



# GOOD MEDICAL PRACTICE IN SEEKING INFORMED CONSENT TO TREATMENT



**Medical Council**  
Comhairle na nDoctúirí Leighis





## INTRODUCTION

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This document<sup>1</sup> provides guidelines for good practice in seeking informed consent to treatment. It is primarily intended for registered medical practitioners, medical schools, those involved in the postgraduate training of doctors, and doctors' employers.

Those involved in educating and training the next generation of doctors should ensure that good practice in consent is part of the curriculum. Those involved in delivering health care – whether as practitioners or managers – should incorporate the guidelines into their policies and their actions. Senior and experienced doctors, in particular, are key role models. By their example, they can demonstrate the importance of the principles and practices outlined in this document. By these means, good practice in seeking informed consent will be embedded in education and training of medical practitioners and in the provision of health care services, to the benefit of patients.

The Medical Council is happy to deal with any queries on this issue. Please contact Professional Standards on +353 1 498 3112 / [professionalstandards@mcirl.ie](mailto:professionalstandards@mcirl.ie).

## 1. CONSENT

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Consent must be given by a patient before any medical procedure can be carried out on him/her. The ethical and legal rationale behind this is to respect the patient's autonomy and his/her right to self-determination. The central idea of autonomy is that one's actions and decisions are one's own. Therefore the patient has the right to decide what happens to his/her own body.

## 2. THERE ARE 5 CRUCIAL ELEMENTS IN CONSENT:

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- **Disclosure:** Patients must be given sufficient information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care. In legal terms this refers to the disclosure of all 'significant' risks, or 'substantial risks of grave adverse consequences'. This is commonly taken to mean risks of over 1-2%, though hard and fast rules are difficult to apply. In elective surgery the test for disclosure is to enquire only if there is any risk, however remote, of grave consequences involving pain for an appreciable time into the future. Statistical frequency is irrelevant.

<sup>1</sup> Approved by Council on 27th February 2008.



- **Comprehension:** Patient comprehension can be increased by avoidance of complex medical terminology where possible, use of lay language, common everyday analogies, numerical explanation of risk factors, pictorial representation of relevant procedures, large font on information leaflets etc. Where possible, time should be given to reflect on the information and questions must be answered.
- **Voluntariness:** The consent process must not be controlled by factors that engineer the outcome, such as persuasion by family members.
- **Competence:** It is presumed that every adult is competent to give consent on his/her own behalf. Sometimes competence can be affected by age or infirmity but this does not justify any impairment of human dignity or personal integrity. A functional approach should be taken to the assessment of an individual's competence. This approach assesses the individual's ability to make the relevant choice depending on their level of understanding and retention of the information, their ability to apply the information to their own personal circumstances and come to a decision.
- **Agreement:** Consent given by the patient is the exercise of a choice, the giving of permission for the intervention. Patients should not feel that their consent is simply a formality, a signature on a page.

The objective of consent is to give the patient the right to decide what is to happen to his/her body, including the right to decide whether or not to undergo any medical intervention even where a refusal may result in harm to themselves or in their own death.

### 3. DOCTRINE OF INFORMED CONSENT:

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One of the difficulties in the area of consent is that there is a difference between the ethical ideal and the reality. The ethical ideal of informed consent is that the patient substantially understands the nature of the procedure he is authorising and the fact that he is authorising it, in other words, that he has a choice in the matter. The legal use of the term 'informed consent' describes the process by which a doctor discloses information to a patient prior to obtaining consent to proceed with treatment.

If a patient is simply presented with a form to sign, it loses all significance as it becomes an undemanding formality that must be complied with for legal purposes. This does not serve the ethical objectives of consent.

### 4. COMMUNICATION SKILLS:

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Effective communication is the key to achieving the objectives of informed consent. Appropriate steps must be taken to find out what patients want



to know and ought to know about their condition, its investigation and treatment. The amount of information given to each patient will vary, according to factors such as the nature of the condition, the mode of investigation, the complexity of the treatment, the risks associated with the treatment or procedure, and the patient's own wishes. For example, patients may need more information to make an informed decision about a procedure which carries a high risk of failure or adverse side effects; or about an investigation for a condition which, if present, could have serious implications for the patient's employment, social or personal life.

## 5. INFORMATION FOR PATIENTS<sup>1</sup>:

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The information which patients want or ought to know, before deciding whether to consent to treatment or an investigation, may include:

- 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 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 re-assessed;
- 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 which the patient may have to meet.

When providing information, patients' individual needs and priorities must be considered. For example, patients' beliefs, culture, occupation or other factors may have a bearing on the

<sup>1</sup> This part has been adapted from the guidance of the General Medical Council in "Seeking patient's consent: the Ethical Considerations" (1998) as well as Irish Supreme Court decisions on the issue of consent to treatment.



information they need in order to reach a decision. Patients should be asked whether they have understood the information and whether they would like more before making a decision.

Any questions the patient raises must be answered as fully as the patient wishes. Information necessary for decision making must not be withheld from a patient unless disclosure would cause the patient serious harm. In this context serious harm does not mean the patient would become upset, or decide to refuse treatment.

Obtaining informed consent cannot be an isolated event. It involves a continuing dialogue keeping patients abreast of changes in their condition and the treatment or investigation proposed. Whenever possible, treatment options should be discussed at a time when the patient is best able to understand and retain the information.

In elective procedures a comprehensive warning must be given in relation to a risk, however remote, of grave consequences involving severe pain into the future. If severe ongoing pain involving further operations is not one of the known complications, it is the responsibility of the doctor to inform the patient of a significant risk which would affect the judgement of a reasonable patient.

In elective surgery, a warning given only shortly before an operation is undesirable as a patient may be stressed, sedated or in pain and therefore may be less likely to make a calm and reasoned decision. The risks should be explained at a previous consultation in relation to the surgery or at least well in advance of the surgery.

## 6. PROFESSIONAL RESPONSIBILITY:

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It is the responsibility of the doctor providing treatment or undertaking an investigation, to discuss it with the patient as s/he will have a comprehensive understanding of the procedure or treatment, how it is carried out, and the risks attached to it. Where this is not practicable, the discussion may be delegated provided the person to whom it is delegated is suitably trained and qualified; has sufficient knowledge of the proposed investigation or treatment, and understands the risks involved. The treating doctor remains responsible for ensuring that the patient has been given sufficient time and information to make an informed decision, and has given consent to the procedure or investigation.

In general, interns are not considered appropriate persons to undertake this responsibility unless the procedure is of a minor nature with which the intern is very familiar, and the relevant information relating to the procedure has been clearly explained to the intern by their supervising consultant.

## 7. EMERGENCY SITUATIONS:

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In an emergency, where consent cannot be obtained, medical treatment may be provided to anyone who needs it, provided the treatment is limited to what is immediately necessary to save life or avoid significant deterioration in the patient's health.



