ISSUES IN PROFESSIONAL PRACTICE

INFORMED CONSENT

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IN PARTNERSHIP WITH

EIDO
Experts in informed consent
FOREWORD

**Issues in Professional Practice** (IIPP) is an occasional series of booklets published by the Association of Surgeons of Great Britain and Ireland to offer guidance on a wide range of areas which impact on the daily professional lives of surgeons. Some topics focus on clinical issues, some cover management and service delivery, whilst others feature broader aspects of surgical working life such as education, leadership and the law.

Informed Consent is a vital component of our professional clinical practice, and it is essential that full information is given to patients to ensure the healthcare professional has met their obligation in informing the patient. This includes information on what the procedure involves, the available alternatives, risks and complications, and the expected outcomes.

Clearly, it is difficult for healthcare professionals to have all this information immediately to hand and, therefore, written information containing all these aspects is vital. The authors of this booklet have highlighted the important issues to be addressed and have presented detailed guidance on best-practice, which will be useful to surgeons of all levels.

EIDO Healthcare has produced a library of operation-specific patient information leaflets covering over 300 procedures. They meet all the criteria for good quality information and are widely endorsed by many leading surgical colleges and associations, including ASGBI; we are delighted, therefore, to have produced this ‘Issue’ in partnership with EIDO.

The Association hopes that this publication, and others in the series (all accessible at: [www.asgbi.org.uk/publications](http://www.asgbi.org.uk/publications)), will provide concise advice and guidance on major current issues, and grow into a helpful and accessible resource to support your professional practice.

Suggestions for any potential topics for future booklets in the **Issues in Professional Practice** series would be welcome.

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WHAT IS CONSENT?

Consent may be defined as follows:

“The voluntary and continuing permission of a competent patient to receive a particular treatment, based on an adequate knowledge of the purpose, nature and likely risks of the treatment, including the likelihood of its success and any alternatives to it. Permission given under any unfair or undue pressure is not consent.”

All the elements of the above definition are important, and there are legal and practical implications attached to all of them.

WHY IS CONSENT NECESSARY?

There have been many explanations of the need for patients to give consent to proposed medical treatment. The Department of Health states, in its *Good Practice in Consent Implementation Guide 2001*:

“Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health professionals and patients”. [1]

The best approach is to deal with consent as part of the process of joint decision-making. The patient and healthcare professional agree the best way forward, based on the patient’s condition, values and preferences, and the knowledge and experience of the healthcare professional.

Lord Donaldson summed up the very practical clinical purpose of obtaining consent in *Re W (A Minor) (Medical Treatment)* [1992]:

“The clinical purpose (of consent) stems from the fact that in many instances the co-operation of the patient, and the patient’s faith or at least confidence in the efficacy of the treatment, is a major factor contributing to the treatment’s success. Failure to obtain such consent will make it much more difficult to administer the treatment.” [2]

Good communication between the healthcare team and the patient and their family is essential in modern day medical practice, with recommendation 62 of the *Bristol Royal Infirmary Inquiry* stating:

“Partnership between patient and healthcare professional is the way forward. The exchange and provision of information is at the core of an open and honest relationship between healthcare professionals and patients.” [3]

Good practice in informed consent ensures an open and honest exchange of information between the healthcare team and the patient and encourages “shared decision making”. This should be a process involving more than one consultation with informed consent being built
The Department of Health states in its *Reference Guide to Consent for Examination or Treatment*:

“The seeking and giving of consent is usually a process, rather than a one-off event. For major interventions, it is good practice, where possible, to seek the person’s consent to the proposed procedure well in advance, when there is time to respond to the person’s questions and provide adequate information (see paragraphs 13–21 above). Clinicians should then check, before the procedure starts, that the person still consents. If a person is not asked to signify their consent until just before the procedure is due to start, at a time when they may be feeling particularly vulnerable, there may be real doubt as to its validity. In no circumstances should a person be given routine pre-operative medication before being asked for their consent to proceed with the treatment.”

In addition to considering best practice in consent in routine medical and surgical practice, we will also consider more complex situations where certain aspects of the ideal consent process are compromised. We will consider the law and guidance from governing bodies in these difficult situations.

