MPS Guide to Consent in the UK

MEDICAL PROTECTION SOCIETY

This booklet was produced as a resource for MPS members in the UK. It is intended as general guidance only. MPS members are always welcome to telephone our medicolegal advice line – 0845 605 4000 – for more specific practical advice and support with medicolegal issues that may arise.

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We are a mutual, not-for-profit organisation offering more than 250,000 members help with legal and ethical problems that arise from their professional practice. This includes clinical negligence claims, complaints, medical council inquiries, legal and ethical dilemmas, disciplinary procedures, inquests and fatal accident inquiries.

Fairness is at the heart of how we conduct our business. We actively protect and promote the interests of members and the wider profession. Equally, we believe that patients who have suffered harm from negligent treatment should receive fair compensation. We promote safer practice by running risk management and education programmes to reduce avoidable harm.

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Summary

- Consent is needed for all clinical examinations, investigations and treatment.
- Decision-making should be a partnership between doctor and patient.
- Patients' beliefs, values, concerns, level of understanding and priorities should be explored to determine what information they want or need.
- Adult patients who can decide for themselves need sufficient information and, whenever possible, time to make a choice.
- A patient's capacity to make decisions depends on being able to:
  - understand what decision needs to be made and why
  - appreciate the likely consequences of making or not making a decision
  - understand, retain, use and weigh up relevant information
  - communicate a decision.
- Patients should be given all information material to their decision before deciding which option to choose. It should be tailored to their individual needs and condition.
- Patients should not be pressurised into making a decision, but must be made aware of any potential harm that may come from delay.
- Children and young people with capacity can consent to treatment, but in most circumstances parents or others with parental responsibility are likely to be involved.
- Adults with capacity can make advance decisions about refusing treatment in case they lose capacity later on.
- Separate legislation in Scotland and England and Wales allows specified others to consent on behalf of adults who lack capacity.
- Consent to clinical examination, some investigations and treatment, is often implied by the patient's co-operation – not expressly stated.
- NHS trusts and other providers usually have policies on the use of consent forms which employees should follow.
- Signed consent forms alone are not proof that consent was valid.
- A significant proportion of clinical-negligence claims include allegations of failure to obtain valid consent.

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Introduction

Consent is a fundamental principle of medical law. The basic rule is simple: No-one has the right to touch anyone else without lawful excuse and if doctors do so it may well undermine patients' trust. Such behaviour may lead to a clinical negligence claim, a complaint to the GMC or even civil or criminal proceedings for assault.

There are three components to valid consent:

- Capacity
- Information
- Voluntariness

Capacity

Both legislation* and the GMC's guidance emphasise that doctors should presume that adults have the capacity to consent to or refuse a proposed treatment unless it can be established that they lack that capacity. Each assessment of an individual's capacity should relate to a specific decision – a patient may, for example, be incapable of understanding the complex implications of a major procedure but still be able to comprehend the risks and benefits of a simple intervention. While the general principles are the same across the UK, the actual test for capacity is slightly different, depending on the jurisdiction.

England and Wales

In England and Wales, the test of capacity is in two parts:

- Does the person have an impairment of, or a disturbance in the functioning of, their mind or brain?
- Does the impairment or disturbance mean that the person is unable to make a specific decision when they need to?

Scotland

In Scotland, incapacity is defined in the Adults with Incapacity Act as being incapable of any of the following:

- Acting
- Making a decision
- Communicating a decision
- Understanding a decision
- Retaining the memory of a decision

The Act does not set out a test of capacity, but says that incapacity "must be judged in relation to particular matters, and not as an 'all or nothing' generalisation".[1] The Scottish government, offers the following guidance for assessing capacity:[2]

- Does the person have a mental disorder (which includes mental illness, learning disability, dementia and acquired brain injury), or severe communication difficulty because of a physical disability (such as a stroke or severe sensory impairment)? If so,
- Has it made the person unable to make the decision or decisions in hand?

Northern Ireland

There is no specific legislation covering mental capacity in Northern Ireland. As such, the common-law test[3] applies:

- Does the patient comprehend and retain treatment information?
- Does the patient believe that information?
- Does the patient weigh that information, balancing risks and needs, to arrive at a choice?

The *Mental Capacity Act Code of Practice*[4] offers useful guidance on assessing an individual's ability to make a decision (see Box 1).

*Adults with Incapacity Act (Scotland) 2000 and Mental Capacity Act 2005

Box 1: Assessing capacity

- Does the person have a general understanding of what decision they need to make and why they need to make it?
- Does the person have a general understanding of the likely consequences of making or not making this decision?
- Is the person able to understand, retain, use and weigh up the information relevant to this decision?
- Can the person communicate their decision (by talking, using sign language or other means)?
- Would the services of a professional (such as a speech and language therapist) be helpful?

And in more complex or serious decisions:

- Is there a need for a more thorough assessment (perhaps by involving a doctor or other professional expert)?

Mental Capacity Act 2005: Code of Practice, p. 41

General advice on assessing capacity

A person's capacity, or lack of it, cannot be judged simply on the basis of age, appearance, condition or any aspect of their behaviour.

The *Mental Capacity Act Code of Practice* stipulates that professionals should never express an opinion on a person's lack of capacity without carrying out a proper examination and assessment; this may entail meeting the patient more than once, particularly where there are communication difficulties. Background information from people close to the patient may also prove useful, but their personal views on what should happen must not be allowed to influence the outcome of the assessment.

In certain circumstances specialist assessment may be required, but in general the assessment consists of conveying information to a patient, discussing it with them to gauge their understanding and then asking questions about the salient points to see if they have grasped them.

Avoid asking questions inviting "Yes" or "No" answers – for example, "Do you understand?" Instead, frame your questions in such a way that the patient will need to give a fuller response – for example, the above question could be re-phrased as "Tell me what you understand by…" Words like "What", "How" and "Tell me" are good for framing open-ended questions.

Assessing capacity can be very difficult where patients suffer from serious communication problems, so employing aids to help them is crucial. Find out from those who are close to the patient what means they normally use to communicate and what tools the patient is familiar with. If you are unsure about how best to assist a patient in these circumstances it may be necessary to involve a speech and language therapist, a translator, or other professionals with special skills or knowledge.

