Implications of consent for medical practice

In the health-care setting, consent is the process whereby permission is given for a health-care professional to provide care to a patient, with an agreement to maintain and respect the patient's autonomy. It is important, therefore, that patients are involved as much as possible when it comes to making decisions about their care so they can make their own choices. Not only does this form part of good medical practice, as laid out by the General Medical Council (2013), but proceeding with treatment without consent could be considered as common assault and battery (Schloendorff v Society of New York Hospital, 1914), or more likely lead to a claim of medical negligence (Bolam v Friern Hospital Management Committee, 1957).

UK law can be classified as either civil or criminal. The civil courts are designed to compensate people who have been caused loss or injury by the wrongful acts of other people. The criminal courts are designed to punish people who have committed a criminal offence. In civil law the burden of proof is on the balance of probabilities, whereas in criminal law the burden of proof is much stricter – 'beyond reasonable doubt' (Elliot and Quinn, 2016). Issues relating to consent are commonly part of civil law where damages are paid for loss or harm.

The legal basis of consent has evolved. This article looks at the main cases that have forged the law, what capacity is, and other current issues in consent.

What are the different types of consent?

Consent can be verbal, written or implied. While all these types of consent are valid, it is good practice and safer medicolegally to document the consent process as evidence that consent has been given (General Medical Council, 2008). Implied consent occurs through actions of the patient rather than direct communication, e.g. when a patient holds out his/her hand as the health-care professional approaches the patient with a cannula. Implied consent can be unreliable as actions can be misunderstood and, as with verbal consent, can be easily denied to have occurred.

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Landmark legal cases and the evolution of consent

Bolam v Friern Hospital Management Committee 1957

Bolam was a patient with a mental illness who claimed that a hip fracture sustained while undergoing electroconvulsive therapy was caused by negligence. At the time, there was divided opinion as to whether physical restraint or muscle relaxant drugs should be used during electroconvulsive therapy, and whether the patient should have been warned about the risk of sustaining a fracture during treatment.

The court held that 'a medical professional is not guilty of negligence if they have acted in accordance with a practice accepted as proper by a responsible body of medical opinion skilled in that particular art'. This came to be known as the 'Bolam test'.

Sidaway v Bethlem Royal Hospital Governors 1985

Mrs Sidaway underwent cervical spinal surgery for symptomatic relief of neck and arm pain. This operation carried a 1–2% risk of spinal cord damage, which she was not warned about by her surgeon. Unfortunately, she was left paralysed as a result of this procedure. The judge rejected Mrs Sidaway's claim of negligence after application of the Bolam test, in that a responsible body of medical opinion agreed that it was not necessary to warn the patient of every risk. However, this case did establish that 'a doctor has a duty to provide sufficient information for their patient to reach a balanced judgement'. This includes discussing how necessary a procedure is, any alternative treatment, and any 'common or serious consequences' of it.

Bolitho v City and Hackney Health Authority 1997

Bolitho was a 2-year-old boy admitted to hospital with respiratory failure as a result of croup. The paediatric registrar was contacted twice by the nurse, but was unable to attend, as she was busy in clinic. Bolitho suffered a cardiac arrest as a result of respiratory failure, and although he was initially revived, the child later suffered severe hypoxic brain damage and died.

Despite her admitted negligence in failing to attend Bolitho, the House of Lords held that the registrar had not breached her duty of care and that Bolitho's injury was not a result of her negligence. Had she attended, she would have been unlikely to intubate him, as he seemed reasonably well at that stage.

The judge stated that evidence must add up to 'logical analysis' and thus Bolam could be pushed aside if the clinical practice accepted by the 'responsible body of medical opinion' puts the patient 'unnecessarily at risk' and the court does not find the practice to be reasonable. 'The issue of reasonableness is for the court [to decide] and not the medical profession'.

Chester v Afshar 2004

Ms Chester underwent spinal surgery for symptomatic relief of a lumbar disc protrusion. Mr Afshar, the surgeon, failed to warn her of the 1–2% unavoidable potential risk that this surgery could worsen her symptoms, which is unfortunately what happened.