**REGULATORY BODIES**

The National Health Service Litigation Authority (NHSLA) is the body responsible for managing risk within the NHS, as well as resolving claims. It creates standards of practice based on lessons learnt from claims. It has standards on patient information and consent (standard 5.2) and consent training (standard 5.3). Its standards are based on the following rationale:

- Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is, therefore, absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Analysis of data of the NHSLA database shows a significant number of claims involving the inappropriate or incorrect taking of consent. It is, therefore, essential that organisations have in place robust and overarching consent training programmes for all staff that are required to obtain or validate the taking of informed consent from patients.

The NHSLA and the General Medical Council (GMC) have collaborated to encourage NHS Trusts to report poor practice in consent within their institutions to the GMC using a standard form, and the extent of that reporting is one of the standards monitored by the NHSLA inspections. Although reporting individual doctors is discouraged, this new process does raise the stakes for trainee doctors and their supervisors, and ensuring that trainee doctors are adequately trained in the process of informed consent is essential to avoid being reported to the GMC in this way.

In 2008, the GMC updated their guidance on consent in the document *Consent: Patients and doctors making decisions together* [5].
LEGAL CONSEQUENCES OF NOT OBTAINING CONSENT

Treatment without the consent of the patient may lead to a criminal prosecution and/or a civil claim.

CRIMINAL ACTIONS

To succeed in obtaining a conviction, the Crown must normally prove both that the person accused had committed an unlawful act, and that he had a guilty mind. If a patient is treated without consent being sought, or against his wishes, assault and battery may be committed. These crimes include putting a person in fear of being touched (assault) and the actual touching (battery).

There are more serious offences under the Offences Against the Person Act 1861, including inflicting actual bodily harm and wounding with intent. However, there are very few prosecutions involving healthcare professionals involving treatment without consent. Consent is a defence to a criminal charge, but it will only be a valid defence if it is “real” consent, and real consent is not obtained if the patient is misled as to the nature or quality of the treatment, or the identity of the person carrying it out.

Written consent forms are evidence of consent having been given, and provide space in which to specify the proposed treatment. In addition to signing consent to that particular treatment, and to confirm that any other procedures that may be necessary have been discussed, the patient is asked to sign a statement of awareness that there is no guarantee that a particular individual will carry out the procedure. These signed statements should operate as a defence to battery in all but the most extreme cases.

In R v Richardson [1998] a dentist had been struck off the dental register but had continued to practise. She was charged with “assault occasioning actual bodily harm”, as she had continued to practise without being qualified to do so. The judge in the Crown Court had accepted the prosecution’s argument that fraud had vitiated the consent of her patients. However, the Court of Appeal ruled that, as the patients were not deceived as to her identity, nor about the nature of the treatment, the fraud did not cancel out their consent, so there was a valid defence to the criminal charge.

CIVIL ACTIONS

The first possible civil action, if there is no consent, is trespass to the person, consisting of the torts (civil wrongs) of assault, battery and, in some cases, false imprisonment. These claims arise only if the claimant alleges that the consent of the patient was not obtained at all, or the treatment was given against the known wishes of the patient. An assault consists of putting a person in immediate fear of a battery, without lawful justification. For example approaching a patient as if to give an unwanted injection.
A battery is a direct act of unwanted touching without lawful justification. For example touching a patient in the course of an unwanted physical examination or carrying out surgery without consent, or against the wishes of the patient.

False imprisonment is the unlawful imposition of total constraint on the freedom of movement of a person. This tort is committed even when the person imprisoned has no idea that this is the case. For example keeping a patient under an anaesthetic for which no consent was given.

It is not necessary to prove all three of these torts in order to succeed in obtaining compensation - one would be adequate.

In *Hamilton v Birmingham Regional Health Authority* [1969] a sterilisation operation was carried out on a woman without first taking consent, when she was given a caesarean section. She brought a successful claim for battery.

In *Murray v McMurchy* [1949] a doctor had discovered, in the course of carrying out a caesarean section operation, that the claimant’s uterus was in a very poor condition because of fibroids, so that another pregnancy might be dangerous for her. He carried out a sterilisation procedure by tying her fallopian tubes. Her claim for battery succeeded. It would not have been unreasonable to wait until a later date to carry out the sterilisation operation to allow time for the claimant to give consent.

