















































*“A man or woman of full age and sound understanding may choose to reject medical advice and medical or surgical treatment either partially or in its entirety. A decision to refuse medical treatment by a patient capable of making the decision does not have to be sensible, rational or even well-considered.”*

The ethical principle underpinning the law is personal autonomy, which includes the right to choose what is to happen to one's own body. The law also reflects human rights standards, expressed in Articles 2, 3 and 8 of the European Convention on Human Rights.

The **Reference Guide to Consent** states:

*“If an adult with capacity makes a voluntary and appropriately informed decision to refuse treatment (whether contemporaneously or in advance), that decision must be respected, except in certain circumstances defined by the Mental Health Act 1983. This is the case even where this may result in the death of the person (and in the death of an unborn child, whatever the stage of the pregnancy).”*

Those responsible for the care of the patient have no duty to ask about the reasons for refusing treatment. In *R v Newcastle Primary Care Trust* [2003] <sup>[21]</sup>, a haemophiliac refused treatment with plasma derived from recombinant Factor VIII. He argued later that the Trust should have sought further information from him about the reasons for his refusal. It was held that the Trust had a duty to act fairly, but this did not require it to seek further information about the patient's reasons for refusing a particular treatment.

The total or partial refusal of treatment should be recorded, and there is space on the Department of Health's standard consent forms for this. Refusal of any additional treatment that may become necessary should also be recorded.

## **OBSTETRICS**

Refusal of treatment can pose real dilemmas in obstetrics, when a woman refuses a caesarean section operation even though that refusal is likely to result in the death of the foetus, and/or her own death. Much depends upon whether the mother had the capacity to consent or refuse the treatment. Although the Mental Capacity Act now applies, the earlier common law is reflected in it, and it is worth looking at some of the earlier cases by way of illustration.

The Court of Appeal issued detailed guidance in the case of *Re MB* [1997] <sup>[22]</sup>. In this case, MB needed to have a caesarean section, but she panicked and withdrew consent at the last moment because of her needle phobia. The hospital obtained a declaration from the court that it would be lawful to carry out the procedure. MB appealed, but agreed later to induction of anaesthesia and her baby was born by caesarean section.

The Court of Appeal upheld the judges' view that MB had not had capacity to refuse treatment, taking the view that her fear and panic had impaired her capacity to take in the information she was given

about her condition and the proposed treatment. In assessing the case the judges reaffirmed the test of capacity:

- An individual's capacity to make particular decisions may fluctuate or be temporarily affected by factors such as pain, fear, confusion or the effects of medication.
- Assessment of capacity must be time and decision-specific.

Another example of a case involving refusal of treatment is *St George's Healthcare NHS Trust v S* [1998] <sup>1231</sup>. In this case, S had pre-eclampsia, and needed to be admitted to hospital for induction of labour, but she refused treatment because she did not agree with medical intervention in pregnancy. Although she had capacity and was not suffering from a serious mental illness, S was detained for assessment under the Mental Health Act. A judge made a declaration overriding the need for her consent to treatment, and her baby was delivered by caesarean section. The Court of Appeal held that S's autonomy had been violated, as her detention had been unlawful and that the authority for the caesarean had been based on false and incomplete information. The Court restated the rules:

- A pregnant woman with capacity can refuse treatment even if that refusal may result in harm to her or her unborn child.
- Patients cannot lawfully be detained and compulsorily treated for a physical condition under the terms of the Mental Health Act.

## ADVANCE DECISIONS

The Mental Capacity Act 2005 makes provision for people to make statements in advance of losing capacity. Such statements must be made when the patient has the required capacity to make decisions about future treatment. People also have the power to appoint deputies to make decisions for them.

An advance decision is legally binding, and must be followed by doctors and other healthcare professionals, as long as it meets certain criteria:

- It must have been made by a person aged 18 or over, who had capacity to make it.
- It must be in writing and witnessed if it applies to 'life-sustaining treatment' (treatment which is necessary to sustain life in the view of a person providing care).

If they are 'valid and applicable', advance decisions have the same effect as if made by that same person with capacity, and remember that a patient with capacity has the right to refuse even life-sustaining treatment.

