



**Consent to Medical
Treatment in Ireland
An MPS Guide for Clinicians**

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Important – please note

Due to the dynamic nature of medical law we suggest that you access our website at www.medicalprotection.org/ireland for the most up-to-date information. January 2015

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Review date January 2017

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Introduction

In most situations, obtaining a patient's valid consent to a procedure or treatment is a simple matter of following straightforward guidelines, but circumstances can occasionally develop in which conflicting principles must be resolved and this can pose a dilemma for clinicians. This booklet has been written as a guide to the ethical and legal principles that should be applied, both in straightforward and more challenging circumstances.

In all circumstances, the overriding duties of a clinician can be summed up as follows:

- To respect the bodily integrity and right to self-determination of patients
- Where it is not possible to obtain a patient's valid consent, to act in the patient's best interests.

To treat patients without their consent is a violation of their constitutional rights and transgresses 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 Medical Council or criminal proceedings for assault.

There are three components to valid consent:

- Capacity
- Information
- Voluntariness.



Capacity

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 (but see Box 1 regarding Wards of Court).

The test of capacity currently applied in the Irish courts is the “C test”, which derives from the English case of *Re C* (see Appendix 1)¹. The test is in three parts, all of which have to be fulfilled for a patient to be deemed competent to make the decision they are being asked to consider:

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

The Mental Capacity Bill which was originally drafted in 2008 is still pending at the time of writing (January 2015). However this draft defines capacity as “the ability to understand the nature and consequences of a decision in the context of available choices at the time the decision is to be made”. It also includes provisions for the establishment of a Guardian Board to replace the Ward of Court. Under this system, it will be possible to appoint personal guardians who will be able to make healthcare decisions on an incapacitated person's behalf.

Box 1: Wards of Court

Although, in general, a person's capacity to make a decision should be assessed in context, under current legislation* a Ward of Court has been deemed to be of “unsound mind” and thus loses the right to make decisions on his/her own behalf. Routine decisions regarding a Ward's day to day welfare are made by a person appointed by the court, but consent to medical treatment must be obtained from the President of the High Court.

Regardless of the legal obligation to refer matters of consent to the court, however, doctors are still bound by professional ethics and these dictate that they must respect patients rights to bodily integrity and involve them in decision-making to the best of their ability (see Box 3 for guidance on this).

* The Lunacy Regulation (Ireland) Act 1871.

At present, no-one outside the courts can consent to treatment on behalf of an incapacitated adult. This does not mean, however, that incapacitated adults should be denied necessary medical treatment. Treatment can – and should – be given if the patient’s doctors, in consultation with the patient’s relatives and carers, conclude that it is in the patient’s best interests. The focus should be on what the patient would consider to be in his/her best interests, not what the doctor would want done if he were in the same position. Any intervention should be the minimum necessary to safeguard the patient’s wellbeing. The guidance in Box 2 is taken from the English Mental Capacity Act Code of Practice. Although it derives from English law, it sets out basic principles that are persuasive or likely to be applicable in Ireland.

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 his/her behaviour and 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 the patient, discussing it with him/her to gauge his/her understanding and then asking questions about the salient points to see if he/she has 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 rephrased as “Tell me what you understand by...” Words like “What”, “How,” “Why,” and “Tell me” are good for framing questions with open-ended answers.

Assessing capacity can be very difficult where the patient suffers from serious communication problems, and in these circumstances it may be necessary to involve a speech and language therapist, a translator, or other professionals with specialist 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.

Box 2: 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 (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.
- 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?
- 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 made by the person.
- 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.



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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.

Even if a patient lacks capacity, there is still an onus upon health professionals to involve patients in as much as is possible in decisions that affect their lives (see Box 3).



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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.

Box 3: Involving patients who lack capacity in decisions

The following advice is taken from the UK's Mental Capacity Act Code of Practice (2005).

Even if the person lacks capacity to make the decision, they may have views on matters affecting the decision, and on what outcome would be preferred. Their involvement can help work out what would be in their best interests.

[There are] a number of practical steps to assist and enable decision-making, which may also be helpful in encouraging greater participation. These include:

- Using simple language and/or illustrations or photographs to help the person understand the options.
- Asking them about the decision at a time and location where the person feels most relaxed and at ease.
- Using specialist interpreters or signers to communicate with the person.

This may mean that other people are required to communicate with the person to establish their views. For example, a trusted relative or friend, a full-time carer or an advocate may be able to help the person to express wishes or aspirations or to indicate a preference between different options.