The second type of relevant civil action is a claim for negligence. Negligence is the correct action when real consent has been given by a patient, but on the basis of allegedly inadequate information. The difference between trespass and negligence in this context was explained in *Chatterton v Gerson* [1981] by Mr Justice Bristow:

>“It would be very much against the interests of justice if actions which are really based upon a failure by the doctor to [adequately] inform, were pleaded in trespass (battery)...Once the patient is informed in broad terms of the nature of the procedure which is intended and gives her consent, that consent is real, and the cause of action on which to base a claim for failure to go into risks and implications is negligence, not trespass.”

In order to succeed in a claim for negligence, generally the claimant must prove that:

1. a duty of care was owed to them by the defendant and;
2. the defendant was in breach of that duty and;
3. the breach of duty caused, or materially contributed to, the damage sustained.

In cases in which it is alleged that inadequate information was provided, the claimant must prove that:

1. a duty of care was owed to them by the defendant to provide adequate information before obtaining consent to treatment and;
2. The duty of care was breached, in that inadequate information was given to the claimant (failure to meet the required standard of care). The failure to provide adequate information led the patient to undergo treatment that they would not have agreed to, had the appropriate information been provided (causation).

Most disputes arise in connection with the second of the above criteria - breach of duty - and the obvious question that arises concerns the detail that should be given to the patient about potential risks and side-effects of the treatment. The seriousness and frequency of any complications are important factors in deciding this. For example, a patient should be informed about a common complication, such as nausea after a general anaesthetic, even if it is not serious. A far less frequent but much more serious complication (less than 1 in 1,000) should also be explained, especially if the patient specifically asks about serious risks. The leading cases on this matter are Pearce v United Bristol Healthcare NHS Trust (1998) [10] and Chester v Afshar (2004) [11], which are explained later.
CONSENT IN PATIENTS WITH CAPACITY

In order for consent to be valid in law, it must be ‘real’. Consent will only be real if:

- The patient has capacity to consent to the particular treatment.
- The patient knows, in broad terms, to what treatment or procedure they are giving consent.
- The patient consents freely to the treatment or procedure.

The Mental Capacity Act 2005 states that a patient must be assumed from the outset to have capacity to consent to treatment. An assessment must never be based simply on age, appearance, assumptions about the patient’s condition, or any other aspect of their behaviour. In addition, the inability to speak English does not constitute a lack of capacity.

The patient lacks capacity to make the decision if they are unable to:

- Understand information relevant to the decision.
- Retain that information.
- Use or weigh that information to arrive at a decision.

They also need to be able to communicate their decision in some way. Further discussion about managing the patient that lacks capacity will be considered later.

The Department of Health, in its 2009 Reference Guide states:

“For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question”.

Consent is permission by the patient to undergo a proposed treatment or procedure, and permission may take a variety of forms. It can be express or implied, verbal or non-verbal, oral or written. In some instances, permission is implied by the simple fact that the patient has presented himself or herself for treatment – for example, holding out an arm for an injection at a GP’s surgery. Formal written consent is not normally required in such circumstances. It is sufficient for the healthcare professional to make a note of the proposed treatment after first explaining its nature and effect to the patient.

In some circumstances oral consent is given, and in other situations a consent form is given to the patient to sign. This is the case for all surgical procedures and the majority of interventional procedures. However, written consent is very rarely a statutory legal requirement, and only arises in highly specialised circumstances, for example under the Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990.

For more about this refer to Point 49 of the GMC’s Consent: Patients and doctors making decisions together.

VOLUNTARINESS

For consent to be real, the patient must consent freely or voluntarily. Thus, any consent is only valid if it is free from persuasion or
coercion. Persuasion or coercion could come from family members, the medical profession, employers, insurers or carers. Patients who are in care homes, in prison, or who are detained under the mental health legislation may be particularly vulnerable to coercion, and it is important that the person taking consent ensures that these patients are consenting voluntarily.