In *Re XB* [2012] <sup>1241</sup>, a patient suffered from motor neurone disease, and was being cared for at home. He had a tracheotomy and a PEG tube, which meant that he was less likely than other MND patients to

die from aspiration or other respiratory complications. At a point when XB was still able to communicate by way of eye movements, he made an advance decision stating that ventilation and artificial feeding should be stopped when he lost mental capacity. The advance decision complied with the MCA, and it made a provision for a review on 2<sup>nd</sup> May 2012. A box headed ‘valid until’ was completed with this date. This raised the possibility that it was intended to be regarded as a time-limited decision. XB subsequently lost all ability to communicate, and thus became incapacitated. Experts stated that his incapacity was permanent.

XB’s GP and the Mental Health Service co-ordinator had witnessed the making of the advance decision and were sure that he had not changed his mind. The review, they said, was their idea, and they were certain that XB himself did not intend the decision to lapse on 2<sup>nd</sup> May. The judge held that the decision was valid and applicable, and that the references to 2<sup>nd</sup> May did not form part of it.

The judge made two important practical points. First, if there is a dispute about an advance decision, all relevant matters should be investigated as soon as possible to avoid last-minute recourse to the court. Secondly, the documentation used to record advance decisions is very important. Organisations that provide pro-forma advance decisions are encouraged to review these.

No one can ever demand a particular treatment in an advance decision; they can only specify the types of treatments they do *not* want to receive. If a doctor considers further treatment would be futile, he is not required by law to carry out every possible procedure to keep a patient alive. In *Burke v GMC* [2005] <sup>[25]</sup> the Court of Appeal ruled that doctors are under no legal obligation to agree to a patient’s request for treatment if they consider the treatment is not in the patient’s best interests.

## DECISION MAKING AND THIRD PARTIES

The MCA introduced some new ways in which third parties may be involved in decision-making, either as proxy decision makers or as advocates. These are:

- Independent Mental Capacity Advocates.
- Lasting Powers of Attorney.
- Court-Appointed Deputies.

## INDEPENDENT MENTAL CAPACITY ADVOCATES

The MCA creates a system of Independent Mental Capacity Advocates (IMCAs), to represent and support people who lack capacity where ‘serious medical treatment’ is proposed. Examples could include where a NHS organisation proposes to place a person in a hospital or care home for longer than 28 days, or where it is intended that the person will be deprived of liberty under Schedules A1 and 1A of the Act.



IMCAs are not decision makers – they are advocates who represent the views and interests of the patient. The Secretary of State for Health and the Welsh Ministers have duties to make arrangements for the provision of IMCA services. IMCAs are given the power to interview patients in private, and to examine relevant records. Detailed guidance and training is available for people who are appointed to act as IMCAs.

The duty to provide an IMCA arises where the organisation proposing the action in question:

*“...is satisfied that there is no other person, other than one engaged in providing care or treatment for a patient in a professional capacity or for remuneration, whom it would be appropriate to consult.”*

The functions of the IMCA are to speak for the patient in relation to the decision in question, and are set out in s36 of the 2005 Act, as follows:

1. Providing support to the person they have been instructed to represent.
2. Obtaining and evaluating relevant information.
3. Ascertaining what the patient’s wishes and feelings would likely to be.
4. Ascertaining what alternative courses of action are available in relation to the patient.
5. Obtaining further medical opinion where treatment is proposed and the advocate thinks that one should be provided.

## **LASTING POWERS OF ATTORNEY**

A Lasting Power of Attorney (LPA) is a document that a person with capacity (the donor) can make, giving power to another person, (the attorney) to make decisions on their behalf. There are two types – the property and affairs LPA, and the personal welfare LPA. Personal welfare LPAs cover issues such as medical treatment, social care and where the person might live. The LPA is made using a form which contains a certificate. This must be signed by an independent person to confirm that the donor fully understands what is involved, and what having an LPA will mean for the donor. The person signing the certificate is also confirming that no fraud or undue pressure has been used to make the donor create the LPA.

## **COURT-APPOINTED DEPUTIES**

In the event of a dispute or other difficulty, section 15 of the MCA gives the Court of Protection certain powers. These include the power to make declarations about whether a person has, or does not, have capacity to make a particular decision, and whether a proposed act is lawful or not. Section 16 gives the Court power to appoint deputies (called Court Appointed Deputies) to make decisions on a person’s personal welfare, property and affairs. These powers extend to:

- Decisions on where the person is to live.
- Decisions on what contact he or she is to have with specified persons.
- Giving or refusing consent to medical treatment.
- Directing a change of person with responsibility for the person's healthcare.