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, but if this is not an option, treatment may be provided to preserve the patient's life or health² or, if the patient is under the age of 18, with parental consent.

Children and young people

Age 16 or 17

Although the age of majority is 18, the law recognises 16 and 17 year olds as having the capacity to consent to medical and dental treatment on their own behalf.³ It is not clear, however, whether someone of this age has a right to refuse as well as consent to treatment as this has not yet been tested in the courts. Theoretically, a parent or legal guardian can consent to treatment that a 16 or 17 year old is refusing, but this is not an ideal situation (especially if the minor concerned has the capacity to understand the implications of his/her decision) and in such circumstances it is probably better to refer the matter to the court to decide.

If a minor of 16 or over is incapable of giving consent, it may be obtained from the young person's parent/guardian (see Box 5) or, if necessary, the court.

Under 16

In law, the consent of the parent or legal guardian is required if a child is under the age of 16. In practice, however, it is reasonable to seek the consent of a minor with the capacity to understand the nature and implications of the proposed treatment or procedure. This should not present a problem if the child and parents are in accord about a decision to consent to treatment. Difficulties can arise, however, if the parents of a minor are in disagreement with clinicians or the patient about what is in the child's best interests.

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. In this situation, the best course is usually to refer the matter to the hospital's legal team or the HSE.

The Irish Constitution recognises the family as "a moral institution possessing inalienable and imprescriptible rights, antecedent and superior to all positive law"⁴ so the courts tend to take the view that parents' wishes should only be overridden in exceptional circumstances – ie, if there is a serious threat to a child's life or wellbeing. But balancing the respective rights of child and parent may not be easy: as Justice Murphy put it in a 2001 Supreme Court case,⁵ "It would be

impossible and undesirable to seek to define in one neat rule or formula for all the circumstances in which the State might intervene in the interests of the child against the express wishes of the parent". (See Appendix 1 for a summary of the case *Northwestern Health Board v HW and CW*.)

If there is reason to believe that a parent's refusal to consent to a child's medical treatment is placing that child at risk, the health board can apply to the District Court for an emergency care order. If granted, the care order will place the child temporarily in the care of the health board, which can then consent to the child's medical treatment.⁶

In the Supreme Court case cited above, the child in question was an infant, and therefore unable to express an opinion for himself. The opinions of children with the capacity to understand the nature and implications of a proposed treatment should, however, carry considerable weight in any decisions about what is in their best interests, even though they lack the legal right to consent to treatment (see Box 4).



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Box 4: Taking a child's wishes into account

"Children and young people should be involved as much as possible in discussions about their healthcare. When you are talking to a child or young person, it is important to give them information in an age-appropriate manner, listen to their views and treat them with respect."

Medical Council, *Guide to Professional Conduct for Ethics for Registered Medical Practitioners* 7th edition (2009) para 43.1

Box 5: Who can consent on behalf of a minor

The minor him/herself

Section 23 of The Non-Fatal Offences Against the Persons Act 1997 provides for minors aged 16 or 17 to consent to surgical, medical or dental treatment. Generally speaking, parental consent is needed for all other minors, and for 16 and 17 year olds who lack capacity, but there may be circumstances in which a person under the age of 16 who demonstrates the maturity to understand the implications of a particular treatment does not wish his or her parents to be involved in that decision. In these circumstances, the patient's confidentiality should be respected.

Parents

A child's mother, whether married or unmarried, has automatic legal guardianship of the child.

The child's father also has guardianship if he is married to the child's mother, either before or after the birth of the child.

A father who is not married to the mother can be appointed as a joint guardian of the child if he and the child's mother have made a statutory declaration to that effect. Alternatively, he can apply to the courts to be appointed a joint guardian.

Legal guardians

Testamentary (ie, named in a deceased parent's will) and court-appointed guardians can make healthcare decisions on a child's behalf.

Foster carers

Foster carers can consent to urgent medical treatment for a child. They can also consent to ancillary treatment, such as a general anaesthetic.*

For non-urgent treatment, consent should be sought from the child's natural parents.

Foster carers or relatives who have been caring for a child for five years or more may be granted a court order that authorises them to consent to "any necessary medical or psychiatric examination, treatment or assessment with respect to the child".**

* Department of Health and Children Circular, *Consent to Medical Treatment for Foster Children*, 6 November 1999.

** Child Care (Amendment) Act 2007, section 43A

Box 5: (continued) Who can consent on behalf of a minor

Health board

If a care order has been made for a child under 16 years of age, the health board can consent to elective treatment in the best interests of the child. It is good practice, however, to also consult the child's parents if possible.