Other aspects to consider are the timing and location of an assessment. Capacity may fluctuate in the course of a day, so choosing the best time to assess someone is important. It is also important to be aware of the possible impact of the environment – if it is strange or intimidating, it may inhibit the patient or make him/her tense and agitated.

Even if a patient lacks capacity, the onus upon health professionals is still to involve patients insofar as is possible in decisions that affect their lives.[5]

Box 2: The five principles of the Mental Capacity Act

1. A person must be assumed to have capacity unless it is established that they lack capacity.
2. 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.
3. A person is not to be treated as unable to make a decision merely because he makes an unwise decision.
4. 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.
5. 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.

Mental Capacity Act 2005, section 1.

Scenario 1

Mrs N is 86 years old and has been in hospital for four weeks since having a stroke. Her speech is unintelligible and she dozes much of the time. She suffers a fractured neck of femur in a fall. The staff on the ward explain what has happened and that she needs an operation. Because she is unable to speak, the staff watch her body language intently to gauge her understanding and give her a picture board to help her communicate. Mrs N is able, through these means, to convince the staff that she understands what has happened and that she wants them to carry out the operation.

Scenario 2

Mrs M is 82 and usually very lively and alert. However, she has recently become very confused, probably due to a urinary tract infection. She is admitted to hospital where it is noted that she has an irreducible femoral hernia. The surgeons who are called to see her suggest immediate repair to avoid the risk of strangulation, but as there is no-one authorised to give proxy consent and there is no imminent danger (the hernia is not strangulated), it is decided to wait in the expectation that she will regain capacity, and then to seek consent to surgical repair.

Fluctuating capacity

Some patients are intermittently or temporarily unable to make a decision for themselves. It may be possible to wait until the patient has capacity or, where this is not the case, patients must be treated in accordance with their best interests or according to consent given by someone authorised to act on the patient's behalf – someone with parental responsibility in the case of a minor, or a person with a lasting power of attorney (a welfare attorney in Scotland).

Children and young people

Patients under the age of 16 may or may not have the capacity to consent to treatment. The test of capacity in children is still whether or not they are Gillick competent. If they are able to understand information about their condition and the implications of either proceeding with the proposed investigations or doing nothing, they should be considered competent to provide consent (See GMC guidance in Box 3).

Unless the patient objects, you should also involve parents or others with parental responsibility, particularly in more serious situations.

Assessments of a patient's capacity to consent should be recorded in the notes.

If the child or young person either lacks capacity or is withholding consent, someone with parental responsibility can consent on his/her behalf (see Box 4). If there are two people with parental responsibility, it is usually sufficient for one to consent, but where decisions may have profound, irreversible consequences, both individuals with parental responsibility should be consulted.

Even when children lack the capacity to give consent, they should still be involved in the decision-making process – for example, in terms of who goes to theatre with them or what toys they take.

In all aspects of caring for children, the child's welfare is the paramount consideration. Occasionally, parents make decisions that are likely to affect a child adversely; they may disagree with the orthodox management of certain conditions, for example, and although this may not be life-threatening, the child may suffer by not having access to conventional treatment. A parent's refusal to consent in these circumstances can be overruled by the courts. As competent adults, they have the right to make decisions that may compromise their own welfare, but they do not have the right to make such decisions on behalf of a child.

Sometimes it may be necessary to apply to the courts for a ruling on whether a particular course of treatment should go ahead. Examples might be when parents are in disagreement – either with doctors or between themselves – about the best interests of the child.

Box 3: GMC guidance

You must decide whether a young person is able to understand the nature, purpose and possible consequences of investigations or treatments you propose, as well as the consequences of not having treatment. Only if they are able to understand, retain, use and weigh this information, and communicate their decision to others can they consent to that investigation or treatment. That means you must make sure that all relevant information has been provided and thoroughly discussed before deciding whether or not a child or young person has the capacity to consent. The capacity to consent depends more on young people's ability to understand and weigh up options than on age. When assessing a young person's capacity to consent, you should bear in mind that:

- at 16 a young person can be presumed to have the capacity to consent (see paragraphs 30 to 33)
- a young person under 16 may have the capacity to consent, depending on their maturity and ability to understand what is involved.

It is important that you assess maturity and understanding on an individual basis and with regard to the complexity and importance of the decision to be made. You should remember that a young person who has the capacity to consent to straightforward, relatively risk-free treatment may not necessarily have the capacity to consent to complex treatment involving high risks or serious consequences. The capacity to consent can also be affected by their physical and emotional development and by changes in their health and treatment.

GMC, *0–18 Years: Guidance for All Doctors* (2007), paras 24–26.

Scenario 3

Thirteen-year-old ES is attending boarding school while his parents are in Africa working for an NGO. One evening his house master, Mr G, brings him to A&E; E has a raised temperature and is complaining of severe abdominal pain.

A diagnosis of acute appendicitis is quickly made, and arrangements to take E down to theatre are put in motion. The doctor asks Mr G for E's parents' contact details, but is told that they are unavailable as they are currently in a locality with no communication infrastructure. Mr G offers to sign the consent form on their behalf, explaining that he is acting in loco parentis* while Mr and Mrs S are away.

The doctor, however, is unsure about this and contacts the trust's solicitor. She tells him that it is likely that Mr G could consent on behalf of E's parents, provided they assigned such rights to him, but suggests that the doctor first assess E's capacity. When his condition is explained to him in terms he can understand, E readily grasps the situation, his need for urgent surgery and the consequences of delay. He is therefore competent to consent to treatment on his own behalf, so parental consent is not necessary.

*"Section 2(9) of the Children Act 1989 states that a person who has parental responsibility for a child 'may arrange for some or all of it to be met by one or more persons acting on his behalf'. Such a person might choose to do this, for example, if a childminder or the staff of a boarding school have regular care of their child." DH, *Reference Guide to Consent for Examination or Treatment* (2001), p. 18.

Box 4: Who has parental responsibility?

Someone with parental responsibility may consent to treatment on behalf of a child up to the age of 18 in England, Wales and Northern Ireland and 16 in Scotland.

