorney, and an independent mental capacity advocate service that has greatly simplified these issues. Importantly in the UK, although relatives of patients can expect to be consulted, they do not have the right to give consent on behalf of a patient who lacks ‘capacity’. In other jurisdictions such as Canada and some States in the USA, arrangements for patients without ‘capacity’ involve the use of a substitute decision maker with a hierarchy of legal substitutes and family members.

In considering surgery on patients who lack ‘capacity’ there are a number of generally agreed principles:

- Patients should be involved in the decision-making process as much as they are able. Where the patient’s prior views are known these should be respected.
- Where ‘capacity’ may return and a procedure is not urgent the procedure should be delayed until ‘capacity’ has returned.

Any intervention should be in the patient’s best interest. This is particularly important where a third party contributing to making a decision on behalf of a patient may have a vested interest in the decision. This may apply to a surgeon who may receive a fee for undertaking an operation or a relative who may stand to gain from an inheritance if the patient does not survive.

In all cases it is sensible to seek the opinion of both medical and other colleagues and it is useful to remember that going to court before the event is likely to be less traumatic than after the event.

Deprivation of Liberty safeguards, introduced into the Mental Capacity Act through the Mental Health Act 2007, additionally allow application to be made to detain a patient who lacks ‘capacity’ for the purpose of care or treatment.

Coercion
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For informed consent to be valid the patient must have made a decision free of outside pressure. Coercion in this context can manifest itself in many ways. The mildest form of coercion, encountered reasonably frequently, is by medical staff or family members who seek to coerce a patient into making a particular decision in the belief it is in the patient’s best interest. Coercion may be subtle but may have sinister motives. For example, a surgeon may seek to dissuade a high-risk patient from having an operation by giving an over bleak assessment of the likely outcome when the surgeon’s true motive is to avoid damage to his published outcome figures. Similarly, a family member may seek to persuade a patient with a chronic infected leg ulcer to undergo an amputation because the family member finds the smell offensive rather than because of any benefit to the patient. Financial coercion of patients remains a controversial subject. The crudest example has been the ‘cash for organs’ controversy where the sale of body parts for transplantation has been the subject of much media interest. In the UK and USA altruistic donation of organs between two strangers is legal but donation in return for payment is not. This area of law is, however, difficult to regulate and there is significant evidence that a ‘cash for organs’ trade goes on in some of the poorest communities in developing countries. The shortage of organs for donation and the evidence that a significant illegal underground trade in organs goes on has led some to question whether the sale of organs should be allowed. This has been considered by the medical ethics committee of the British Medical Association who remain opposed to the practice.11

Children

The issue of gaining consent for the treatment of children is complex and the law varies from country to country and sometimes between different states within the same country. In each case the child’s age and their capacity are of crucial importance. In general, very young children will not have the ‘capacity’ to make medical decisions whereas older teenagers will. However, there is no specific age at which ‘capacity’ can be assumed. As with adults ‘capacity’ is procedure specific. For example, a young child brought to the emergency department with an asthma attack who has previously had nebulizers may have ‘capacity’ to give consent to treatment with a nebulizer. However, the same child may not have sufficient understanding to give consent for complex invasive surgery. Where a child does not have ‘capacity’ to make a decision they should still be involved in the decision-making process as much as possible.