The courts

If a child has been made a Ward of Court, the consent of the court is needed before medical treatment can be carried out, except in an emergency, where it is permissible to proceed with treatment in the child's best interests.

The District Court can make an emergency care order placing a child in the care of the local health board if there is uncertainty or dispute about the validity of a refusal of treatment on the part of a parent or a minor aged 16 or more.

Consent to disclosure of personal health information

"[An] individual may be assumed to be competent to give consent on reaching the age of 16 in line with current medical practice. Where the individual is below that age, consent may still be given but this requires that the medical practitioner involved must assess whether a child or young person has the maturity to understand and make their own decisions about the handling of their personal health information."

"...Where the individual is below [16 years], the general practitioner should exercise professional judgment, on a case by case basis, on whether the entitlement to access should be exercisable by:

- (i) the individual alone,
- (ii) a parent or guardian alone, or
- (iii) both jointly. In making a decision, particular regard should be had to the maturity of the young person concerned and his or her best interests. ... In all of this, the general practitioner should have regard to both the established medical ethics position and the role of parents in their duty of care as laid down in case law."

ICGP and GPIT, *Managing and Protecting the Privacy of Personal Health Information in Irish General Practice* (2003)

A balance must be found between:

- The best interests of the child.
- The wishes of the child, if known.
- The wishes of the parents.

The weight given to each of the above will depend on the circumstances; the “best interests” argument will carry more weight, for example, if the child’s life is at stake.

If there are two people with parental responsibility, it is usually sufficient for one of them to give consent, but where decisions may have profound, irreversible consequences, both of them 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.



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Box 6: Assessing a child’s maturity

Although they have no legal footing in Ireland, the Fraser Guidelines (derived from the Gillick case in England – see Appendix 1) nevertheless provide a useful template for decision making when considering offering contraceptive services to under 16s without parental knowledge or permission.

The Fraser Guidelines

- The young person understands the advice being given.
- The young person cannot be convinced to involve parents/carers or allow the medical practitioner to do so.
- It is likely that the young person will begin or continue having intercourse with or without treatment/contraception.
- If the treatment/contraception is not given, the young person’s physical or mental health (or both) is likely to suffer.
- The young person’s best interests require contraceptive advice, treatment or supplies to be given without parental consent.

Medical Practitioners 7th edition (2009) para 43.1

Sexual health

There is no set minimum age for contraceptive advice and treatment, but it should be borne in mind that the legal age of consent for sexual intercourse is 17. If there is reason to believe that a child or young person is being exploited or abused, child protection procedures should be implemented. Otherwise, provided the young person concerned has the maturity to understand the implications of her decisions (see Box 6), her confidentiality should be respected, even if this means not involving her parents in treatment decisions (see Box 5). This position is endorsed by the Data Protection Commissioner.⁷

There are sometimes difficult judgments to make in these situations and it can be a delicate balancing act to accommodate competing ethical and legal considerations. Aspects to weigh in the balance are:

1. The age of the child – obviously, the younger and more immature the patient, the more seriously you should consider instituting child protection procedures or involving his/her parents.
2. The child's rights and best interests. You should, as far as possible, respect the child's confidentiality and make his/her health and welfare your primary concern.
3. The special place that the family occupies in the Irish Constitution (see page 9)
4. The law on consent. The Non-Fatal Offences Against the Persons Act provides for children of 16 or above to consent to medical or surgical treatment. It has nothing to say, however, about children under that age. The Criminal Law (Sexual Offences) Act 1993 has more serious penalties for sexual relations with under 15s than with under 17s.

It is extremely important that, in making these difficult judgments, you are able to justify your decision if it is later called into question. Comprehensive documentation of your reasoning at the time is therefore vital. If you are at all uncertain about the best course of action to take in these circumstances, you can always contact MPS for advice.

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 *Good Medical Practice in Seeking Informed Consent to Treatment*, the Medical Council has set out what patients ought to know before deciding whether to consent to treatment or an investigation. (See Box 7.)

Discussion of all the issues surrounding a proposed investigation or treatment is an integral part of the patient's clinical care. Discussions about the options available to the patient may take place over several consultations, all forming a part of the consent process. Clinical negligence claims alleging invalid consent rarely turn merely on the presence or absence of a consent form, but usually involve in-depth analysis of the information and advice provided to the patient and whether he/she was given all the information material to the decision.