The judge found that although Mr Afshar had not been negligent in performing the operation, it was a breach of duty not to warn her of this risk. Ms Chester argued that had she been told about this risk, she

would not have chosen to have her operation on the planned date, but instead taken her time to consider other options and consult with her family. The judge found in favour of Ms Chester, saying that had she had the operation on a different day, it may have been successful.

This case highlights that a patient has the right to be informed of a significant 'small but well-established risk of a serious adverse outcome' after surgery.

Montgomery v Lanarkshire Health Board 2015

Mrs Montgomery gave birth to a boy in 1999. She had gestational diabetes, which carries a 9–10% risk of shoulder dystocia. The baby unfortunately had shoulder dystocia during labour, and he subsequently suffered cerebral palsy. The obstetrician had not warned her of this risk, nor had she discussed the alternative possibility of delivery by caesarean section.

Mrs Montgomery sought damages on behalf of her son, alleging negligence by the obstetrician. She claimed that had this risk been explained to her, she would have asked for a caesarean section instead. The obstetrician's policy was not to routinely warn diabetic women about shoulder dystocia as the risk is 'very small' and more women might then opt for a caesarean section, which she believed was 'not in maternal interest'.

The Supreme Court judge concluded that the doctor should have advised Mrs Montgomery of the risk. Doctors have a duty to ensure that a patient is aware of any 'material risks', that is, anything that the patient is likely to attach significance to, or that the doctor should reasonably be aware that the particular patient would be likely to attach significance to.

Whether a risk is material cannot be reduced to percentages. Instead, the significance of a risk must reflect a variety of factors such as its nature, the effect it would have on the patient's life were it to occur, the importance of the benefits sought to be achieved by having the treatment, and the alternatives available with their subsequent risks.

Unless a doctor thinks that risk disclosure may be seriously detrimental to the patient's health, the doctor may be found negligent if a patient suffers damage as a result of an undisclosed risk.

Capacity

'Mental capacity' is about being able to make your own decisions. The Mental Capacity Act 2005 and Adults with Incapacity (Scotland) Act 2000 provide the legal framework that protects and empowers individuals who may lack capacity to make decisions about their care. These acts fundamentally ensure patient autonomy, so even if a decision is considered unwise, it does not indicate lack of capacity. Patients with capacity have the absolute right to accept or refuse treatment, even if they are in a life-threatening condition.

Before concluding that someone lacks capacity for that specific decision in question, all measures possible should be taken to allow the patient to fulfil the four-stage assessment (*Table 1*). These include, but are not limited to, making sure the patient has received all relevant information and that regarding alternative treatment options, trying different forms of communication to portray these, and changing the environment the patient is in so that he/she feels more at ease. It may also be necessary to delay the decision until a time when the patient has improved and therefore is in a better state to understand the situation he/she is in. However, if despite these measures the patient cannot satisfy the conditions above, according to the Mental Capacity Act the patient is unable to make a decision about the specific issue in question and will therefore be treated as lacking capacity. The Mental Capacity Act can be applied to anyone aged 16 years or above.

Table 1. How to assess capacity

In 2005, the Mental Capacity Act set out a two-stage process to determine capacity:
1. The clinician has to determine whether there is 'existence of an impairment, or disturbance in the functioning of the mind or brain'. This may be the result of a medical condition, illness or other factors such as drug and alcohol use
2. Does this impairment or disturbance render the patient unable to make a specific decision should he/she need to? A patient is able to make a specific decision if he/she can: a. Understand the relevant information b. Retain that information c. Weigh it up as part of the decision-making process d. Communicate his/her decision

Who can give consent?

Adults

There is a presumption that an adult aged 18 years or over is competent and therefore can give consent or refuse treatment. According to the Mental Capacity Act 2005, no one else can make a decision on behalf of an adult who has capacity. Where undue influence is suspected, consent is invalid (Re T, 1992). This is different in Scotland, where the legal age of capacity is 16 years.