Unless she lacks capacity herself, a child's mother automatically has parental responsibility.

A father will have parental responsibility if any of the following conditions apply:

- He is married to the mother of his child (or was married to her at the time of the child's birth).
- He has made a parental responsibility agreement with the mother.
- He has obtained a court order granting him parental responsibility.
- The child was born after 15 April 2002 in Northern Ireland, 1 December 2003 in England or Wales, or 4 May 2006 in Scotland and the father is named on the child's birth certificate.

Other individuals or organisations (such as Social Services) may be given parental responsibility by court order, or by being appointed as a guardian on the death of a parent.

Information

Provision of information is key to obtaining valid consent. Unless patients have sufficient information, they are not in a position to decide what is best for them. In *Consent: Patients and Doctors Making Decisions Together*, the GMC has set out what patients ought to know before deciding whether to consent to treatment or an investigation. (See Box 5.)

Discussions about the options available to the patient may take place over several consultations. Carried out properly, the process should be more than a one-sided delivery of information – it should include an exploration of the patient's understanding, knowledge, beliefs, values and concerns, identifying the factors that are significant to them. The information should then be tailored accordingly. The GMC warns against making assumptions about a patient's level of understanding or the information they might want or need,[6] placing considerable emphasis on being led by the patient's agenda rather than the doctor's. This will usually require sensitive questioning as well as respectful listening (see paras 7–10 and 28–31).

Some patients don't want to know all the details about treatments and their attendant risks and benefits, making it difficult to secure their valid consent. The GMC advises that, in this situations, although the patient's wishes should be respected as far as possible, the doctors "must still give them the information they need in order to give their consent". Regardless of their lack of interest in the details, at a bare minimum they will still need to know why the investigation or treatment is being proposed and what it will entail in terms of pain or discomfort and anything they must do to prepare for it.[7] When a patient does not want to hear all (or any of) the relevant details of an investigation or treatment, this should be documented in their medical record.

Patients' questions should be answered fully and honestly. The only justification for withholding information from a patient is if there are good grounds for believing that it would cause serious physical or mental harm to the patient. Such circumstances are extremely rare, and when they do occur, it is important to document the decision to withhold and the rationale behind it.

If intervention is needed urgently, it may be impossible to provide all the information set out in Box 5; even so, the patient should be given a broad outline of what is being recommended and why, and if the patient asks questions, the doctor's responsibility is to answer them.

Box 5: Information to be given in the consent process

You must give patients the information they want or need about:

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

GMC, *Consent: Patients and Doctors Making Decisions Together* (June 2008), para 9.

Voluntariness

Patients overtly coerced into undergoing treatment they plainly do not want can rightly claim that their "consent" was not given freely and is therefore not valid. Cases of overt coercion are rare, but there are many circumstances in which patients may feel that they have been covertly pushed into accepting treatment they would prefer not to have had. For example, in some circumstances patients may find it very difficult to say "No" to the proposed treatment, or to challenge the doctor's assumption that they would have no objections to going ahead, so it is best to check that they have no misgivings before proceeding.

Relatives, friends and caregivers (and sometimes employers) can also exercise considerable influence in a patient's decision-making, and this might sometimes develop into undue pressure. If there is a likelihood that this is the case, check that the patient has truly considered all the options and is aware that they have a right to refuse the proposed procedure.[8]

Patients who are detained by the Police, Immigration Services, Prison Authorities or under mental health legislation may be particularly vulnerable, and under these circumstances you should try to ensure that they are aware that they can refuse treatment if they so wish. Patients detained under the Mental Health Act may be treated for their mental disorder without their consent (depending on the section of the Act that applies), but not for physical ailments unless these arise from the mental disorder.

Scenario 4

Mr H is a plasterer in his late forties. He has been experiencing pain in his left knee, on and off, for several years, but this has been adequately managed with a combination of physiotherapy and NSAIDs. One day, he comes to see his GP, Dr J, complaining of intense pain and limited movement in his knee. Dr J, noting Mr H's history and finding, on examination, that the knee is slightly swollen, recommends an intra-articular injection of Kenalog. As he is aware that Mr H is self-employed and needs to be able to return to work as soon as possible, he suggests that he administer the injection there and then.

Mr H is doubtful about having an injection straight into the joint, but Dr J brushes aside his doubts, saying that it will get him "up and running in no time". He points out that it is unlikely he will get another appointment at the practice until the following week, which will only delay his recovery. Mr H reluctantly acquiesces, and allows Dr J to administer the injection. Unfortunately, he subsequently develops septic arthritis in the joint. Although this is successfully treated with antibiotics, he loses several more weeks' work and decides to sue Dr J. His claim alleges invalid consent, not only because he had not been warned about the small risk of infection, but because he had felt coerced into making a hasty decision.

Other aspects of consent

Advance decisions and advance statements

Adults with capacity can make known what their preferences would be regarding medical treatment if they later lose their capacity.

An advance decision to refuse treatment made by an adult (ie, 18 or over) is legally binding in England and Wales under the terms of the Mental Capacity Act. It must specify the treatments being refused, may set out in what circumstances the refusal should apply, and may be made verbally or in writing. If, however, the refusal relates to life-sustaining treatment, the decision must be in writing, signed and witnessed. It must also clearly state that the refusal stands even if it will place the individual's life at risk.

Before acting on an advance decision to refuse treatment, doctors must be satisfied that it is still valid and applies to the current circumstances. If there is any doubt about this, the patient should be provided with care to secure his/her best interests while the issue is resolved, if necessary by reference to the courts.

An advance statement is a more general document setting out the individual's wishes regarding decisions about their care and treatment. It may also include information about their beliefs and preferences as an aid to those who will have to decide what is in their best interests. This is not a legally binding document, but doctors have a duty to take the wishes of patients who lack capacity into account (if they are known) when making treatment decisions.