It is not always practicable for the court to make a single decision. Over time, it may be necessary for further decisions to be made, so most deputies are likely to be family members of the person lacking capacity, though a spouse has no legal right to be appointed as deputy. If decisions about care needs are complex, the court may appoint a deputy who is independent of the family. In any event, the court will decide the extent of the powers to be given to each deputy. The court can also change the powers of the deputy and remove the deputy.

## CONSENT IN SPECIFIC AREAS OF CLINICAL PRACTISE

Whilst the principles detailed above apply to all areas of clinical practise, there are specific aspects to consider in the field of organ donation and transplantation, anaesthetics and research. These specifics are outlined below with reference to more detailed information for those readers who wish to know more in these areas.

## CONSENT IN ORGAN DONATION AND TRANSPLANTATION

The majority of transplants are from deceased donors, but nearly 40% of kidney and 5% of liver transplants are from living donors. There are distinct consent requirements for all types of donors and recipients.

### LEGAL FRAMEWORK

Legislation on the removal, storage and use of organs from the deceased and the storage and use from the living patient is covered by the Human Tissue Act 2004 <sup>1261</sup> in England, Wales and Northern Ireland, and the Human Tissue (Scotland) Act 2006 <sup>1271</sup> in Scotland. The issue of consent (known as ‘authorisation’ in Scotland) runs throughout this legislation. The removal of organs from the living is also covered under common law and the MCA where appropriate.

### DECEASED DONATION

The Human Tissue Act states that, where an adult makes a decision to consent (or not consent) to organ donation taking place after their death, then that consent is sufficient for the activity to be lawful. The wishes of the deceased in life therefore take precedence, so that, for example, being on the Organ Donor Register is considered as consent. The Human Tissue Authority Code of Practice 2 states in section 99:

*“Once it is known that the deceased person consented to donation, the matter should be discussed sensitively with those close to the deceased. They should be encouraged to recognise the wishes of the deceased and it should be made clear, if necessary, that they do not have the legal right to veto or overrule their wishes. There may nevertheless be cases in which donation is considered inappropriate and each case should be assessed individually.” <sup>1281</sup>*

If the deceased person’s wishes are not known, then views should be sought from a nominated representative or a person in qualifying relationship as specified in the Act.

The UK Organ Donor Register is an ‘opt-in’ system, but Wales are currently developing legislation to introduce an ‘opt-out’ option. Under this system, consent to the removal and use of organs and tissues for transplantation would be deemed as having been given unless the deceased objected during their lifetime, and where the next of kin will be involved in the decision making process. This has generated some controversy, and there are strong views on both sides.

## LIVING DONATION

Living donations involve the donor having major surgery that is of no direct benefit to them. Therefore, it is important that these patients have a thorough physical and psychological evaluation and that, as part of the consent process, they understand the risks involved. As with all forms of consent, it is also important that there is no evidence of duress, coercion or reward.

The Human Tissue Authority (HTA), under the Human Tissue Act, regulates all living donation in the UK, and all donors must be seen by an independent assessor who submits a report to the HTA. Before approving the case, the HTA must be satisfied that consent for removal has been given, that consent is lawful (voluntary, informed and with capacity) and that there is no evidence of reward.

## TRANSPLANTATION

The risks involved in transplantation are complex, and must be explained to patients. NHS Blood & Transplant and the British Transplantation Society have produced guidelines <sup>(29)</sup> that deal specifically with all the complexities that arise within transplantation, and make recommendations on best practice. They also provide guidance on effective ways to convey risk.

In summary, the overall risks and benefits should be discussed and the consent process started prior to the patient going onto the national transplant list. If there are particular organ types or characteristics that the patient does not wish to receive, then the patient should specify this. It is recommended practice to confirm a patient's consent annually, as well as when admitted for the transplant. A further discussion may be required when a deceased organ becomes available, if there are specific risk factors that need to be discussed.

## CONSENT FOR ANAESTHESIA

The same ethical principles and legal framework apply to consent for anaesthesia and analgesia as for any other medical treatment. However, patients do not present themselves to have an anaesthetic *per se* – the anaesthetic is provided to facilitate surgery, procedures or investigations. Consent for anaesthetic procedures is, therefore, always taken in the context of the proposed procedure. The risks and benefits of particular anaesthetic techniques are framed by the surgical context. In common situations, where surgical, anaesthetic and patient factors all fall within ‘normal’ practice and experience, this is unlikely to pose particular issues for the surgical/anaesthetic team. There will, however, be situations where these factors necessitate greater discussion between team members. For instance, cosmetic surgery in a patient with significant cardio-respiratory disease may be surgically straightforward, but carry significant risk to the patient during and after anaesthesia and surgery.