When patients ask questions about proposed treatments and their available options, responses should be full and honest – there is no place for omitting facts because the patient might be anxious or worry about the potential consequences. The only justification for withholding information from patients is where disclosure would be likely to cause serious harm to their mental or physical health. These circumstances are extremely rare.

If intervention is needed urgently, it may be impossible to provide all the information set out in Box 7; 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 7: Information the patient should be given in the consent process

- Details of the diagnosis, and prognosis, and the likely prognosis if the condition is left untreated.
- Uncertainties about the diagnosis, including options for further investigation prior to treatment.
- Options for treatment or management of the condition, including the option not to treat.
- The purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief; preparation for the procedure; and what the patient might experience during or after the procedure, including common and serious side effects.
- For each option, explanations of the likely benefits and the probabilities of success; discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused by, or necessitated by, the treatment.
- Advice about whether a proposed treatment is experimental.
- How and when the patient's condition and any side effects will be monitored or reassessed.
- The name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team.
- Whether doctors in training will be involved, and the extent to which students may be involved in an investigation or treatment.
- A reminder that patients can change their minds about a decision at any time.
- A reminder that patients have a right to seek a second opinion.
- Where applicable, details of costs or charges that the patient may have to meet.

Medical Council, *Good Medical Practice in Seeking Informed Consent to Treatment* (2008), para 5.e having intercourse with or without treatment/contraception.

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, patients may sometimes 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.

Patients who are detained by the Gardaí, 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. Adult patients detained under the Mental Health Act 2001 do not lose their right to consent to treatment, except where the responsible consultant considers the patient incapable of giving consent for treatment that is “necessary to safeguard the life of the patient, to restore his or her health, to alleviate his or her condition, or to relieve his or her suffering”.⁹ Special conditions apply for psychosurgery and ECT, and for extending a medication regimen beyond three months.¹⁰

Scenario 3

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 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 for compensation. 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

End of life decisions

When patients are seriously ill and lack the capacity to make medical decisions on their own behalf, clinicians are obliged to make treatment decisions in the patient's best interests. This might include choosing not to intervene if a treatment or procedure would be burdensome and of little benefit to the patient. The Medical Council advises:

“There is no obligation on you to start or continue a treatment, or artificial nutrition and hydration, that is futile or disproportionately burdensome, even if such treatment may prolong life. You should carefully consider when to start and when to stop attempts to prolong life, while ensuring that patients receive appropriate pain management and relief from distress.”¹¹ and “You must not participate in the deliberate killing of a patient by active means.”¹²

Perhaps the most vexed question is that of “do not resuscitate” (DNR) orders. The decision not to intervene in the event of a patient suffering a heart attack should not be taken lightly, or in isolation. Ideally, such decisions should be made in consultation with the healthcare team, the patient (if possible or advisable) and with the patient's relatives and carers. The decision, and the reasons for it, should be clearly documented in the patient's records.

There is currently no specific guidance on DNRs available in Ireland.

Clinicians might also find the joint statement published by the British Medical Association, the Resuscitation Council (UK) and the Royal College of Nursing a useful resource in this regard (see the Further Reading section at the end of this booklet). Also see the Medical Council's *Guide to Professional Conduct and Ethics* (2009), paragraph 22.

Advance directives

An advance directive is a statement made by a competent adult in anticipation of a time in the future when he or she may lack the capacity to make healthcare decisions. Such statements usually take the form of advance refusal of specified treatments, but may also contain information about the patient's values and beliefs.

At present there is no legislation covering advance directives in Ireland and there is very little relevant Irish case law to clarify their legal status, but a discussion document published by the Medical Council states, in its 2009 *Professional Conduct and Ethics Guide*, “An advance treatment plan has the same ethical status as a decision by a patient at the actual time of an illness and should be respected on

condition that:

1. the decision was an informed choice, according to the principles of informed consent in paragraph 33
2. the decision covers the situation that has arisen, and
3. the patient has not changed their mind.”¹³

A case heard in the Supreme Court in 1996¹⁴ has some relevance here. Though it did not feature an advance directive, the justices set out the ethical, constitutional and legal considerations regarding end of life decisions, and their deliberations indicate that the courts would give considerable weight to advance directives that met the above criteria. (See Appendix 1 for a summary of the case.)

If there is any doubt about the validity or applicability of an advance decision, 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.

Clinical trials and research

The Control of Clinical Trials Act 1987 makes it an offence to include a person in a clinical trial without his or her valid consent, given voluntarily in light of the information set out in Box 8. The consent must be in writing and signed by the participant.