The situation regarding advance decisions (or directives) in Scotland and Northern Ireland is governed by common law rather than legislation. Provided that the decision was made by an adult with capacity and that it clearly sets out what treatment is being refused, and in what circumstances, it is highly likely that the courts would consider this a legally binding directive. GMC guidance states:

"Any valid advance refusal of treatment – one made when the patient was competent and on the basis of adequate information about the implications of his/her choice – is legally binding and must be respected where it is clearly applicable to the patient's present circumstances and where there is no reason to believe that the patient had changed his/her mind."[9]

In England and Wales, under the Mental Capacity Act, health professionals are protected from liability for providing treatment if there is doubt about the validity or applicability of an advance decision, and no liability is incurred for withholding or withdrawing treatment if those responsible for care reasonably believe that a valid and applicable advance decision exists.

Consent by proxy

It used to be the case that no-one had the right to consent to treatment on behalf of an adult, regardless of that adult's level of capacity. This is no longer the case in Scotland, England and Wales, where legislation has been introduced that allows capable adults to appoint someone to make healthcare decisions on their behalf if they become incapacitated.

In Scotland, an adult can appoint a welfare attorney to make decisions about his/her personal welfare. This power only takes effect, however, if the individual concerned no longer has the capacity to make a decision for him/herself.

In England and Wales, someone with a personal welfare Lasting Power of Attorney (LPA) can make decisions on behalf of an incapacitated adult about most aspects of that person's social and physical care, depending on what was stipulated by the donor in drawing up the LPA. They are not empowered to make decisions about life-sustaining treatment unless this was expressly authorised by the patient. (See Box 6.)

Box 6: Personal welfare LPAs

A personal welfare LPA allows attorneys to make decisions to accept or refuse healthcare or treatment unless the donor has stated clearly in the LPA that they do not want the attorney to make these decisions. Even where the LPA includes healthcare decisions, attorneys do not have the right to consent to or refuse treatment in situations where:

- the donor has capacity to make the particular healthcare decision
- the donor has made an advance decision to refuse the proposed treatment
- a decision relates to life-sustaining treatment (unless the LPA document expressly authorises it)*
- the donor is detained under the Mental Health Act.

LPAs cannot give attorneys the power to demand specific forms of medical treatment that healthcare staff do not believe are necessary or appropriate for the donor's particular condition. Attorneys must always follow the Act's principles and make decisions in the donor's best interests. If healthcare staff disagree with the attorney's assessment of best interests, they should discuss the case with other medical experts and/or get a formal second opinion. Then they should discuss the matter further with the attorney. If they cannot settle the disagreement, they can apply to the Court of Protection. While the court is coming to a decision, healthcare staff can give life-sustaining treatment to prolong the donor's life or stop their condition getting worse.

Adapted from *MCA Code of Practice* paras 7.26–7.30

If a patient who lacks capacity has appointed a welfare attorney, then this person should be consulted when making decisions about the patient's care and treatment (see Box 7). If there is no LPA, and there is a need for someone to make ongoing decisions about a patient's care, the Court of Protection may appoint a deputy to fulfil this role.

Box 7: Consulting a personal welfare attorney

"When healthcare or social care staff are involved in preparing a care plan for someone who has appointed a personal welfare attorney, they must first assess whether the donor has capacity to agree to the care plan or to parts of it. If the donor lacks capacity, professionals must then consult the attorney and get their agreement to the care plan. They will also need to consult the attorney when considering what action is in the person's best interests."

MCA Code of Practice para 7.25

*"An attorney can only consent to or refuse life-sustaining treatment on behalf of the donor if, when making the LPA, the donor has specifically stated in the LPA document that they want the attorney to have this authority." (*MCA Code of Practice*, para 7.30)

Determining the patient's best interests

When a patient lacks the capacity to consent to, or refuse, medical treatment, the doctor concerned will have to decide what is in the patient's best interests (see Box 8). In doing so, the focus should be on what the patient would consider his/her best interests, not what the doctor would consider his/her best interests if he were in the same position.

The guidance in Box 9 is taken from the *Mental Capacity Act Code of Practice* and should prove useful to anyone having to determine a patient's best interests, regardless of whether the Act applies in their country.

In England and Wales, if a patient lacks capacity and has no-one (other than paid workers) to represent his/her interests, an Independent Mental Capacity Advocate (IMCA) must be consulted whenever serious medical treatment or a change of accommodation is being contemplated.

In Scotland, when non-emergency treatment is considered to be in the patient's best interests, the doctor with overall responsibility for the patient's care must certify that the patient is not capable of consenting to the proposed treatment. The certificate authorises the doctor to "do what is reasonable in the circumstances, in relation to the medical treatment, to safeguard or promote the physical or mental health of the adult".[10]

Box 8: Treating patients who lack capacity

1. Benefit (ie, your intervention must be necessary and must benefit the patient)
2. Minimum intervention (ie, your intervention must be the minimum necessary to achieve the purpose)
3. Take account of the wishes of the adult (ie, you must take account of the adult's present and past wishes and feelings and you must try every possible means of communicating with the adult to find out what these are)
4. Consultation with relevant others (ie, you must take into account the views of the adult's nearest relative and primary carer, and of any other person with powers to intervene in the adult's affairs or personal welfare, or with an interest in the adult, so far as it is reasonable and practicable to do so)
5. Encourage the patient to use residual capacity (ie, you must encourage the adult to use any skills he or she has to participate in decision-making)

Adults with Incapacity (Scotland) Act 2000

Box 9: Best interests

A person trying to work out the best interests of a person who lacks capacity to make a particular decision … should:

- encourage the person to take part, or to improve their ability to take part, in making the decision
- try to identify all the things that the person who lacks capacity would take into account if they were making the decision or acting for themselves
- try to find out the views of the person who lacks capacity, including:
  - the person's past and present wishes and feelings – these may have been expressed verbally, in writing or through behaviour or habits.
  - any beliefs and values (e.g. religious, cultural, moral or political) that would be likely to influence the decision in question.
  - any other factors the person themselves would be likely to consider if they were making the decision or acting for themselves.
- not make assumptions about someone's best interests simply on the basis of the person's age, appearance, condition or behaviour.
- consider whether the person is likely to regain capacity (e.g. after receiving medical treatment). If so, can the decision wait until then?
- not be motivated in any way by a desire to bring about the person's death. They should not make assumptions about the person's quality of life.
- if it is practical and appropriate to do so, consult other people for their views about the person's best interests and to see if they have any information about the person's wishes and feelings, beliefs and values. In particular, try to consult:
  - anyone previously named by the person as someone to be consulted on either the decision in question or on similar issues
  - anyone engaged in caring for the person
  - close relatives, friends or others who take an interest in the person's welfare
  - any attorney appointed under a Lasting Power of Attorney or Enduring Power of Attorney made by the person
  - any deputy appointed by the Court of Protection to make decisions for the person.
- For decisions about major medical treatment or where the person should live and where there is no-one who fits into any of the above categories, an Independent Mental Capacity Advocate (IMCA) must be consulted.
- When consulting, remember that the person who lacks the capacity to make the decision or act for themselves still has a right to keep their affairs private – so it would not be right to share every piece of information with everyone.
- see if there are other options that may be less restrictive of the person's rights.
- weigh up all of these factors in order to work out what is in the person's best interests.

MCA Code of Practice, pp. 65–6

Research

The GMC states that seeking consent is fundamental to research involving people and that consent is only legally valid and professionally acceptable when patients have the capacity to give consent, have been properly informed, and agreed to participate in the research programme without coercion. The GMC goes on to state "You must ensure that any individuals whom you invite to take part in research are given the information which they want or ought to know, and that is presented in terms and a form that they can understand."[11] The information that should be provided is set out in Box 10.

Section 30 of the Mental Capacity Act deals with medical research where the patient lacks capacity, making intrusive research unlawful unless it is (a) part of a research project approved by a recognised Ethics Committee and (b) has the potential of benefiting the patient without posing a disproportionate burden or is intended to shed light on the causes or treatment of their medical condition or something similar.

Any research that does not benefit the participant directly must carry negligible risks of harm. Moreover, it must not interfere with his/her freedom of privacy.

Box 10: What patients should know before agreeing to participate in clinical trials and research

- What the research aims to achieve, an outline of the research method and confirmation that a Research Ethics Committee has approved the project;
- The legal safeguards provided for participants;
- The reasons that the patient or participant has been asked to participate;
- If the project involves randomisation, the nature of the process and the reasons for it, and the fact that in double blind research trials, neither the patient nor the treatment team will know whether a patient is receiving the treatment being tested or is in the control group;
- Information about possible benefits and risks;
- An explanation of which parts of treatment are experimental or not fully tested;
- Advice that they can withdraw at any time and, where relevant, an assurance that this will not adversely affect their relationship with those providing care;
- An explanation of how personal information will be stored, transmitted and published;
- What information will be available to the participant about the outcome of the research and how that information will be presented;
- Arrangements for responding to adverse events;
- Details of compensation available should participants suffer harm as a result of their participation in the research.

GMC, *Research: The Role and Responsibilities of Doctors* (2002), para 20.

How long does consent last?

For many elective procedures, consent is taken in the outpatient department weeks or sometimes months prior to admission for surgery. There is no specific time limit on consent taken in advance, but further questions may occur to patients, or doubts about the wisdom of their decision may creep in during the interim. Patients' conditions may also change during the intervening period, or new information about the procedure may have become available. NHS consent forms have a space at the end for confirming consent prior to the procedure; this should be used as a prompt to find out if there have been any material changes since consent was first taken, and to ask the patient if there are any further questions.

Implied and express consent

Patients undergoing investigations or treatment that carry a higher risk will normally give express consent – either by signing a consent form or stating that they agree to go ahead with treatment. The GMC says that written consent should be taken where:

- the investigation or treatment is complex or involves significant risks
- there may be significant consequences for the patient's employment, or social or personal life
- providing clinical care is not the primary purpose of the investigation or treatment
- the treatment is part of a research programme or is an innovative treatment designed specifically for their benefit.[12]

Written consent is required by law for fertility treatment – the relevant forms can be obtained from the Human Fertilisation and Embryology Authority. The Mental Health Act 1983 also requires written consent to be taken in some specific cases.

However, consent is often implied by the patient's compliance, an obvious example being when a patient rolls up a sleeve so that a blood sample can be taken. Nevertheless, patients should be told about the nature and purpose of any examination, investigation or procedure beforehand.

Patient information leaflets

Numerous studies have shown that patients retain comparatively little information given to them during a consultation, particularly if they are anxious or in pain. Many patients find it helpful if they are given written information as a reminder of the key points discussed. However, written information is not a substitute for detailed discussion with patients and must be seen as an adjunct to, not a replacement for, that discussion. If information leaflet are used to augment discussion with a patient, this should be documented in the patient's notes. Before sharing any literature with a patient, it should be checked to make sure that it's accurate and up to date.

When patients are being asked to absorb a great deal of detailed and complex information, it may be helpful to audio-record the consultation and give the patient a copy to take home and mull over to help their decision-making.

Recording consent and consent forms

Apart from certain treatments carried out under the Mental Health Act and some forms of fertility treatment, there is no legal requirement to obtain written consent, but most health organisations, including NHS trusts, independent hospitals and primary care trusts, have policies stipulating when written consent should be obtained. Employees are expected to be familiar with these and adhere to them.

The presence of a signed consent form does not in itself prove valid consent to treatment – the important factors will always be the quality, extent and accuracy of the information given beforehand. Being able to demonstrate this afterwards depends on contemporaneous notes recording the key points discussed and relevant warnings given to the patient.

Scenario 5

Mr S attends the A & E department of his local hospital with a severe allergic reaction thought to be from an insect bite. In addition to topical applications, he is given antihistamines. The following day he is involved in a road traffic accident, having failed to stop at a road junction. He claims that he was not informed that the medication could cause drowsiness and that it would be inadvisable for him to drive. But the doctor at the hospital is adamant that appropriate warnings were given. However, these were not recorded in the notes. Mr S subsequently makes a claim and the trust's solicitors advise settlement as they would be unable to prove that appropriate warnings were given.

Refusing consent

Consent law would be completely pointless if it did not protect a patient's right to refuse treatment. Doctors cannot override a patient's refusal of treatment simply because they think it is a foolish or illogical decision. But neither can clinicians disregard patients who choose not to take their advice.