## INFORMATION FOR CONSENT FOR ANAESTHESIA

A general principle for the anaesthetist is suggested by the AAGBI guidance:

*“What would this patient regard as relevant when coming to a decision about which, if any, of the available options to accept?”* [30]

In practice, this means providing information about the common complications associated with anaesthesia and surgery, such as pain, nausea and vomiting, and sore throats after general anaesthesia. For procedures where there is a reasonable choice between techniques, such as general versus regional anaesthesia, or morphine-based versus epidural-based post-operative analgesia, the anaesthetist should provide adequate information about the risks and benefits of the alternatives.

Often, the anaesthetist and/or surgeon will have a preferred technique. It is quite reasonable to suggest this to the patient. However, it is not appropriate to put undue pressure on a patient to accept one technique over another, however much the anaesthetist may feel it might benefit the patient. Information about a proposed technique should not be withheld purely because the anaesthetist or surgeon feels it might put off a patient.

The risks associated with neuraxial (spinal and epidural) anaesthesia are better understood following the Royal College of Anaesthetists National Audit Projects [31], and estimates of risk are widely available. It is a relatively frequent cause of complaint from patients who experience problems in the post-operative period that they feel they were given insufficient information about neuraxial anaesthesia and analgesia before their surgery.

Where patients may be at particular risk from anaesthesia and surgery (such as patients with significant co-morbidity), the anaesthetist should discuss this directly with the patient as it may influence their decision about whether to have the proposed surgery. Similarly, there may be specific personal circumstances which necessitate detailed discussion of particular risks (such as nerve injury in patients whose jobs are dependent on fine motor skills).

As with consent for surgery, consent for anaesthesia is not a single event, but involves all the interactions that the patient has with the healthcare team. The information given by the surgeon and pre-operative clinic staff may be given extensive consideration by the patient even before they see the anaesthetist. It is important that, as far as possible, the patient is given consistent information by all members of the team. Written information is an important component of this, and provides more detail than can usually be given during the anaesthetic pre-operative assessment.

### **‘COMPARTMENTALISATION’ OF CONSENT**

Occasionally, patients may wish to consent to only some aspects of the proposed anaesthetic technique - so called ‘compartmentalisation’ of consent. For example, a patient may consent to general anaesthesia, but refuse a central venous catheter. In practice, this is uncommon, and can usually be resolved through discussion. If it cannot be resolved, anaesthetists are under no obligation to provide what they consider to be unsafe care, and are entitled to refuse to provide anaesthesia under such restrictions.

The most common example of this relates to Jehovah’s Witnesses who have valid advance directives refusing administration of blood. In an elective situation, the anaesthetist may choose to refer such patients to colleagues who are content to practice within this restriction. In an emergency, the anaesthetist must provide care in the best interests of the patient whilst complying with the advance directive.

### **TIMING OF ANAESTHETIC CONSENT**

With day of surgery admissions becoming the norm, it is important that patients are given appropriate information beforehand. Otherwise, the anaesthetist will be providing patients with information and choices with only a very limited time for the patient to consider their options.

### **DOCUMENTATION OF ANAESTHETIC CONSENT**

At present, in accordance with guidance from the Association of Anaesthetists of Great Britain and Ireland (AAGBI), anaesthetists do not take formal written consent for anaesthesia. This does not, in any way, obviate the need for the anaesthetist to discuss the risks, benefits and alternatives of the proposed anaesthetic technique. Operative and anaesthetic records should all have space for the anaesthetist to document this discussion. Simply ticking the box on the NHS consent form for general anaesthesia, local anaesthesia or sedation is not an adequate demonstration of consent for anaesthesia. The NHS Consent form has an explicit statement by the patient:

*“I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this.”*

There is, therefore, an obligation on individual surgical teams, and on organisations, to provide adequate time and resources for the anaesthetist to discuss anaesthetic issues with patients.