In England and Wales children aged 16 and 17 years would normally be expected to have ‘capacity’ and therefore the consent process is essentially identical to that in an adult. In these circumstances it would seem reasonable to encourage the child to seek the views of their parents but if the child is disinclined so to do then their confidentially should be respected unless there are specific circumstances in which disclosure
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should be made to protect the child from harm. Very occasionally the
courts have agreed to overrule a competent child’s decision not to
undergo treatment if the treatment has been considered to be in the
child’s best interest. Children aged 16 and 17 who lack ‘capacity’ to take
decision are treated differently from adults who lack ‘capacity’ in that a
parent or more strictly a person with parental responsibility can give
consent. The Children’s Act 1989[12] sets out who legally has parental
responsibility but in some respects the act does not fit in with modern
domestic arrangements that may include strong caring relationships
without the formality of marriage or, in the case of parents of the same
sex, civil partnership. In particular, fathers do not have an automatic legal
right to give consent for treatment of their children. Where there is
disagreement between parents or where parents refuse consent to
treatment that a surgeon considers to be in the child’s best interest then
it is sensible to involve the courts. The arrangements in Scotland for
children aged 16 and 17 years, who lack ‘capacity’ is different—parents
cannot give consent on their behalf but rather they are treated in the
same way as adults who lack ‘capacity’.

Whereas children of 16 years and older are presumed to have ‘capacity’,
those under 16 years are not. Nevertheless some children under 16 years
will have ‘capacity’ to consent to some procedures. This is sometimes
referred to as Gillick competence after the House of Lords ruling in the
case of Gillick versus West Norfolk and Wisbeck Area Health Authority
1985.[13] This ruling established that ‘the parental right to determine
whether or not their minor child below the age of sixteen will have
medical treatment terminates if and when the child achieves sufficient
understanding and intelligence to understand fully what is proposed.’
This ruling has been followed in Australia, Canada, and New Zealand. In
practice a surgeon consulted by a child under 16 years must first
establish whether the child is competent to give consent for the
procedure in question. If the child is found to be competent, the surgeon
should discuss with the child whether they wish a parent or other adult to
be involved in the decision-making process but if the child does not, their
confidentiality must be respected and the child be allowed to make the
decision on their own behalf.

If a child under 16 years does not have ‘capacity’ to give or refuse
consent then an adult with parental responsibilities should make the
decision on the child’s behalf.
Difficulties in obtaining consent for the treatment of children who lack ‘capacity’

In the vast majority of cases there is clear agreement between health professionals and parents as to the best treatment for the child. In these cases obtaining consent is straightforward. Difficulties can arise if there is disagreement between the parties or where one or other parent lacks ‘capacity’. Where parents disagree with a treatment plan that the surgeon feels is in the child’s best interest, for example where blood transfusion is considered in a child whose parents are Jehovah’s Witnesses, then it is sensible to seek a second opinion prior to proceeding to involvement of the courts. Occasionally there will be disagreement between parents particularly when parents are estranged. In these cases it is not a legal necessity to obtain the consent of both parents and treatment can be given, if it is in the child’s best interest, with the consent of one parent. However, where the child’s main carer is the parent objecting, then it is sensible to proceed with caution and perhaps involve the courts anyway. Occasionally one or other parent may not be able to give consent, either because they lack ‘capacity’ or because the parent is a child themselves. In these cases it is sensible to seek the views of other important carer’s of the child, for example grandparents.
Consent for procedures that are not therapeutically beneficial to the child (e.g. bone marrow harvest for donation to a sibling)

The concept of the patient’s best interest is fundamental to decision making in patients, including children, who do not have ‘capacity’. Where a child lacking in ‘capacity’ is volunteered as a bone marrow donor by parents who are primarily considering the interests of the recipient child, this concept is tested. It could perhaps be argued that preserving the life of the recipient child is in the best interest of the donor child, but this seems an artificial argument and it could be equally argued that in later life when it comes to dividing an inheritance one more sibling might be a disadvantage. An alternative argument is that we allow parents to make decisions that disadvantage one child in favour of another. Many little sisters freezing on the touchline while an older brother plays football will attest to this. The important issue then becomes the degree of harm done to the donor child. The current view is that bone marrow harvest is perhaps ‘no big deal’ and therefore permissible, but that a more invasive procedure such as kidney donation would not be.