A 'lasting power of attorney' can be assigned by a competent patient in advance to make medical decisions for him/her, should the patient lose capacity in the future. Lasting power of attorneys came into law with the Mental Capacity Act 2005, and can cover health and personal welfare, and property and financial affairs.

Children

In law, a child is anyone under the age of 18 years. An adult with 'parental responsibility' can agree to treatment on behalf of a child up to the age of 18 years (*Table 2*).

Children under 16 years of age are presumed to lack capacity. However, the 'Gillick test' can be used to determine whether a person has legal capacity to consent, based on his/her level of maturity and intelligence to understand the nature and implications of the proposed treatment (Gillick v West Norfolk and Wisbech AHA, 1986; General Medical Council, 2008). While children aged 16 and 17 years are often presumed to be competent, and so can accept treatment, under the Family Law Reform Act 1967 refusal of life-saving treatment can be overruled despite Gillick competence.

Table 2. Who has parental responsibility?

All mothers automatically (throughout the UK)
Married fathers – if married to the mother when the child was born (in England, Wales, Northern Ireland) or at conception (in Scotland)
Unmarried fathers – with court orders or a 'parental responsibility agreement'
People looking after a child, authorized by someone with parental responsibility to take medical decisions on their behalf
By court order, i.e. residence and parental responsibility orders
From Children Act 2004

Waiving consent

Some patients may waive consent or not want to know details about the proposed treatment. Where possible, basic information should be given about what the treatment involves and what it aims to achieve. While it is important to respect the patient's wish not to know, doctors should provide ongoing opportunities for the patient to further explore any concerns as the patient's wishes may change with time. It is good practice to document this clearly in the patient's notes (General Medical Council, 2008).

In rare circumstances, omitting details surrounding consent may be justified if a health-care professional believes that full disclosure would cause serious harm to the patient's health. It is not acceptable, however, to omit information for fear of the patient becoming upset or that he/she might refuse treatment altogether (General Medical Council, 2008).

'Best interests' decisions

Where an adult lacks capacity or an emergency situation arises and the patient is incapacitated and unable to give consent, a doctor can act in his/her 'best interests' and consent for him/her to undergo treatment (Department of Health, 2007). A doctor cannot override a competent adult's decision on the basis of best interests. This decision should be one based upon objective criteria, as described in the Mental Capacity Act 2005, rather than an opinion formed from personal views.

While the Mental Capacity Act does not define 'best interests' clearly, there are factors to consider when trying to make a decision on behalf of someone else (*Table 3*).

Where appropriate, it may also be necessary to consult others to help in the best interests decision. These include close friends or family, anyone previously named by the patient to be consulted, and, under the Mental Capacity Act 2005, any deputy or lasting power of attorney appointed by the court.

Table 3. Factors to consider when making a 'best interest' decision

Considering all the relevant circumstances relating to the decision in question
Not discriminating against age or appearance of a patient
Encouraging the patient to participate in the decision-making process as much as practically possible
Taking into account the patient's past and present wishes and feelings, particularly written statements
Considering the patient's beliefs and values
If the decision involves withdrawal of life-sustaining treatment the decision-maker must not be motivated by the desire to bring about the patient's death

Table 4. When can confidentiality be breached?

When the patient gives consent to do so
Sharing relevant information with other health-care agencies to assist in the management of that patient, e.g. social services
If the patient has a notifiable communicable disease, e.g. tuberculosis, meningitis
Reporting gunshot and knife wounds
If there is a risk of serious harm to others (W v Egdell, 1989)
Disclosure to the Driver and Vehicle Licensing Agency
Reporting on adverse drug reactions
Disclosing information required by law (e.g. Data Protection Act 1998, section 251 of the NHS Act 2006, in the investigation of fraud by the NHS Counter Fraud Service, The Abortion Act 1967)
Disclosing information to tax inspectors for doctors in private practice. (Every effort should be made to anonymise and separate medical information from financial)
To enable medical research and education for the wider benefit of society, e.g. in the production of databases for cancer registries (General Medical Council, 2009)

What is an 'advance directive'?