## INFORMED CONSENT FOR RESEARCH

Informed consent for research follows the same principles outlined in the rest of this document. However, there are more stringent rules in terms of the provision of information and the need for written consent, as well as whether research on patients without capacity is allowable.

The **International Conference on Harmonisation - Good Clinical Practice Guidelines** provides guidance on consent for trials:

*“Freely given informed consent should be obtained from every subject prior to clinical trial participation.”*

The guidelines continue:

*“A subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.”*

In the area of research, different consent rules apply to different types of trials; for example where the trial is a CTIMP (Clinical Trial of Investigative Medicinal Product).

In the UK, research that is carried out on human subjects must have approval from the National Research Ethics Service (NRES) and local Research and Development approval - this combined application process is known as Integrated Research Application System (IRAS). One of the fundamental responsibilities of the ethics committees within IRAS is to ensure that the consent process has been carried out to the highest standard. This will include a high level of information made available to the patient.

## FULL DISCLOSURE OF INFORMATION

The need to provide full information is especially important with the implementation of the Data Protection Act 1998 and the Freedom of Information Act 2000, which allows patients access to information about research trials in which they are involved (subject to some exceptions). The GMC, in their recently updated **Consent to Research** guidance states:

*“The information people will need to decide whether to take part in research will be included in the participant information sheet. The National Research Ethics Service (NRES) gives advice on the design of information sheets and consent forms, and the key points they should cover. You should follow that advice if you are developing information sheets or consent forms”.*

Information for participants should include:

- The purpose of the study.
- Why the participant has been chosen.
- The voluntary nature of participation and that participants may withdraw from the trial at any time without penalty or loss of benefits to which they were otherwise entitled.
- The trial procedures to be followed, including all invasive procedures.
- Those aspects of the trial which are experimental.
- Important potential benefits and risks.

## RESEARCH IN PATIENTS WHO LACK CAPACITY

With regard to research on children, a parent, or someone else with parental responsibility for a minor who does not have Gillick-competence, can give consent for the child to participate in therapeutic research that is of *direct benefit* to the child. If the benefit is *indirect*, perhaps to benefit another family member, parental consent will be valid as long as it is given in full knowledge of the possible risks and benefits. Guidelines have been issued by the Royal College of Paediatrics and Child Health to help ethics committees when considering research on child subjects. The guidance explains the need to obtain the agreement of the child, even if they are not Gillick-competent and cannot understand fully all that is explained.

Parents should consider the risks and benefits for the child of participating in the research, in the same way as they would when consenting to established treatment. If the research carries only small risks, parental consent may be valid even if the research is not likely to benefit the child directly. These matters have not yet been settled by the courts, and it is not possible to describe any rules with certainty. Health professionals should be very cautious about engaging in research that is not of direct benefit to a child, unless the risks are very small and are fully explained to those with parental responsibility. The question is whether the parents have acted reasonably in giving consent and have consented in full knowledge after appropriate reflection.

The Department of Health's official advice on this matter should be supplemented by the EC Directive on Clinical Trials, which states that:

- Where children are involved in trials, there must be a real need to use children rather than adults as subjects.
- Informed consent should be sought from the child's (under 16 years) parents.
- Health professionals who are experienced in dealing with children should give the child information about the trial and its potential risks and benefits, according to the child's capacity.
- An explicit refusal by a child should not be overridden without full consideration by the investigator.
- Trials should be designed in such a way as to minimise pain, discomfort, fear and foreseeable risks.

The European Convention on the Rights of the Child and the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects (2000) states:

*"For a research subject who is legally incompetent, physically or mentally incapable of giving consent, or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorised representative in accordance with the applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons."*



## SUMMARY

Informed consent is central to any medical or surgical intervention on a patient. All clinicians should be familiar with the principles and practice of informed consent as described in this document.

Consultants have a responsibility to ensure that their trainees are adequately trained and that there is documentation of this training.

Best practice in informed consent will protect clinicians from being reported to the GMC and possibly from litigation.

Association of Surgeons of Great Britain and Ireland

*ISSUES IN PROFESSIONAL PRACTICE*

Informed Consent

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EIDO Healthcare produces high quality endorsed patient information leaflets and medico-legal e-learning resources to help health professionals reduce their risk of litigation.

The information contained in this booklet is an abridged version of *be INFORMED*, EIDO's online consent training tool, which has been approved for 12 CPD points.

To find out how EIDO can support your consent needs, use the following contact details:

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