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Informed Consent for Interventional Radiology Procedures



Dr. Michael Burns

*****@***beaumont.ie

Radiology Specialist Registrar -
Beaumont Hospital
Dublin, Ireland



Prof. Michael J. Lee

*****@***rcsi.ie

Consultant Radiologist -
Beaumont Hospital
Dublin, Ireland

As interventional radiology develops as a specialty, the issue of informed consent is becoming more important and in many cases more complex. The doctrine of informed consent relates to the right of every competent adult to decide what will happen to his or her body, and to protect one's bodily integrity from unauthorised intrusions. This encompasses every action by a physician ranging from a simple physical examination to a complex surgical procedure. Implied consent is the term used to describe how patients consent to everyday patient-physician interactions that are without risk. For example, implied consent is assumed when a patient proffers his or her arm in order to have blood pressure measured. Different standards apply when more complex procedures and treatments are undertaken.

Litigation & Patient Consent

Many of the legal cases relating to the definition of informed consent have taken place in the United States. *Mohr v. Williams* (1905) involved a surgeon who, during an operation, determined that the patient's left ear was diseased and operated on it although that patient had consented for an operation on her right ear. Hearing in the left ear had deteriorated and the court found that the physician was guilty of battery by operating without consent. The judgment described valid consent where "a physician advises a patient to submit to a particular operation, and the patient weighs the dangers and risks incident to its performance, and finally consents." [1] is established the idea of informed consent as a full decisional process.

CIRSE, the European Society for Cardiovascular and Interventional Radiology, has published recommendations on informed consent. These state that details of the proposed treatment, common and serious side effects and the probability of success should be discussed with the patient, who should be made aware of alternative treatment options available. Should all possible risks or adverse effects be discussed, no matter how unlikely? Current guidelines from the Irish Medical Council require the disclosure of all significant risks or substantial risks of grave adverse consequences. The General Medical Council (GMC) in the UK advises that patients must be told if an investigation or treatment might result in a serious adverse outcome, even if the likelihood is very

small. They should also be told about less serious side effects or complications if they occur frequently.

On occasion, a patient may indicate that they do not wish to be informed about the proposed treatment and its risks. While their wishes should be respected, the physician should explain the potential consequences of their lack of information and that the patient's consent may not be valid. The physician should record the fact that the patient has refused this information and should make it clear that the patient may change their mind and receive more information at any time.

Gaining Consent for Interventional Procedures

There are certain issues that arise concerning informed consent for interventional radiology procedures. Informed consent should always be obtained before the procedure and the best setting for this is in a preprocedural outpatient clinic. However in a 2003 survey, only 22 percent of European interventional radiologists generally obtained consent in the outpatient clinic. As interventional radiology moves further towards becoming an independent clinically based specialty, it is likely that use of outpatient clinics will increase.

If consent is being obtained after the patient has been admitted, this should be done on the ward on the preceding day. If obtaining consent in the interventional suite, the radiologist should ensure that the patient has their reading glasses with them if required so that they may read the consent form. Consent should always be obtained before sedation is given.

Who Should Obtain Consent?

This leads to another issue – who should obtain consent? The patient's consent should be obtained by the operator who is to perform the procedure. This responsibility may be delegated to a suitably trained and qualified physician who has sufficient knowledge of the proposed treatment and understands its risks. In addition, guidelines from the General Medical Council advise that the delegating physician must ensure that the patient has been given enough time and information to make an informed decision. In this context, it is worth pointing out that obtaining informed consent is a dynamic process involving discussion with the patient. While the patient's signature on a consent form may be evidence of that discussion, it does not in itself mean that informed consent has been obtained.

The primary purpose of the consent form is to provide written information to the patient in addition to a verbal discussion. Currently in the author's hospital, a generic consent form is used (see fig. 1, p. 14). A similar form was used by 83 percent of European radiologists in one study. However, a recent Eurobarometer patient survey found wide variations in the use of consent forms prior to surgical procedures. Written consent was obtained in 90 percent of cases in Germany but in only 56 percent of cases in Finland and 46 percent of cases in Greece. It is reasonable to suppose that similar variations may exist in radiology departments. Many radiologists write the side effects and potential complications of the procedure on the form that have been discussed with the patient.

An alternative is to use customised forms containing information unique to the procedure recommended. This practice is to be encouraged as it provides additional information for the patient and may save time for the radiologist. It also offers an opportunity to standardise the consent process at a local, national or even international level. CIRSE has published quality improvement guidelines on many interventional procedures. These detail typical complications and their rates, and provide a useful source of information.

Importance of Informational Leaflets

Information leaflets are another important resource in informing the patient. 61 percent of European radiologists provide information sheets relating to the procedure to their patients. These should be made available to the patient as far in advance of the procedure as possible. To facilitate this, they should be provided in the outpatient clinic and on the ward. Increasingly, patients are turning to the Internet to learn about their own conditions and proposed treatments. CIRSE has developed a "Patients and Public" section on its website that provides information on many interventional radiology procedures.

In the United States, the Society of Interventional Radiology provides similar information on its website. A comprehensive collection of leaflets prepared by the Royal College of Radiologists and the British Society of Interventional Radiology are available for download from the RCR website. Where available, specialist nurses may also have a role in educating patients in advance of their procedure.

Interventional radiology procedures are often open-ended and the therapeutic option chosen may vary depending on the initial imaging acquired during the procedure. It is therefore important to discuss with the patient all options and scenarios that may arise during the procedure. Consent must be obtained beforehand if treatment is to be undertaken. For example, if a femoral angiogram identifies a stenosis, the radiologist must not proceed to angioplasty without the patient's prior consent.

When the Patient's Capacity to Understand is Diminished

Problems may arise where the patient's capacity to give consent is affected by infirmity. There are currently no pan-European guidelines or legislation governing this complex area. It is the responsibility of each radiologist to be aware of the legislation and ethical guidelines operating in their jurisdiction. The Irish Medical Council advises that each patient should be assessed on a functional basis regarding their capacity to consent.

The patient may be regarded as lacking the capacity to give consent if they cannot understand or retain the information provided, if they are unable to apply that information to their own circumstances and come to a decision or if they are unable to communicate their decision. A judgment that a patient lacks the capacity to make a particular decision does not imply that they are unable to make other decisions or will be unable to make this or other decisions in the future.

In this situation, the next step is to find out whether any other person has legal authority to make decisions on the patient's behalf. If so, that person's consent should be sought. Failing that, the radiologist must decide what treatment to provide. Consideration should be given to the patient's past and present 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, and the views of other health professionals involved in the patient's care.

What of the situation where an interventional radiologist is asked to perform an embolisation to achieve haemostasis in an unconscious trauma patient? In this type of emergency situation where a patient is seriously ill, they may not be able to give consent. Medical treatment should be provided as needed but should be limited to what is immediately necessary to save life or avoid significant deterioration in the patient's health. The treatment provided should be the least restrictive of the patient's future choices. If the patient regains capacity while in the radiologist's care, they should be informed of what has been done and the reasons for doing so.

Planning for the Future

How should interventional radiologists plan for the future with regard to informed consent? Increasingly complex procedures will require informed consent well in advance. The interventional radiologist should meet patients in the outpatient clinic. Imaginative use of resources such as DVDs and multimedia web-based presentations will supplement traditional information leaflets. The radiologist must keep abreast of changes to legislation and ethical guidelines in their own jurisdictions, especially regarding the issue of capacity to consent. More aggressive measures to

prolong life will be accompanied by increasing use of advance treatment plans. A consensus on complication rates and standardisation of the consent process will be led by the relevant societies.

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