An 'advance directive' is a legal document, as described in the Mental Capacity Act 2005, that allows a patient with capacity to express how he/she would like to be treated in a specific situation should he/she lack capacity at that time in the future. Patients are only able to refuse treatment and cannot demand a specific treatment or other form of care. Equally, patients cannot create an advance directive for life-sustaining treatment. Refusal of treatment does not prevent the provision of 'basic care and comfort'. A valid advance directive will override best interests decisions, but not a decision made by a lasting power of attorney if he/she was appointed by the patient after the advance directive was drawn up (Mental Capacity Act 2005).

Breaching confidentiality

There are situations in which valid consent may be overridden and confidentiality breached. This is often for the patient's or public's best interests. *Table 4* lists common circumstances when this might occur.

Consent for research

When seeking consent from a patient for research, the same legal principles apply. However, it is particularly important to explain how the proposed treatment may differ from conventional methods and any potential risks or uncertainties. The patient should have the right to withdraw from the research without prejudice or discrimination as a result of his/her decision (General Medical Council, 2008; Department of Health, 2009). Clinical trials are covered by the Medicines for Human Use (Clinical Trial) Regulations 2004.

The Human Tissue Act 2004 regulates the removal, storage and use of human tissue. This includes safeguards regarding the use of organs from the dead and sets out whose consent is needed in which circumstances. 'DNA theft' is also included in this act, making it illegal to have human tissue with the intention to analyse its DNA without the consent of the person from whom the sample came.

Conclusions

In light of recent legal cases, there is a greater focus on patient autonomy and informed consent is an established part of the law in England and Wales (Montgomery v Lanarkshire Health Board, 2015). Clinicians

must tell patients what the patient thinks he/she should know (informed consent), and not what the clinician thinks the patient should know ('consent') (Bolam v Friern Hospital Management Committee, 1957).

There is increased uncertainty for 'the defence' as the court has made it easier for claimants to establish liability. Factual evidence is becoming more important because it is likely that clinicians will need information to challenge whether or not a patient would consider a risk material. There is less sway by expert witnesses and the opinion of like-minded medical bodies to justify the actions of clinicians, as their role has been shifted more to assist in deciding what the court deems to be a reasonable course of action.

Doctors must ensure that patients understand the severity of their condition, anticipated benefits and accompanying risks of any proposed treatment and that they are aware of any alternatives. Discussions must be clear and understandable. Ultimately clinicians must engage in greater dialogue with patients so that doctors can try to identify what the patient deems 'material'. Only then can the clinician be sure that the patient is able to make an appropriate informed decision. **BJHM**

Conflict of interest: none.

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Re T (adult refusal of medical treatment) (1992) 4 All ER 649
Schloendorff v Society of New York Hospital (1914) 105NE 92
Sidaway v Bethlem Royal Hospital Governors (1985) AC 871
W v Egdell (1989) EWCA Civ 13

KEY POINTS

- 'Informed consent' is about respect for patient autonomy – telling the patient what the patient thinks he/she should know, not what the clinician thinks the patient should know.
- All adults are presumed to have capacity to accept or refuse treatment, unless proven otherwise.
- An unwise decision does not necessarily mean that the patient lacks capacity.
- The Mental Capacity Act 2005 was enacted to empower patient autonomy and protect those who lack capacity.
- A lasting power of attorney can be assigned by a patient in advance to make medical decisions for him/her, should the patient lose capacity in the future.
- An advance directive allows a patient with capacity to express how he/she would like to be treated in a specific situation should he/she lack capacity at that time in the future.
- Where an emergency situation arises and the patient is unable to give consent, a doctor must act in the patient's 'best interests' and consent for the treatment.
- Best interests does not allow a doctor to override a competent adult's decision.