Where alleviating a patient’s illness is an objective of the trial, and the patient has the capacity to consent but is unable to sign, the consent must be obtained by the doctor who is treating his or her condition in the presence of two witnesses, who must then sign a written expression of the patient’s consent.¹⁵

If a patient is not capable of giving consent, written consent must be obtained from “a person or persons, independent of the person who applied to undertake or is conducting the trial, who in the opinion of the ethics committee is or are competent to give a decision on such a participation”.¹⁶

Participants’ written consent must also be obtained before including them in other forms of research, and the same requirements regarding informed consent apply. If a potential research participant lacks the capacity to consent, “Parental or guardian’s consent must be sought, but such consent can only be accepted where the research in question is clearly in the best interests of the subject concerned, or where the research concerned carries minimal risk or impact on the subject concerned”.¹⁷

Participants in clinical trials and other research should be told that they have the right to withdraw from the research at any time without penalty. A patient’s care should not be compromised in any way by his or her refusal to participate in research.

Box 8: What patients should know before agreeing to participate in clinical trials

- a. the objectives of the trial
- b. the manner in which the substance or preparation is to be administered
- c. the risks and any discomfort involved in, and the possible side effects of, the trial
- d. whether or not a pharmacologically inactive substance or preparation is to be administered to some persons in respect of each of whom a consent has been given to being a participant in the trial.

Control of Clinical Trials Act (1987), section 9(3)

Regarding consent to the collection, use and storage of personal information, the Data Protection Commissioner has issued the following guidance:

“The key issue is respect for the patient’s reasonable expectation that their health information will be kept confidential and not used or disclosed without their consent other than to those directly involved in patient care and directly related activity.

“In the absence of a specific legal basis to underpin the processing of personal health data for research or clinical audit purposes, consent needs to be part of the process in order to meet the legal obligations as set out in the Data Protection Acts. Capturing an explicit and informed patient consent for further processing of a person’s data for research purposes at the first opportune point a person presents to the health services and thereafter as necessary, is advocated as the optimal way forward both from a data protection and efficiency perspective. Such an approach should be systematically built into health facility procedures so that the patient fully understands what further use is planned for their personal information and the safeguards that will be put in place. The patient should be given an opportunity to explicitly grant or deny consent for such use. The consent should also be sought in a context where it can be freely given without any sense on the patient’s part that refusal would carry a penalty, whether real or implied, in relation to treatment.”

Data Protection Commissioner, *Data Protection Guidelines on Research in the Health Sector*, section 4.

When should consent be taken?

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. It is good practice, therefore, to confirm consent prior to the procedure, using this as an opportunity 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. The fact that consent has been confirmed should be documented, either in the patient's medical record or as a (signed and dated) supplementary note on the original consent form.

As a general principle of good practice, if the treatment is not urgent, patients should be given plenty of time to think about their options before they consent to treatment and be encouraged to ask further questions. The commentary delivered by Mr Justice Kearns in a Supreme Court case¹⁸ confirms this view (see Appendix 1, *Fitzpatrick V White* [2007] IESC 51).

Implied and express consent

Patients undergoing invasive procedures should normally give express consent – either by signing a consent form or stating that they agree to go ahead with treatment.

Written consent should always be taken where:

- There are significant risks or side effects associated with the proposed treatment or procedure.
- The patient's lifestyle, employment or personal relationships could be adversely affected by the outcome of the treatment or procedure.
- The treatment or procedure is being undertaken as part of a research programme.
- The main purpose of the proposed treatment or procedure is not the patient's clinical care.

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.

Any discussions with patients about the risks and benefits of a proposed procedure or treatment should be documented in the medical record.

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 leaflets are used to augment discussion with a patient, this should be documented in the patient's notes.

Scenario 4

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 Sykes subsequently makes a claim and the hospital's solicitors advise settlement as they would be unable to prove that appropriate warnings were given.

Recording consent and consent forms

Apart from certain treatments carried out under the Mental Health Act 2001, there is no legal requirement to obtain written consent, but it is generally considered good practice to make some record of the consenting process. Most health organisations, including public hospitals, independent hospitals, clinics and general practices, 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.

Refusing consent

“Every adult with capacity is entitled to refuse medical treatment. You must respect a patient's decision to refuse treatment, even if you disagree with that decision. In these circumstances, you should clearly explain to the patient the possible

consequences of refusing treatment and offer the patient the opportunity to receive a second medical opinion if necessary.”¹⁹

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 he/she is 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, he/she 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 his/her mind.

Scenario 5

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, however, 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.

Scenario 6

Dr T is a newly qualified doctor working 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.

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.