HOW MUCH INFORMATION?
Over recent years, there has been a shift in the amount of information given to support the consent process. The traditional approach was for the healthcare professional seeking consent to decide how much to tell a patient about the risks and side-effects of treatment. However, the emphasis has changed in recent years, and patients’ questions must be answered honestly, even though this might cause them anxiety (see Chester v Afshar [2004]). The standard of care to be applied in this situation is that of a person of similar professional standing to the person asking for consent, and this rule is based on tests formulated in two leading cases:

• The Bolam test (formulated as a defence to clinical negligence in Bolam v Friern Hospital Management Committee [1957]) [12]
• The Bolitho test (modifying the Bolam test, in Bolitho v City and Hackney Health Authority [1997]) [13]

The Bolam test is used to determine whether a healthcare professional has acted negligently, in a way that falls below the standard expected of a “responsible body of medical opinion”.

The standard of care expected of a health professional is determined on the basis of evidence provided by medical expert witnesses. When the Bolam test was applied, it was possible for a health professional to escape liability for negligence by finding an expert willing to testify that what they had done was acceptable to other health professionals with the same qualifications and level of experience. The judge was not allowed to reject that evidence, even if there was strong evidence from the claimant’s expert stating the opposite view.

However, the case of Bolitho now allows judges to reject the evidence of an expert witness if they consider that it is not “logically defensible”. This modification means that it is no longer possible for a health professional to escape liability for negligence simply by finding a suitable expert to support the defence case. The modified test has been applied in consent cases.

In Pearce v United Bristol Healthcare NHS Trust [1998], Lord Woolf made it clear that responsible medical opinion would take into account what the reasonable patient would regard as material risks, and inform patients about them so that they can be weighed in the balance by the patient before deciding whether or not to have the proposed treatment. In the course of judgment, Lord Woolf went on to say:

“If there is a significant risk which would affect the judgment of a reasonable patient, then in the normal course it is the responsibility of the doctor to inform the patient of that risk, if the
information is needed, so that the patient can determine for him or herself as to what course he or she should adopt.”

There is often a fine line between poor communication and negligent failure to inform a patient. For example, in Carver v Hammersmith and Queen Charlotte’s Special Health Authority [2000] 144 the claimant was under the mistaken impression, following a consultation, that the Bart’s test was a diagnostic test that would indicate whether the baby she was carrying had Down’s syndrome. In fact, the test was only a screening test which could only give her an indication. She was able to prove that if she had known this, she would have opted for an amniocentesis, which is a diagnostic test, and would have had a termination had she discovered that she was carrying a Down’s syndrome child. Her claim for damages was successful.

The most vital question on information provision was settled in Chester v Afshar [2004]. It concerned the issue of what information should be provided when the patient asks detailed questions. Here, the claimant alleged that the defendant had negligently failed to advise, explain or counsel her about the true risks attached to spinal surgery. The surgery was carried out by the defendant, and the claimant suffered motor and sensory impairment and further pain.

There was a conflict of recollection between the claimant and defendant as to what precisely was said, but the evidence indicated that there was no mention of paralysis as a possible side-effect of the surgery, and that the defendant had merely said that he had “not crippled anyone” yet. The claimant argued that, if she had been told of the small risk of paralysis (around 1% - 2%), she would not have agreed to have the operation when she did, but would have made further enquiries as to whether surgery was necessary. She did accept, however, that she would probably have had the operation eventually.

The case turned on whether the defendant had been negligent in his failure to warn the claimant of the very small risk of paralysis. This was a matter of information provision prior to obtaining the consent of the patient to treatment. The claimant was able to produce convincing detail about the lack of information given during the consultation and the defendant’s apparent confidence about his ability to perform the operation successfully. The defendant had made no notes about how much he had told the claimant, and was unable to convince the court that he had given as much information as necessary.

The case contains statements by senior judges indicating that UK law is committed to the central principle of patient autonomy. Lord Hope emphasised that each patient should be treated as an individual and given as much time as they need to reach the decision about treatment:

“For some the choice may be easy - simply to agree to or to decline the operation. But for many the choice will be a difficult one, requiring time to think, to take advice and to weigh up the alternatives. The duty is owed as much to the patient who, if warned, would find the decision difficult as to the patient who
As can be seen from the changes in case law, it is now essential that full information is given to patients to ensure the healthcare professional has met their obligation in informing the patient. This includes information on what the procedure involves, the available alternatives, risks and complications, and the expected outcomes. Clearly, it is difficult for healthcare professionals to have all this information immediately to hand and, therefore, written information containing all these aspects is vital.

