

What constitutes patient consent?

There are three issues to consider in the consent process – the obligation to warn, the content of the warning and the time of the warning, writes **Aisling Gannon**, head of healthcare at Beauchamps Solicitor



The essential basis of the consent process is that the patient consents voluntarily and that consent is based on sufficient relevant information. When a patient consents to any operation, procedure or clinical trial, it must be based on knowledge of the nature, consequences and alternatives associated with the proposed treatment. It is also necessary to obtain an individual's informed consent if he/she is to participate in education and research. A healthcare professional should inform the patient fully of the advantages/disadvantages, risks/benefits and alternatives to the proposed course of treatment.

Where relevant, capacity, age and mental capability must also be considered. For example, children under the age of 16 are presumed to be legally incompetent to make decisions about medical treatment and therefore such decisions may be made by their parents/legal guardians. There may be circumstances where a child under the age

of 16 years may give consent, for example, if the child concerned has sufficient maturity, understanding and intelligence to enable him/her to fully appreciate the nature, purpose and the likely consequences of undergoing or refusing the proposed procedure.

Legal principles

The issue of consent was considered recently by the Supreme Court in *Fitzpatrick v Whyte* (as the nominee of the Royal Victoria Eye and Ear Hospital) where a plaintiff suffered double vision as a result of an elective procedure to repair a strabismus. He claimed that he would not have consented to the procedure had he been informed of this possibility. The plaintiff claimed that the warning given to him by his doctor some 30 minutes before the operation was invalid. There was no allegation of negligence relating to the performance of the operation. The plaintiff lost his case in the High Court and

limited the scope of his appeal to the “lateness” of the warning. He claimed that the “lateness” of the warning rendered it nugatory and ineffective and that his consent to the operation was therefore inadequate.

There are three issues to consider therefore in the consent process: the obligation to warn, the content of the warning and the time of the warning.

Obligation to warn

The Supreme Court upheld, and restated in even more vigorous terms, that the consent test is a “patient centred” test as previously set out in *Geoghegan v Harris* ([2000] 3 IR 536). This has been referred to as the “subjective-objective” test.

Content of the warning

Walsh v Family Planning Services Ltd. & Ors confirmed that in elective surgery “any risk that carries the possibility of grave consequences involving severe pain for the patient must be disclosed” ([1992] IIR 496). In *Geoghegan v Harris* the court suggested that any consideration of “materiality” would involve consideration of both (a) the severity of the consequences and (b) the statistical frequency of the risk. Putting it

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another way, a risk may be seen as material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it. This was upheld in *Fitzpatrick v Whyte*.

Time of warning

In *Fitzpatrick v Whyte* the court held that on the facts of the case that the hospital was not negligent in obtaining consent on the morning of the elective procedure but cautioned against such a practice generally.

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Consent process

It is important to remember that consent is not simply a question of getting a signature on a form – it is an entire process. The process should begin at the very point that the procedure is first clinically proposed. The risks should be explained fully at this point and the patient or their representative given every opportunity and encouragement to ask questions to ensure that there is complete understanding.

The process continues to the actual day and time of the procedure when the explanation should be given again in a calm and unhurried fashion, preferably by the person who will carry out the procedure, with questions answered in the same way. Only then can a signature on the form be relied on as evidence of consent.

In certain limited circumstances consent can also be implied. The

most common example is when a patient is receiving an injection and raises his/her arm in preparation for it. Implied consent can also be deemed to arise where a patient is unconscious and unable to consent. For example, in an emergency or life threatening situation where the patient is unable to consent or to appreciate what is required the healthcare professional acting in the best interests of the patient may administer the necessary medical

treatment to save the patient's life or preserve the health of the patient without an informed consent.

If intervention is considered to be clinically in the patient's best interest it is appropriate to proceed. It is not a convenience test – it must be necessary and the threat of the danger to the patient's life or health must be immediate. **HM**

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