Withdrawing consent

Patients with capacity can also withdraw consent for continuing treatment. If, during a procedure, a patient indicates that he/she 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 7

Mr D has been admitted as a day case for colonoscopy for investigation of rectal bleeding. He finds the colonoscopy extremely uncomfortable and insists that the procedure be stopped. This happens just as 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 further sedation being administered so the colonoscopy can be continued and the lesion biopsied.

Summary

- Consent is needed for all clinical examinations, investigations and treatment.
- 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 in a meaningful way.
- Patients should be given all information material to their decision before deciding which option to choose.
- Patients should not be pressurised into making a decision, but must be aware of any potential harm that may come from delay.
- Young people of 16 or over can consent to treatment on their own behalf but it is not yet clear if they can refuse treatment if they are under 18.
- Consent for treatment of a child under the age of 16 should usually be sought from the child's parent/guardian, but there may be circumstances in which the consent of a mature minor on his/her own is sufficient.
- Consent to clinical examination, some investigations and treatment, is often implied by the patient's co-operation and does not have to be expressly stated.
- 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.

References

1. This was set out in a High Court judgement (*Fitzpatrick & Anor v K & Anor*). See Appendix 1 for a summary.
2. Medical Council, *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* 7th edition [2009], para 39.1
3. Non-Fatal Offences Against the Person Act 1997, section 23.
4. Constitution of Ireland (November 2004 edition) Article 41(1)
5. *Northwestern Health Board v HW and CW* [2001] 3 IR 622.
6. Child Care Act 1991, section 13.
7. www.dataprotection.ie
8. www.irishstatutebook.ie/1993/en/act/Pub/0020/index/html
9. Mental Health Act 2001, section 57(1).
10. Mental Health Act 2001, sections 58, 59 and 60.
11. Medical Council, *The Guide to Professional Conduct and Ethics for Registered Medical Practitioners* [2009], para 22.2
12. *Ibid*, para 22.6
13. Medical Council, *The Guide to Professional Conduct and Ethics for Registered Medical Practitioners* [2009], para 41.2
14. *In the Matter of a Ward of Court (withholding medical treatment)* [1996] 2 IR 79
15. Control of Clinical Trials Act 1987, section 7(a)
16. Control of Clinical Trials Act 1987, section 7(b)
17. Irish Council for Bioethics, *Operational Procedures for Research Ethics Committees: Guidance 2004* [2004], para 6
18. *Fitzpatrick v White* [2007] IESC 51
19. Medical Council, *The Guide to Professional Conduct and Ethics for Registered Medical Practitioners* [2009], para 40.1.

Appendix 1

Key cases referred to in the text

Fitzpatrick & Anor v K & Anor [2008] IEHC104

This High Court judgment, handed down by Miss Justice Laffoy, clarifies a medical practitioner's responsibilities regarding informed consent and sets out the test of capacity that should be applied.

The case concerned Ms K, a young woman recently arrived in Ireland from the Democratic Republic of Congo, who suffered a major postpartum haemorrhage shortly after giving birth to a baby boy in the Coombe Women's Hospital. It was only when the delivery team were preparing to give her an emergency blood transfusion that she told them (via her birth friend, who was acting as interpreter) that she was a Jehovah's Witness and did not want to be transfused.

Due to communication difficulties, the patient's exhausted state, and the fact that she had told the hospital that she was a Catholic when she booked in, her care team had doubts about the validity of her refusal to consent to the blood transfusion, without which she was likely to die. The hospital therefore applied for an emergency court order allowing them to transfuse the patient despite her refusal. This was granted, the blood transfusion was given and Ms K survived.

The subsequent court case was brought by the hospital, seeking a declaration that it was entitled to apply for the court order. Ms K brought a counterclaim, alleging (among other things) that, by overriding her refusal to consent to the blood transfusion, the hospital had committed assault. The judge found in favour of the hospital.

In a lengthy judgment, in which she considered a number of issues, the judge set out the following principles regarding the matter of consent:

1. There is a presumption that an adult patient has the capacity, that is to say, the cognitive ability, to make a decision to refuse medical treatment, but that presumption can be rebutted.
2. In determining whether a patient is deprived of capacity to make a decision to refuse medical treatment whether:
 - a. by reason of permanent cognitive impairment
 - b. temporary factors.