Health professionals will be aware of the worrying amount of inaccurate and misleading information online, which can hinder patients from making appropriately informed decisions. This is why EIDO Healthcare has produced a library of operation-specific patient information leaflets covering over 300 procedures. They meet all the criteria for good quality information and are widely endorsed by many leading surgical colleges and associations, including ASGBI.

**DELEGATED CONSENT**

The clinician in immediate charge of the treatment should usually be the person who seeks consent from the patient. However, the GMC and Department of Health both advise that consent need not always be taken by a doctor, and it is possible for the consultant in charge to delegate the responsibility to a junior doctor or another healthcare professional. If they do this, they should make sure that the person they delegate to:

a) Is suitably trained and qualified.

b) Has sufficient knowledge of the proposed investigation or treatment, and understands the risks involved.

c) Understands, and agrees to act in accordance with, the guidance in the GMC guidelines.

If the consent process is delegated, the healthcare professional should be supported with high-quality written information (such as that mentioned above), and have access to the consultant with responsibility for the care of the patient. Medical trainees should observe the generic standards for training, which state:

> “Before taking consent, both trainee and supervisor must be satisfied that the trainee understands the proposed intervention and its risks, and is prepared to answer associated questions the patient may ask. If they are unable to do so, they should have access to a supervisor with the required knowledge. Trainees must act in accordance with the GMC guidance Consent: Patients and doctors making decisions together (2008).”

[15]

The recent agreement between the GMC and NHSLA, mentioned earlier, emphasises the importance of trainees being appropriately trained in informed consent.

It is not only doctors who need to be trained in all aspects of the consent process - nurses and other healthcare professionals must also
ensure that they obtain permission from patients for procedures which they undertake. This is likely to happen when verbal or non-verbal consent is given at the point of treatment. As mentioned earlier, routine procedures (such as taking blood pressure) do not normally require a consent form to be signed. If there is any doubt that a patient agrees to a particular procedure, the matter should be discussed with them, even if the procedure is as routine as a blood test. If their consent is obtained, it should be recorded.

**CONSENT FORMS**
The Department of Health has developed standardised consent forms that are recognisable throughout the NHS. However, there may be local needs in different areas of the country and customisation of forms is acceptable (where appropriate) to meet these needs. A leaflet for patients entitled *About the Consent Form*, should be made available to patients before they are asked to sign.

A set of model consent forms has been published by the Department of Health. These are easily-accessible on the internet, and most NHS healthcare professionals will already be familiar with them. The forms are set out as follows:

| Consent form 1 | Patient agreement to investigation or treatment. |
| Consent form 2 | Parental agreement to investigation or treatment for a child or young person. |
| Consent form 3 | Patient/parental agreement to investigation or treatment (procedures where consciousness not impaired). |
| Consent form 4 | Form for adults who are unable to consent to investigation or treatment. |

Patients are required to sign the form to confirm that:

- They consent to the treatment.
- They understand that no particular individual can be guaranteed to carry out the treatment.
- There has been an opportunity to discuss anaesthesia if appropriate.
- They understand that additional procedures will only be carried out if required to save the patient’s life or prevent serious harm (patients have the opportunity to state any additional treatments that they do not wish to be carried out).

Forms should contain:

- The signature of the patient.
- The signature of a witness, if necessary.
- The signature of a health professional treating the patient, to confirm that the patient has agreed to the procedure in advance and has no further questions.
- Space for special notes, such as an advance decision, or a patient’s withdrawal of consent.
The consent form should be accompanied by a statement, signed by the healthcare professional, confirming that the procedure has been explained to the patient, including benefits and any serious or frequent risks. The form also requires the healthcare professional to give details of any additional procedures that might become necessary, together with their benefits or risks.

The form also allows the healthcare professional to record:

- Details of any leaflets or tapes given to the patient.
- Details about whether the procedure involves general anaesthesia, local anaesthesia or sedation.
- A statement that an interpreter should be used, and that the information has been interpreted for the patient.