Similar arguments are used when considering surgical procedures on children that are undertaken primarily because of parent’s cultural and religious beliefs. Male circumcision and female genital mutilation fall into this category. The World Health Organization estimates that between 100 million and 140 million women and girls have undergone female genital mutilation. Despite this there is widespread support for the view that it causes unacceptable harm and it is specifically prohibited in the United Kingdom, Sweden, and Belgium and prohibited under more general legislation in many other countries. Male circumcision is more difficult. It is an intrinsic part of two major religions, Islam and Judaism, and is undertaken on millions of young boys globally. In the vast majority of cases the harm done is limited and short lived, but in a small number of cases significant harm is done. Historically, law makers seeking to ban circumcision have largely been motivated by a desire to repress communities of the Jewish or Muslim faith rather than any primary concern for the child’s right. However, a body of medical opinion is opposed to circumcision on religious grounds. In 2012 this view was supported by a district court in Cologne, Germany, where a doctor was charged following complications in a 4-year-old boy on whom a circumcision had been performed for religious reasons. The court, while acquitting the doctor, ruled that circumcision that was not medically necessary was an assault and conflicted with the child’s right to subsequently decide on their religious beliefs. The case caused considerable concern among the Muslim and Jewish communities worldwide and attracted support from other religious leaders seeking to safeguard religious freedoms. The German government legislated to overturn the ruling in December 2012 and religious circumcision therefore remains legal in Germany. In other jurisdictions it remains common practice but untested in law.
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Emergency care

In the emergency situation the ability of a surgeon to obtain consent may be limited by the patient’s ‘capacity’ if the patient is seriously ill with significant impairment of consciousness, and may be limited by time if the patient’s best interest is served by immediate treatment. In the former case the matter is straightforward and should be dealt with as in any patient lacking ‘capacity’ excepting the fact that there is limited opportunity for a surgeon to consult others. The latter situation is more difficult. The patient may be fully conscious and have ‘capacity’ but the need for emergency intervention may limit the clinician’s ability to fully inform the patient and to be informed of the patient’s wishes. In this situation a pragmatic approach must be adopted using what time is available to explain the patient’s options as fully as the time permits while at the same time providing the immediate treatment needed to save life or prevent a serious deterioration in the patient’s condition. It is important to be aware that initial treatment of an individual may allow a situation to be stabilized and allow time for fully informed consent to definitive treatment.

Procedures requiring consent

Legally any touching of another human being, whether in a medical or non-medical context, requires consent. In normal life this consent is often implied and we accept a varying degree of contact from others depending on the situation. A rugby player accepts being tackled by his opposite number during the course of a game but would find it unacceptable elsewhere; a passenger entering a crowded train carriage accepts a greater degree of contact with fellow passengers than would otherwise be appropriate. Much of medical contact with patients takes place on the same basis. A doctor asking to take a patient’s blood pressure would regard the rolling up of a patient’s sleeve as implying consent. In all cases the onus rests on the doctor to ensure that the patient fully understands the implications of the procedure and gives their consent free from coercion. The same doctor who asked a patient to give a blood sample and accepted a rolled up sleeve and proffered antecubital fossa as consent, would be falling short of acceptable standards if he/she had not explained to the patient the nature of the test to be undertaken and its possible implication for the patient. On a pragmatic basis the greater the implications of the intervention the greater the care needed in obtaining and recording consent.
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Recording consent

Consent to measure a patient's blood pressure would not normally be recorded, and consent to undertake physiotherapy on a patient may be recorded in the patient's notes by the practitioner but not necessarily signed by a patient. Consent for all surgical procedures is always recorded on a specific consent form which documents the nature of the discussion had with the patient and to which the patient adds their signature as a record of their consent. The consent form is a record and, as with any record, it is only valid if it is a true reflection of the discussion and decision making that has taken place. Where patients lack 'capacity' to make the decision a specific consent form exists in which the doctor should record the decision-making process and also who has been consulted in making the decision about treatment.

Further reading


References


3. Schloendorff vs Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92 (1914).


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