If the patient is not giving clear reasons for refusing the proposed treatment, it may be worth probing a little further to find out whether they are harbouring hidden fears and anxieties that could be assuaged with further information and discussion. Any such discussion, however, must be conducted sensitively and respectfully, otherwise it could be construed as coercion.

Occasionally, it may be appropriate to assess the patient's capacity, but the patient's refusal should never, in itself, be taken as evidence of lack of capacity. If the patient is capable, they should be given all material information to ensure that the refusal is truly informed. Available alternatives should then be offered, with a reminder that the patient can change their mind.

Scenario 6

Mrs D is 42 and has recently discovered a lump in her breast. She is told that malignancy cannot be excluded and an urgent referral to a specialist is required. She asks the GP to defer the referral, explaining that her daughter is currently preparing for important exams in five weeks time and she does not want to cause her any anxiety. Dr F, her GP, cannot understand how she can take such a risk but it is clear on talking to her that she fully understands the implications of her decision. Dr F records his findings along with Mrs D's reasons for not agreeing to an immediate referral.

Who should take consent?

As consent is a process centred on discussing the benefits, side effects and potential complications of proposed treatments and procedures, the person who takes consent must also be able to provide all necessary information to the patient and so, ideally, the person taking consent should be the same person providing that aspect of the patient's care. As that is not always practicable, obtaining consent can be delegated to others – not necessarily doctors – providing that they are suitably trained and qualified, have sufficient knowledge of the proposed investigation or treatment and understand the risks involved, and otherwise act in accordance with the guidance set out by the GMC and the Department of Health. Doctors who delegate responsibility for obtaining consent remain responsible for ensuring that their patients have been given sufficient time and information to make an informed decision before embarking on treatment, and that their consent to proceed is valid.

Scenario 7

Dr T is an F1 doctor doing a rotation in gynaecology. Mrs V is admitted prior to a Uterine Artery Embolisation (UAE) and Dr T is asked to confirm her consent to the procedure, which she gave three weeks earlier in the outpatients' department. Further questions and some concerns have occurred to Mrs V in the intervening weeks, and she particularly wants to know how the UAE will affect her chances of conceiving and carrying a baby to term. Dr T has only a sketchy, theoretical, understanding of the procedure, which he has never seen performed. He is therefore not competent to obtain Mrs V's consent and must refer her questions to the radiologist who will be carrying out the procedure.

Withdrawing consent

Patients with capacity can also withdraw consent for continuing treatment. If, during a procedure, a patient indicates that she/he wants you to stop, you should stop the procedure as soon as it is safe to do so and then explain the consequences of not proceeding further, without implying coercion. It is important to let patients know that stopping a procedure will not compromise their care.

The rights of patients who lack capacity should also be respected in this regard. If they indicate that they want a procedure to stop because they are in pain or discomfort, their wishes should be complied with, as above.

Scenario 8

Mr D is admitted as a day case for colonoscopy for investigation of rectal bleeding. As he wants to be able to drive himself home after the procedure, he chooses not to have any sedation. He finds the colonoscopy extremely uncomfortable and insists that the procedure be stopped. This happens just when the surgeon identifies a suspicious-looking lesion in the transverse colon.

The surgeon stops the procedure and then explains the situation to Mr D, who agrees to sedation being administered so the colonoscopy can be continued and the lesion biopsied. Arrangements are then made to contact a friend to collect Mr D after the procedure.

Appendix 1

Key cases that have shaped consent law

Consent law is not set in stone; it has evolved considerably over the last 120 years and continues to be refined through case law, GMC guidance and legislation.

In 1896 in the case of *Beatty v Cullingworth*,[13] the patient, who was a nurse, consented to removal of her right ovary, specifically telling the surgeon beforehand that if both ovaries were found to be diseased, neither should be removed. The surgeon said that she should leave that to him to which she made no reply. At operation, both ovaries were removed as the left as well as the right was found to be diseased. When the case came to trial, the judge said "If a medical man undertook an operation, it was a humane thing for him to do everything in his power to remove the mischief." The jury returned a verdict for the defendant (surgeon) despite the absence of consent.

Almost 60 years later, the courts were equally protective of the doctor's position in the case of *Hatcher v Black*.[14] Mrs Hatcher, who occasionally broadcast for the BBC, went into hospital for a partial thyroidectomy. Understandably, she asked if there was any risk to her voice and was reassured by the doctors. During the course of the operation the recurrent laryngeal nerve was damaged. Postoperatively she could not speak properly and never broadcast again. In summing up, Lord Denning found that the surgeon had lied to the patient by telling her there was no risk to her voice when he knew that the risk existed. He went on to say that not one of the doctors that had been called to give evidence had suggested that the surgeon did wrong and that all agreed that it was a matter for his judgment. Lord Denning concluded "They did not condemn him; nor should we."

In 1972, there was a radical development in consent law in the United States. In California, the case of *Canterbury v Spence*[15] introduced the doctrine of informed consent. The claimant consulted Dr Spence because of severe pain between his shoulder blades and was advised to undergo surgery after a myelogram showed distortion of the thoracic vertebrae. Before the procedure, the 19-year-old patient did not ask any questions or voice any reservations about the proposed treatment. Postoperatively, Mr Canterbury suffered incontinence and had difficulty in walking. At trial, the judge stated "The patient's right of self decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is the information material to the decision."

But 13 years later, in the UK, the House of Lords rejected the doctrine of informed consent in the *Sidaway*[16] case. Mrs Sidaway consulted a neurosurgeon as she had persistent pain in her back. She was advised to undergo surgery and was told of the risks of damaging the nerves emerging from the spinal column but not of the risk of spinal vein thrombosis, reckoned to be a less than one per cent risk. Unfortunately, Mrs Sidaway developed a postoperative hemiplegia secondary to spinal vein thrombosis and sued on the grounds that, had she known of the risk, she would not have consented to undergo surgery.

The Law Lords were not unanimous in their view, but the majority decided that when counselling patients prior to surgery or any other procedure, "the degree of disclosure required to assist a patient to make a rational choice as to whether or not to undergo a particular treatment must primarily be a matter of clinical judgment".