A CONTINUING PROCESS

Consent is often a continuing process rather than a ‘once and for all’ event. In the final report of the Bristol Inquiry (2001), consent was one of the main issues upon which comments were made:

“Patients should always be given the opportunity and time to ask questions about what they are told, to seek clarification and to ask for more information. It must be the responsibility of employers in the NHS to ensure that the working arrangements of health professionals allow for this, not least that they have the necessary time.

Patients should be supported in dealing with the additional anxiety sometimes created by greater knowledge.”

Patients should be made aware that they are free to change their minds during the course of treatment, though the possible drawbacks of so doing must be explained if appropriate.

There is a final “confirmation of consent” section on the consent form which confirms that the patient wishes to continue with the procedure at the end of the consent process. This is usually signed by the healthcare professional performing the procedure on the day of the procedure.

A PARTICULAR TREATMENT

Consent relates to the particular treatment under consideration. Therefore, new or additional treatments require fresh consent from the patient, except in the case of an emergency when the life of the patient is at risk. If a surgeon carrying out an operation considers it necessary to carry out a procedure not originally explained to the patient, it would normally be unlawful for the surgeon to continue without further consent being provided. A possible exception to this is when the defence of necessity applies. In this case, it must be established that it is essential that a procedure should not be delayed, and the treatment must be in the best interests of the patient. The medical condition of the patient must also be such that it would be unreasonable, and not merely inconvenient, to wait for the patient to regain consciousness and give consent.
CONSENT AND PATIENTS WHO LACK CAPACITY

After many years, during which the law on mental incapacity and consent to treatment was evolving in the courts, Parliament intervened with the Mental Capacity Act in 2005, which aimed to clarify and build upon the common law. This followed an extensive consultation involving members of the public, lawyers and experienced practitioners in the field. The Act provides a framework to protect the interests of people who lack capacity to make decisions for themselves. The Act also established a new Court of Protection, in place of the office of the Supreme Court called by the same name, and made provisions relating to the Convention on the International Protection of Adults.

The Mental Capacity Act (hereafter referred to as the MCA) section 1, sets out the following principles:

“A person must be assumed to have capacity, unless it is established that he lacks capacity.

A person is not to be treated as unable to make a decision, unless all practicable steps to help him to do so have been taken without success.

A person is not to be treated as unable to make a decision merely because he makes an unwise decision.

An act done, or decision made, under this Act for, or on behalf of, a person who lacks capacity must be done, or made, in his best interests.

Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person’s rights and freedom of action.”

The MCA and Code of Practice are important here, as they contain various definitions which are based on the law developed in cases. Patients with learning disabilities and other conditions such as dementia, in which capacity may be limited, could be capable of making simple decisions, but not more complex decisions about medical treatment.

The Act deals specifically with people who do not have sufficient capacity to make treatment decisions for themselves. Section 2 of the Act defines situations in which a person may lack capacity. It states:

“For the purposes of this Act, a person lacks capacity in relation to a matter if at the material time they are unable to make a decision for themselves in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.

It does not matter whether the impairment or disturbance is permanent or temporary.

A lack of capacity cannot be established merely by reference to:

• a person’s age or appearance, or
• a condition, or an aspect of their behaviour, which might lead others to make unjustified assumptions about their capacity.
In proceedings under this Act or any other enactment, any question whether a person lacks capacity within the meaning of this Act must be decided on the balance of probabilities.”

The functional test for capacity in the MCA’s Code of Practice is as follows:

“The health professionals responsible for the patient must decide, on a balance of probabilities, whether an individual has capacity to make a particular decision. It is necessary to consider:

1. Whether there is a temporary or permanent impairment of, or disturbance in, the functioning of the patient’s mind or brain.
2. Whether that impairment or disturbance renders that patient unable to make the decision in question.

The patient will be unable to make the decision if they are unable to:
• understand information relevant to the decision
• retain that information
• use or weigh that information to arrive at a decision
• communicate the decision by speech, writing, signs or some other means”

In the case of Re T (Adult: Refusal of Medical Treatment) [1992] 16, Lord Donaldson said:

“An adult patient who suffers from no mental incapacity has an absolute right to choose whether to consent to medical treatment or to refuse it, or to choose one rather than another of the treatments being offered. This right of choice is not limited to decisions that others would regard as sensible. It exists notwithstanding that the reasons for making the choice are irrational, unknown or even non-existent.”

