

AN ESSENTIAL GUIDE TO CONSENT

ADVICE FOR THE UNITED KINGDOM

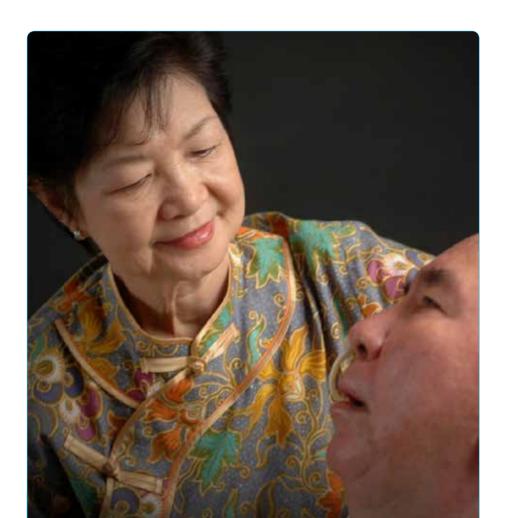


INTRODUCTION

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

THE FIVE PRINCIPLES OF THE MENTAL CAPACITY ACT:

- A person must be assumed to have capacity unless it is established that they lack 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.
- 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.

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.

FNGI AND AND WAI FS

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 (Scotland) Act 2000 as being incapable of any of the following:

- · Acting on a decision
- · 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". The Scottish Government offers the following guidance for assessing capacity:

- 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 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?

ASSESSING CAPACITY

THE MENTAL CAPACITY ACT CODE OF PRACTICE

The Mental Capacity Act Code of Practice contains guidance on assessing an individual's ability to make a decision:

- 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)?

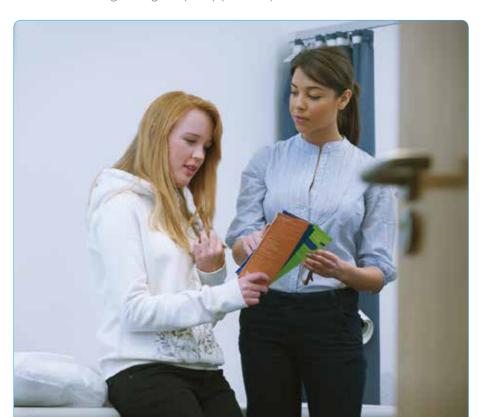
FLUCTUATING CAPACITY

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 personal welfare lasting power of attorney (a welfare attorney in Scotland).

CHILDREN AND YOUNG PEOPLE

In all aspects of caring for children, the child's welfare is the paramount consideration.

Patients under the age of 16 may or may not have the capacity to consent to treatment. The test of capacity in children is 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. In Scotland the test is contained in the Age of Legal Capacity (Scotland) Act 1991.



WHO HAS PARENTAL RESPONSIBILITY?

Someone with parental responsibility may consent to treatment on behalf of a non-competent 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. Where the child is competent and there is a dispute you should seek advice.

Also see the GMC guidance, 0-18 Years: Guidance for All Doctors (2007), paras 22-41.



Unless patients have sufficient information, they are not in a position to decide what is best for them

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 (2008), the GMC has set out what patients ought to know before deciding whether to consent to treatment or an investigation. In addition, a Supreme Court judgment in March 2015 stated that patients must be made aware of any "material risks" involved in a proposed treatment, together with reasonable alternatives. The judgment, made in the case Montgomery v Lanarkshire Health Board, describes the test of materiality as when "a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it".

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 leaflets 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 is accurate and up to date.

VOLUNTARINESS

Patients overtly coerced into undergoing treatment they 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 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.

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.

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

ADVANCE DECISIONS AND ADVANCE STATEMENTS

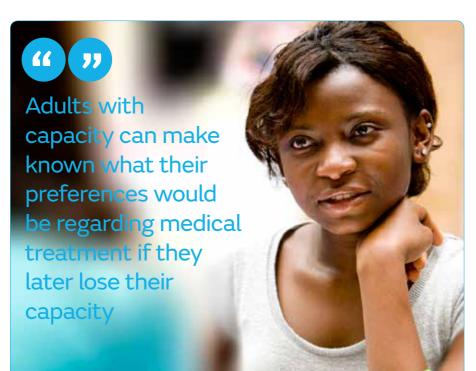
Adults with capacity can make known what their preferences would be regarding medical treatment if they later lose their capacity. They must have capacity at the time of making the decision.

A valid 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.

The situation regarding advance decisions (or directives) in Scotland and Northern Ireland is governed by common law rather than legislation.

Before acting on an advance decision to refuse treatment, doctors must be satisfied that it is still valid and applies to the current circumstances.

See the GMC guidance, Treatment and Care Towards the End of Life: Good Practice in Decision Making (2010), for more information.



CONSENT BY PROXY

In Scotland, England and Wales, capable adults can appoint someone to make healthcare decisions on their behalf if they become incapacitated. This is explained in full in the *Mental Capacity Act Code of Practice*, and the Adults with Incapacity (Scotland) Act 2000.

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. In England and Wales the Mental Capacity Act Code of Practice outlines the best interests test:

- 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 (eg, 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
- Do 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 (eg, after receiving medical treatment). If so, can the decision wait until then?
- Do not be motivated in any way by a desire to bring about the person's death. Do 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

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.

Guidance on ensuring this is provided in the GMC's supplementary documents Good Practice in Research and Consent to Research (both 2010).

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's guidance Consent: Patients and Doctors Making Decisions Together (2008) outlines the differences between implied and express consent, as well as advising on the correct approach.

WHO SHOULD TAKE CONSENT?

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 Department of Health and your own regulator.

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.

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 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.

CASES

Scenario 1

Mrs N is 86 years old and has had 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

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

Scenario 3

Thirteen-year-old E is attending boarding school while his parents are in Africa working. One evening his house master, Mr G, brings him to the Emergency Department (ED); 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. However, even if E had been deemed not competent to make a decision, the treatment could still have gone ahead as it was in E's best interests. The consequences of not operating in this case would be profound.

* "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 (2nd edition) (2009), p37.

Scenario 4

Mr H is a plasterer in his late 40s. 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 steroid. As he is aware that Mr H is selfemployed 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.

Scenario 5

Mr S attends the ED 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.

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.

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.

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.

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