3. The three-stage approach to the patient's decision-making process adopted in the C case [The English case, *Re C*] is a helpful tool in applying that test. The patient's cognitive ability will have been impaired to the extent that he or she is incapable of making the decision to refuse the proffered treatment if the patient
 - a. has not comprehended and retained the treatment information and, in particular, has not assimilated the information as to the consequences likely to ensue from not accepting the treatment
 - b. has not believed the treatment information and, in particular, if it is the case that not accepting the treatment is likely to result in the patient's death, has not believed that outcome is likely
 - c. has not weighed the treatment information, in particular, the alternative choices and the likely outcomes, in the balance in arriving at the decision.
4. The treatment information by reference to which the patient's capacity is to be assessed is the information that the clinician is under a duty to impart – information as to what is the appropriate treatment, that is to say, what treatment is medically indicated, at the time of the decision and the risks and consequences likely to flow from the choices available to the patient in making the decision.
5. In assessing capacity it is necessary to distinguish between misunderstanding or misperception of the treatment information in the decision-making process (which may sometimes be referred to colloquially as irrationality), on the one hand, and an irrational decision or a decision made for irrational reasons, on the other hand. The former may be evidence of lack of capacity. The latter is irrelevant to the assessment.
6. In assessing capacity, whether at the bedside in a high dependency unit or in court, the assessment must have regard to the gravity of the decision, in terms of the consequences that are likely to ensue from the acceptance or rejection of the proffered treatment.

In an addendum to the judgment, the judge recommended that:

1. All maternity hospitals have guidelines in place for managing obstetric haemorrhage in women who refuse blood transfusion.
2. Women be routinely asked, when they book in, if they would accept a blood transfusion in an emergency.
3. The Medical Council publish guidelines on assessing a patient's capacity to give a valid refusal to medical treatment and on the role of advance directives.

Re C [1994] 1 WLR 290

C was a 68-year-old man suffering from chronic paranoid schizophrenia and detained in a special hospital in England. He brought a case in the High Court, after the hospital had refused to give him assurances that it would not, at some time in the future, carry out a below-knee amputation to treat his gangrenous foot.

A vascular surgeon had estimated C's chances of survival at 15% if he did not have an amputation, but C had refused the surgery and his foot was treated conservatively, with some success. However, on the grounds that C's capacity was impaired by his mental illness, the hospital was unwilling to confirm that it would not carry out the amputation at some future date.

Despite the fact that C displayed grandiose delusions of being a world-renowned doctor, the court found that he was competent to decide this matter for himself because he had demonstrated (a) that he could understand and retain the treatment information, (b) believe it and (c) weigh it in the balance to arrive at a choice.

Fitzpatrick v White [2007] IESC 51

Mr Fitzpatrick was admitted to the Royal Victoria Eye and Ear Hospital as a day case for surgery to correct a slight squint for cosmetic reasons. Unfortunately, although the procedure was performed proficiently, over the following months there was a gradual slippage in the medial rectus muscle behind Mr Fitzpatrick's eye, which resulted in a worse squint and double vision.

He brought proceedings against the hospital, claiming negligence, and lost the case at trial. His appeal to the Supreme Court was confined to the claim that his consent to the operation was not valid because it had been obtained only 30 minutes beforehand.

Although the court did not uphold his appeal, on the grounds that there was "nothing in the evidence to suggest the plaintiff could not assimilate or properly understand what he was being told", Mr Justice Kearns, in his summing up, gave this warning: "I would make the point strongly ... that in other cases where a warning is given late in the day, particularly where the surgery is elective surgery, the outcome might well be different." Expanding on this subject, he made the following comments:

"There are obvious reasons why, in the context of elective surgery, a warning given only shortly before an operation is undesirable. A patient may be stressed, medicated or in pain in this period and may be less likely for one or more of these reasons to make a calm and reasoned decision in such circumstances. ... While I have noted the views of a number of the experts to the effect that this practice

of warning day patients on the day of their operation had its advantages, it seems to me that the disadvantages were far greater, including the possibility of an embittered patient later asserting that he was too stressed or in too much pain to understand what was said or to make a free decision and that he was thus effectively deprived of any choice.”

Gillick v West Norfolk and Wisbech Area Health Authority [1985] 3 All ER 402 (HL)

In 1980, the Department of Health and Social Security in England published a circular to reassure doctors that they would not be acting unlawfully in prescribing contraceptives to girls under 16 years old, as long as they were acting in good faith to protect patients against the harmful effects of sexual intercourse.

On learning this, Mrs Gillick sought an assurance from her local area health authority that her daughters would not be given advice or contraception without her consent. When this was refused, she challenged the legality of the guidance.