Rogers v Whitaker[17] was an Australian case in which a woman who wanted to return to work sought advice from an ophthalmic surgeon as she had suffered an eye injury years before and had been left with an unsightly and blind eye. She was told there was nothing that could be done to restore her sight, but there was scope for cosmetic improvement. Prior to the operation, she asked three times if there was anything that could go wrong and was reassured that no serious complications were associated with the surgery. Unfortunately, she developed sympathetic ophthalmitis in her good eye and was rendered totally blind. She sued the surgeon, saying that she should have been warned of this rare complication of surgery. The defence to her claim was based on the grounds that the risk was so small, estimated at just 1 in 14,000, that there was no duty to warn the patient about it. The courts found in the patient's favour on the grounds that the risk of total blindness, no matter how small, was material to the patient's decision and it was negligent not to advise her of the risk so that she could decide whether or not to go ahead with surgery.

The next major development in the UK was in 1998, when the GMC published *Seeking Patients' Consent: The Ethical Considerations*, which set out in explicit terms the information doctors ought to provide to patients before seeking consent to treatment.

In 2004, another neurosurgical negligence claim – *Chester v Afshar*[18] – was considered by the House of Lords. Its effect was to make more important than ever the need to ensure that patients are fully informed, understand the information they are given and have sufficient time, where possible, to reflect on their decision.

Miss Chester had a discectomy for low back pain. The procedure was undertaken competently, but Miss Chester was one of the two per cent of patients left with cauda equina syndrome as a result of surgery. She then sued the surgeon, claiming that he had failed to warn her of this risk.

She won that point but, in addition, the *Chester* case established on policy grounds that the patient's autonomy and dignity required that she be allowed the time to make an informed decision. So, in the wake of *Chester v Afshar*, it is imperative that care is taken to warn patients about all risks material to their decision and, when time permits, that they are encouraged to consider their options over time before deciding whether or not to undergo treatment.

As the cases outlined above show, the paternalistic model of doctor–patient relations has gradually been replaced over the years with a much more patient-centred approach to consent. Nowadays, doctors are expected to work in partnership with patients to agree on treatment options, with the patient's needs and wants as the primary consideration. This is the approach adopted by the GMC in its 2008 guidance, *Consent; Patients and Doctors Making Decisions Together.*

Appendix 2

Relevant legislation

Adults with incapacity (Scotland) Act 2000

The Adults with Incapacity (Scotland) Act 2000 was one of the first pieces of legislation passed by the Scottish Parliament and received Royal Assent on 9 May 2000. The idea was to provide a system to allow decisions to be made on behalf of adults who could no longer decide for themselves on issues of property, financial affairs and personal welfare, including medical treatment.

The Act defines incapacity as follows:[19]

"'incapable' means incapable of

a) acting; or

b) making decisions; or

c) communicating decisions; or

d) understanding decisions; or

e) retaining the memory of decisions,

"… by reason of mental disorder or of inability to communicate because of physical disability; but a person shall not fall within this definition by reason only of a lack or deficiency in a faculty of communication if that lack or deficiency can be made good by human or mechanical aid (whether of an interpretative nature or otherwise); and

"'incapacity' shall be construed accordingly."

In addition to the Act itself, there is a *Code of Practice* containing further guidance for those having to make decisions on behalf of others. The Scottish government has also recently produced a very useful guide to communication and assessing capacity.[20]

There are two types of attorney under the Act:

1. Continuing powers of attorney for managing specified aspects of an individual's property or financial affairs when the person no longer has the capacity to deal with those matters, and
2. Welfare attorneys, who are authorised to make decisions about personal welfare, including consenting to medical treatment.

Section 5 of the Act deals with medical treatment and research so that adults with incapacity can be provided with medical treatment aimed at maintaining or improving their physical health. The scheme requires the doctor who has overall responsibility for medical treatment to certify that the patient is incapable of consenting to a particular form of treatment or procedure. This allows the doctor to provide treatment that is reasonable in the circumstances and also to delegate that treatment to other individuals involved in the patient's care. Certificates are now valid for up to three years, but can be revoked or replaced by a new certificate if circumstances have changed.

The authority to provide treatment under the Act

If a welfare attorney has been appointed and there is a disagreement with the medical team on the best form of treatment, the issue can be put before the Court of Session.

The *Code of Practice* published under Part 5 of the Act contains general information about the Act and clarifies how medical treatment can be provided to adults who cannot give consent themselves.

Mental Health (Care and Treatment) (Scotland) Act 2003

Part I of this legislation supports the Adults with Incapacity Act by stipulating that the discharge of functions under the Mental Health Act should be with regard to "the present and past wishes and feelings of the patient" and should take into account the views of

i) "the patient's named person;

ii) any carer of the patient;

iii) any guardian of the patient; and

iv) any welfare attorney of the patient"

The Mental Capacity Act 2005

The Mental Capacity Act 2005 applies only to England and Wales and came fully into force in October 2007. It introduced a number of changes into English law. For the first time, competent adults are able to appoint people they trust to make treatment decisions on their behalf if they become incompetent at a later date. The Act also provides statutory backing to advance refusal of treatment.

In both these circumstances, the adult must be aged 18 or over; for all other purposes the Act defines an adult as a person of 16 or over.

The Act sets out a number of principles (see page 8). In addition to the presumption that all adults have capacity unless it can be demonstrated otherwise, patients cannot be regarded as lacking capacity unless all practicable steps have been taken, without success, to help them come to a decision; the fact that someone has made an unwise, perhaps even life-threatening, decision cannot in itself be taken as evidence of incapacity.

The Act defines a lack of capacity in the following terms:

"… a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself 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) a person's age or appearance, or

b) a condition of his, or an aspect of his behaviour, which might lead others to make unjustified assumptions about his capacity."[21]

It goes on to define an inability to make decisions:

" … a person is unable to make a decision for himself if he is unable

a) to understand the information relevant to the decision

b) to retain that information

c) to use or weigh that information as part of the process of making the decision, or

d) to communicate his decision (whether by talking, using sign language or any other means).