Lord Goff said, in Airedale NHS Trust v Bland [1993] 17:

“If an adult patient of sound mind refuses, however unreasonably, to consent to treatment ... by which his life would or might be prolonged, the doctors responsible for his care must give effect to his wishes, even though they do not consider it to be in his best interests.”

More recently, the courts have emphasised the importance of respecting patients’ autonomy in the context of consent. For example, in the latest and most crucial decision on consent, Chester v Afshar [2004], Lord Walker said:

“In a decision which may have a profound effect on her health and well-being a patient is entitled to information and advice about possible alternatives or variant treatments.”
However, capacity can fluctuate. People who usually have capacity may at certain times lack it, for example, when they are sedated. There are also certain groups of patients, for example some elderly people, whose capacity may vary from time to time. The MCA states that it does not matter whether the impairment to capacity is permanent or temporary. It follows that the same patient may be capable of consenting at one time, but incapable at another.

If medical intervention is required, the general advice is that it is better to wait, if possible, for the patient to recover capacity before giving treatment. However, if the patient requires immediate treatment, this may not be possible, and the rules relevant to all incapacitated patients apply. The views of the next of kin should be taken into account as to whether the patient without capacity would have wanted to go through with the procedure, but relatives cannot consent on behalf of the patient. There is one exception to this, in that a relative may be given authority if they have “Lasting Power of Attorney for personal welfare”. This can extend to medical matters, but is a formal legal process with written certification (see ‘End of Life’ section).

In law, a child or ‘minor’ is a person under eighteen years old, but under section 8 of the Family Law Reform Act 1969, a person aged 16 may consent to treatment in the same way as an adult. Children under the age of 16 are a group who generally lack capacity to consent for themselves. For younger children, the parent, or person with parental responsibility, consents on behalf of the child. However, it is wise to involve the child in the decision-making process as far as they are able to understand. Older children may have ‘Fraser’ or ‘Gillick’ competence and, therefore, need to be treated differently.

This term refers to a ruling by the House of Lords in the leading case of *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 118. The case concerned the specific question as to whether doctors, in accordance with government guidance, should be able to give contraceptive advice or treatment to children under 16 without parental consent. Since the case was decided, the rules laid down in it have been applied more widely in the assessment of whether a child has sufficient maturity to make her own decisions and to understand what is involved in them. Lord Fraser provided guidance on the matter, in what have become known as the Fraser guidelines. At the time, these applied specifically to contraceptive advice, but are now used more generally:

"...a doctor could proceed to give advice and treatment provided he is satisfied in line with the following criteria:

1. That the girl (although under the age of 16 years of age) will understand his advice.

2. That he cannot persuade her to inform her parents or to allow him to inform the parents that she is seeking contraceptive advice.

3. That she is very likely to continue having sexual intercourse with or without contraceptive treatment."
4. That unless she receives contraceptive advice or treatment her physical or mental health or both are likely to suffer.

5. That her best interests require him to give her contraceptive advice, treatment or both without the parental consent.”

Axon, R v Secretary of State for Health [2006] makes clear that the principles stated in the Gillick case apply to decisions about treatment and care for sexually transmitted infections and abortion too, and also that a girl under the age of 16 would be entitled to have any information about her sexual health or related matters kept confidential as long as she is Gillick-competent.

The Department of Health’s guidance is that the families of children in this age group should be involved in decisions about their care, unless there is a very good reason for not involving them:

“If the child is Gillick-competent and is able to give voluntary consent after receiving appropriate information, that consent will be valid, and additional consent by a person with parental responsibility will not be required. It is, however, good practice to involve the child’s family in the decision-making process, if the child consents to their information being shared.”

If, however, a child with capacity under the age of sixteen insists that the family should not be involved, the child’s right to confidentiality must be respected, unless such an approach would put the child at serious risk of harm - as stated in the Gillick case, parental rights are of a dwindling nature (see the Axon case outlined above).