This case went to the House of Lords for a final decision, which established that parents’ rights to consent on behalf of their children ends when the child is able fully to comprehend the proposed treatment. (See Box 6 for the guidelines derived from this case.)

In the Matter of a Ward of Court (withholding of medical treatment) [1996] 2 IR 73

The Ward of Court in this case was a 45-year-old woman. She had been in a near persistent vegetative state for 23 years and was being fed via a gastrostomy tube. Her mother, with the support of the rest of her family, applied to the High Court for permission to have the feeding tube removed and to allow life-threatening infections to take their course without antibiotic intervention. The High Court judge consented to this on behalf of the Ward, but the institution in which the Ward was living and the Attorney General appealed against the decision.

The Supreme Court considered the following issues, as set out by Justice Denham:

1. Whether withdrawing the feeding tube and the non-treatment of infections or other conditions, other than in a palliative way, was in the best interests of the Ward.
2. If so, would it be lawful?
3. Whether the court, in permitting such action, had failed in defending the Ward’s constitutional rights, including the right to life.
4. Whether the Ward would have the right to refuse such treatment if she was competent and, if she did have that right, did she lose it by virtue of her incapacity?

5. If she does retain the right to refuse treatment, can it be exercised on her behalf by someone else? If so, by whom?
6. What should be taken into account when such decisions are being made on her behalf?
7. Whether the High Court judge's decision to support the family's application was based on credible evidence that it was in the Ward's best interests to withdraw artificial nourishment.

Four out of the five justices hearing the case upheld the High Court ruling. In their deliberations, they considered whether artificial nutrition and hydration constitutes medical intervention and whether its withdrawal would be in the Ward's best interests. The four justices who upheld the decision concluded that tube feeding does amount to medical intervention because it is intrusive and that withdrawing such intervention would be in the Ward's best interests. They took the view that withdrawing artificial means of sustenance would not be tantamount to terminating her life; it would be allowing nature to take its course. Justice Hamilton spelt it out in these terms:

“As the process of dying is part, and an ultimate, inevitable consequence, of life, the right to life necessarily implies the right to have nature take its course and to die a natural death and, unless the individual concerned so wishes, not to have life artificially maintained by the provision of nourishment by abnormal artificial means, which have no curative effect and which is intended merely to prolong life.

“This right, as so defined, does not include the right to have life terminated or death accelerated and is confined to the natural process of dying. No person has the right to terminate or to have terminated his or her life, or to accelerate or have accelerated his or her death.”

Northwestern Health Board v HW and CW [2001] 3 IR 622

In this case, the Supreme Court upheld a High Court decision not to allow the Northwestern Health Board to carry out a PKU test on an infant boy in opposition to his parents' wishes.

In the original High Court case, the judge set out the issue as follows:

“There is no doubt that medical opinion would emphatically state that it is in Paul's best interest to have the PKU test done ... The question I have to answer is whether this objective benefit to Paul overrides the rights of his parents, in effect, to decide that they do not want Paul to have the discomfort, and discomfort is as strong a word as could be used for it, of a pinprick in his heel, and are prepared to take the risk that he does not suffer from any of the relevant conditions.”

He concluded that: “If the State were entitled to intervene in every case where a professional opinion differed from that of parents, or where the State considered

the parents were wrong in their decision, we would be rapidly stepping towards the Brave New World in which the State always knows best. In my view that situation would be totally at variance with both the spirit and word of the Constitution.”

Four out of the five Supreme Court justices hearing the case upheld this view. The position was further clarified by the Hon Mrs Susan Justice Denham: “In seeking the balance to be achieved between the child’s rights within and to his family, and the family (as an institution) rights, and the parents’ right to exercise their responsibility for the child, and the child’s personal constitutional rights, the threshold will depend on the circumstances of the case. Thus, if the child’s life is in immediate danger (eg, needing an operation) then there is a heavy weight to be put on the child’s personal rights superseding family and parental considerations.”

Appendix 2

Relevant legislation

Child Care Act 1991

Children Act 1997

Constitution of Ireland

Control of Clinical Trials Act 1987

Lunacy Regulations (Ireland) Act 1871

Mental Health Act 2001

Non-Fatal Offences Against the Person Act 1997

Sexual Offences Act 2006

Status of Children Act 1987

Appendix 3

Further reading

Guidance and reports

Data Protection Commissioner, *Guidelines on Research in the Health Sector* (2007)
www.dataprotection.ie

The Irish Council for Bioethics, *Is it Time for Advance Healthcare Directives?* (2007)
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(October 2007) www.bma.org.uk/ethics/ethicswebresources.jsp

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