"A person is not to be regarded as unable to understand the information relevant to a decision if he is able to understand an explanation of it given to him in a way that is appropriate to his circumstances (using simple language, visual aids or any other means).

"The fact that a person is able to retain the information relevant to a decision for a short period only does not prevent him from being regarded as able to make the decision.

"The information relevant to a decision includes information about the reasonably foreseeable consequences of

a) deciding one way or another, or

b) failing to make the decision."[22]

Where patients lack capacity, any treatment should be provided on the basis of promoting the patient's best interests.

Exactly what is in someone's best interests will depend upon his/her specific circumstances and is not confined to purely medical considerations. The Act requires that all factors, including religious beliefs or values expressed by the patient when competent be taken into consideration. No decisions can be made merely on the basis of age, appearance or behaviour, and patients must be encouraged to participate in the process of deciding what is to be done even if they lack the capacity to give consent.

Advance decisions

Section 24 of the Act allows competent individuals to make advance decisions about specified treatments they would not wish to be carried out under certain circumstances.

Where there are doubts about whether the patient may have changed his/her mind or whether the advance decision applies to the precise circumstances the patient is now in, the courts may be asked to determine whether or not an advance decision exists and is valid and applicable. Pending the declaration of the court, treatment to sustain life or prevent serious deterioration of the patient's condition should be provided.

No liability is incurred by health professionals for withholding or withdrawing treatment if those responsible for care reasonably believe that a valid and applicable advance decision exists.

Individuals with capacity can grant a lasting power of attorney to others who can then make decisions about their welfare, property and affairs. However, there are a number of restrictions – the powers of an attorney do not extend to refusing or continuing life-sustaining treatment unless the patient expressly gave authority to that effect.

A *Code of Practice* (see reading list) is also published under the Act, providing more accessible advice on how to assist patients who are unable to make treatment decisions on their own.

Appendix 3

Further reading

Relevant GMC guidance

www.gmc-uk.org

Consent: Patients and Doctors Making Decisions Together (June 2008)

0–18 Years: Guidance for All Doctors (October 2007)

Good Medical Practice (2006)

Research: The Role and Responsibilities of Doctors (February 2002)

Withholding and Withdrawing Life-Prolonging Treatments: Good Practice in Decision-Making (2002)

Department of Health publications

Good Practice in Consent Implementation Guide: Consent to Examination or Treatment (November 2001)

Seeking Consent: Working with People with Learning Disabilities (November 2001)

Seeking Consent: Working with Older People (November 2001)

Reference Guide to Consent for Examination or Treatment (April 2001)

Seeking Consent: Working with Children (January 2001)

Seeking Consent: Working with People in Prison (July 2002)

Northern Ireland

Department of Health, Social Services and Public Safety, *Good Practice in Consent: Consent for Examination, Treatment or Care* (March 2003)

Scotland

A Good Practice Guide on Consent for Health Professionals in NHS Scotland (June 2006)

Government publications

England and Wales

Mental Capacity Act 2005: Code of Practice (April 2007) Published by the Department for Constitutional Affairs: www.dca.gov.uk

Explanatory booklets relating to the Mental Capacity Act www.publicguardian.gov.uk

Scotland

www.scotland.gov.uk

Adults with Incapacity (Scotland) Act 2000: Code of Practice (2002)

Adults with Incapacity (Scotland) Act 2000: Workbook and Guidance for Social and Healthcare Staff: Pack 2.

Adults with Incapacity (Scotland) Act 2000: Communication and Assessing Capacity: A Guide for Social Work and Healthcare Staff (2007) Published by the Civil and International Justice Directorate.

BMA guidance

www.bma.org.uk

Consent Toolkit, third edition (August 2007)

Advance Decisions and Proxy Decision-Making in Medical Treatment and Research (June 2007)

Medical Treatment for Adults with Incapacity: Guidance on Ethical and Medico-Legal Issues in Scotland, second edition (October 2002)

The Mental Capacity Act 2005 – Guidance for Health Professionals (April 2007)

Books

English, Veronica, *Assessment of Mental Capacity: Guidance for Doctors and Lawyers*, second revised edition, (April 2004) BMJ Books

BMA Ethics Department, *Medical Ethics Today: Its Practice and Philosophy* (2003) BMJ Books

Bartlett, Peter, *Blackstone's Guide to the Mental Capacity Act 2005*, 2nd Revised edition (February 2008) Oxford University Press

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3. *Re C* (adult: refusal of medical treatment) [1994]
4. *Mental Capacity Act 2005: Code of Practice.*
5. GMC, *0–18 Years: Guidance for All Doctors (*2007*)*.
6. GMC, *Consent: Patients and Doctors Making Decisions Together* (June 2008) para 8.
7. GMC, *Consent: Patients and Doctors Making Decisions Together* (June 2008) para 14.
8. GMC, *Consent: Patients and Doctors Making Decisions Together* (June 2008) para 42.
9. GMC, *Withholding and Withdrawing Life-Prolonging Treatments: Good Practice in Decision-Making* (2002)
10. *Adults with Incapacity (Scotland) Act 2000: Explanatory Notes*, para 171.
11. GMC, *Research: The Role and Responsibilities of Doctors* (2002), para 19.
12. GMC, *Consent: Patients and Doctors Making Decisions Together* (June 2008) para 49.
13. *Beatty v. Cullingworth*, 44 CENT. L. J. 153 (Q.B. 1896)(unreported)
14. *Hatcher v Black, The Times* 2 July (1954)
15. *Canterbury v Spence* (1972) 464 F (2nd) 772
16. *Sidaway v Governors of Bethlem Royal Hospital* [1985] 1 All 643
17. *Roger v Whitaker* (1992) 175 CLR 479
18. *Chester v Afshar* [2004] UKHL 41.
19. *Adults with Incapacity (Scotland) Act 2000, section 6.*
20. Scottish Government, *Adults with Incapacity (Scotland) Act 2000: Communication and Assessing Capacity: A Guide for Social Work and Health Care Staff* (October 2007).
21. *Mental Capacity Act 2005*, section 2.
22. *Mental Capacity Act 2005*, section 3.

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