

Consent to medical treatment

A doctor working in partnership with a patient to make good clinical decisions goes to the heart of good medical practice. It is essential for the therapeutic relationship of mutual respect and trust between doctor and patient to exist. It is a fundamental principle of medical law and necessary to protect a patient's autonomy. Doctors must respect that a patient must give permission for any medical treatment or examination to be carried out.

When obtaining consent from a patient, a doctor must have a full understanding of the procedure or treatment, how it is carried out and the risks associated with it and be in a position to inform the patient accordingly.

Informed consent

It is the doctor's responsibility to ensure that a patient has been given sufficient time and information to make an informed decision about the treatment or investigation proposed, including the prescription of medication.

Obtaining informed consent requires practitioners to keep their patients up-to-date with any changes in their condition and any treatment or investigation proposed.

The HSE National Consent Policy (available on the HSE website) provides guidance on how to best support patients in assessing the risk and benefits of various treatments such as:

- *Design and employ communications that use plain language;*
- *Avoid explaining risks in purely descriptive terms (such as low risk), try to supplement with numerical data;*
- *Use absolute numbers or percentages, avoid using relative risk or percentage improvements;*
- *Use visual aids e.g. pictographs wherever possible, to maximise understanding.*

Any discussions with patients about the risks and benefits of a proposed procedure or treatment should be documented in the patient's records. Adequate time should be allocated to communicate with patients to obtain informed consent.

Information leaflets are not a substitute for detailed discussion. If leaflets are given to augment discussion with a patient this fact should be documented in the patient's notes.

Please also refer to *The Royal College of Surgeons Ireland (RCSI) Code of Practice for Surgeons (2018)*, para 4.1 (available on the RCSI website).

Screening tests

It is important to realise that consent does not only apply to procedures but also to other forms of treatment and investigations, such as screening tests, e.g., genetic screening, PSA levels, etc.

Most often this would take the form of verbal or implied consent; nonetheless the principles of including the patient in the decision-making process, and recording the information shared during the discussion, do apply. This is particularly relevant where there are conflicting views in the medical world as to the appropriateness of testing or potential benefit to the patient.

Prior to undertaking a screening test, the patient's informed consent should be obtained. The patient should be fully informed about the implications of having the test, the possible causes of abnormal levels and the

likely management should the investigation highlight any concerns. Providing the patient with a leaflet would be helpful. Informed consent should be documented in the patient's medical record along with the advice that has been given to the patient including providing a patient information leaflet.

Verbal v written consent

Patients can give consent orally or in writing, or they may imply consent by complying with the proposed examination or treatment, for example, by rolling up their sleeve to have their blood pressure taken.

For physical examinations, doctors should always explain what is involved and obtain verbal consent before proceeding. Doctors should be aware of obligations regarding offering a chaperone for any intimate examinations. Please see our factsheet on Chaperones (available on our website).

When carrying out minor or routine investigations or treatments, if a doctor is satisfied that the patient understands what is proposed and the reasons for it, it is usually sufficient to have verbal consent.

Patients should be asked to sign a consent form where:

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

When should consent be taken?

For some procedures, such as elective surgery, consent may be obtained from the patient during an outpatient consultation, prior to admission for surgery. This may be several weeks prior to the surgery. Whilst there is no specific time limit on consent taken in advance, the patient may have further questions and dilemmas regarding the surgery or treatment. Patients should be given time prior to the surgery to consider options and ask further questions.

It is good practice, therefore, to confirm consent prior to the procedure, e.g. at the patient's admission to the clinic/hospital, using this as an opportunity to find out if there have been any changes since consent was first taken, and to ask the patient if there are any further questions.

Document, including date and time, confirmation of the consent in the patient's file or as a supplementary note on the original consent form.

Who should take consent?

Ideally the consultant providing the treatment or surgery should undertake the consent process with the patient. However, it may be necessary on occasions to delegate the process to another doctor providing they are suitably trained, qualified and have sufficient knowledge of the proposed surgical intervention or proposed treatment and understand the risks involved.

If consent has been taken by a colleague, consent should be confirmed prior to the procedure by the Consultant undertaking the procedure. This confirmation should be documented, as above.

Refusal of consent

Every adult with capacity is entitled to refuse medical treatment or withdraw consent and doctors must respect a patient's decision to refuse treatment or withdraw consent, even if they disagree with that decision.

In these circumstances, a doctor should explain clearly to the patient the possible consequences of refusing treatment and, where possible, offer the patient a second medical opinion. It is very important to take detailed notes of any such discussions with a patient.

Capacity

Please also see Medisec's fact sheet on Assessing Capacity for Medical Treatment (available on our website).

Ordinarily, adults are presumed to have the capacity to make decisions about their own medical treatment. Under the Assisted Decision-Making (Capacity) Act 2015 (which is not yet fully commenced), a person lacks capacity to make a decision if they are unable:

- to understand the information relevant to the decision,
- to retain that information long enough to make a voluntary choice,
- to use or weigh that information as part of the process of making the decision, or
- to communicate his or her decision (whether by talking, writing, using sign language, assistive technology, or any other means).