There are some cases decided by the courts, in which the refusal by a minor with capacity to undergo a procedure has been overruled by an adult on application to the court. Where a child who is under 16, but Gillick-competent, (or a person between the ages of 16 and 18) refuses treatment, it is possible that such a refusal could be overruled if it would, in all probability, lead to their death, severe permanent injury, or grave and irreversible mental or physical harm (see the case of Re W (a minor) (medical treatment)).
CONSENT AND ‘END OF LIFE’ ISSUES

Healthcare professionals face some very difficult dilemmas when caring for patients at the end of their lives. Patients with capacity are able to make decisions together with their doctors and carers about their end of life treatment, and guidance is provided to doctors by means of the End of Life Pathway [20]. If patients lack capacity, the provisions of the Mental Capacity Act and Code of Practice apply.

Despite numerous guidance documents, there are several well-publicised and controversial cases in which the courts have been asked to assist healthcare professionals in the decision-making process. The courts tend to be involved in many difficult situations, and, in some cases, the media often report on the legal and ethical issues.

REFUSAL OF LIFE-SUSTAINING TREATMENT

The BMA has issued advice for doctors on withholding and withdrawing life-prolonging treatment, and certain aspects of that advice have attracted criticism. However, some parts of the document contain sound advice, and the guidance that follows here is a helpful reflection of the position taken by the courts:

“It is not an appropriate goal of medicine to prolong life at all costs with no regard to its quality or the burdens of treatment”, but “treatment should never be withheld, when there is a possibility that it will benefit the patient.”

The BMA also advises that, if local or national guidelines exist for the management of a particular condition, these should be consulted as part of the clinical assessment of the patient, and additional advice should be sought where necessary.

The Department of Health’s Reference Guide to Consent emphasises that, because of the gravity of decisions of this kind, assessments of capacity and patients’ best interests are of great importance. Everyone concerned with the care of the patient should be consulted and can make a contribution to the assessment. Details of all discussions with relatives, carers and multi-disciplinary teams should be recorded in the patient’s notes.

Time and again, the courts have commented that it is unnecessary to bring cases before them concerning patients, with capacity, who refuse treatment. Patients with capacity should be allowed the freedom to refuse to undergo treatment and other procedures, and should not be put under pressure by staff or relatives to give their consent. Treatment without consent amounts to assault and battery, as explained earlier. An adult with capacity has the right to refuse treatment, even if that refusal is contrary to medical advice and may appear irrational to those with clinical responsibility for the patient. In the case of Re T (Adult: Refusal of Medical Treatment) [1993] Butler-Sloss LJ summed up the position as follows:
“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] 1, 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] 2. 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] [23]. 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] [24], 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\textsuperscript{nd} 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\textsuperscript{nd} May. The judge held that the decision was valid and applicable, and that the references to 2\textsuperscript{nd} 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] [25] 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 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 [26] in England, Wales and Northern Ireland, and the Human Tissue (Scotland) Act 2006 [27] 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.” [28]

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 [29] 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?”

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, 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.
REFERENCES

[12] Bolam v Friern Hospital Management Committee [1957] 1 WLR 582
[13] Bolitho v City and Hackney Health Authority [1997] 4 All ER 771
[14] Carver v Hammersmith and Queen Charlotte’s Special Health Authority [2000] unreported
[18] Gillick v West Norfolk and Wisbech Area Health Authority [1985] 3 All ER 402 (HL)
[19] Axon, R (on the application of) v Secretary of State for Health & Anor [2006] EWHC 37 (Admin)
[21] R (On the application of L) v Newcastle Primary Care Trust, [2003] EWHC 3252
[22] Re MB (an adult: medical treatment) [1997] 38 BMLR 175 (CA)
[23] St George’s Healthcare NHS Trust v S; R v Collins and others, ex parte S [1998] 3 All ER 673
[24] Re XB [2012] EWHC 1390 (Fam)
[25] Burke, R (on the application of) v General Medical Council & Ors [2005] EWCA Civ 1003
[31] National Audit of Major Complications of Central Neuraxial Block in the United Kingdom http://www.rcoa.ac.uk/nap3
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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