Medical Council guidelines

Paragraph 10 of the Medical Council Guide to Professional Conduct and Ethics for Registered Medical Practitioners (available on the Medical Council website) provides general guiding principles in relation to capacity to consent.

The Guide states that:

every adult patient is presumed to have the capacity to make decisions about their own healthcare. As their doctor, you have a duty to help your patients to make decisions for themselves by giving them information in a clear and comprehensible manner and by ensuring that they have appropriate help and support. The patient is also entitled to be accompanied during any such discussion by an advocate of their own choice.

There are instances where a person's capacity to provide consent can be affected by infirmity. In this regard, the Medical Council advises that a functional approach should be taken, when considering the capacity requirements in such an instance. The criterion in assessing the relevant choice depends on the following:

- The patient's level of understanding and retention of the information they have been given.
- Their ability to apply the information to their own personal circumstances and come to a decision
- Their ability to communicate their decision, with help or support where needed.

The considerations for a clinician to take if the patient has no other person with legal authority to make decisions on their behalf are the following, as per Medical Council Guidelines (paragraph 10.6):

- *Which treatment option would provide the best clinical benefit for the patient?*
- *The patient's past and previous wishes if they are known.*

- *Whether the patient's capacity is likely to increase.*
- *The views of other people close to the patient who may be familiar with the patient's preferences, beliefs and values.*
- *The views of other health professionals involved in the patient's care.*

Consent and minors

Paragraph 18 of the Medical Council Ethical Guide states:

18.1 When treating children and young people, your primary duty is to act in their best interests. You should involve them as much as possible in discussions about their healthcare, give them information suitable for their age, listen to their views and treat them with respect.

Patients aged 16 years and over are entitled by law to give their own consent to surgical medical or dental treatment and patients aged 18 years and over can consent to psychiatric treatment.

A refusal of treatment by a patient between 16 and 18 years which is against medical advice and parental wishes is of uncertain legal validity. Consideration should be given to seeking legal advice if this situation arises.

Patients aged under 16

If a patient aged under 16 years seeks to make a healthcare decision on their own behalf, they should be encouraged to involve their parents in the decision, bearing in mind the paramount responsibility to act in the patient's best interests.

The Medical Council Ethical Guide goes on to say:

18.3 Where the patient is under the age of 16 years, the parent(s) or guardian(s) will usually be asked to give their consent to medical treatment on the patient's behalf.

18.4 When patients under 16 want to make a healthcare decision without the knowledge or consent of their parent(s) or guardian(s), you should encourage them to involve their parent(s) or guardian(s) in the decision.

18.5 If a young person refuses to involve a parent/guardian, you should consider the young person's rights and best interests, taking into account:

- *the young person's maturity and ability to understand the information relevant to the decision and to appreciate its potential consequences*
- *whether the young person's views are stable and reflect their core values and beliefs*
- *whether the young person's physical or mental health, or any other factors are affecting their ability to exercise independent judgement*
- *the nature, purpose and usefulness of the treatment or social care intervention*
- *the risks and benefits involved in the treatment or social care intervention*
- *any other specific welfare, protection or public health considerations, covered by relevant guidance and protocols such as the 2011 Children First: National Guidelines for the Protection and Welfare of Children (or any equivalent replacement document). Where this is the case, the relevant guidance or protocols must be followed.*

18.6 This assessment of maturity should be made for all young people under 16, including those who have been diagnosed with an intellectual disability.

In some cases a patient under 16 may not wish to involve their parents and the Medical Council Ethical Guide says that you can provide treatment in such cases provided you have considered the factors above. Medisec recommends that you note your decision making process carefully in any such circumstances.

18.7 You should provide treatment for young people without informing their parent(s) or guardian(s) if, having considered the factors in paragraph 18.5, you consider that it is in the patient's best interests to do so and the patient has sufficient maturity and understanding to make the decision.

Confidentiality and children

It is important to note that children and young people have a right to confidential medical treatment but parents and guardians also have a legal right to access medical records of their children until they are 18. You should tell children and young people that you cannot give an absolute guarantee of confidentiality. Please see our factsheet on Confidentiality and Children (available on our website).

In summary

Ensure adequate consent is obtained prior to any investigation or procedure, e.g.,

- The nature and purpose of the procedure has been fully explained.
- The patient has been warned of the risks involved.
- The alternatives to the procedure have been discussed.
- A patient information leaflet was given (if available).

Record all verbal and written consent in the patient's record indicating that consent was obtained, and the risks/benefits explained.

Often undue emphasis is placed on the signing of a consent form. More important is a detailed discussion with patients, which needs to be clearly recorded in their notes.

If you have any specific queries in relation to consent, please contact a member of the Medisec team.

"The contents of this publication are indicative of current developments and contain guidance on general medico legal queries. It does not constitute and should not be relied upon as definitive legal, clinical or other advice and if you have any specific queries, please contact Medisec for advice".