

## Patient Informed Consent for Digestive Endoscopy

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This paper reports the recommendations of the Ethics Workshop on informed consent held at the First European Symposium on Ethics in Gastroenterology, held on the island of Kos, Greece [1]. Kos was the island on which Hippocrates lived and worked almost 2,500 years ago, and his best-known aphorism – “the duty of the physician is to help, or at least to do no harm” – remains just as pertinent today as it was then.

The issue of informed consent is a cornerstone of good medical practice. It is a dynamic process rather than a single event and represents a genuine, un-pressured decision made after complete information has been given to the patient, which he/she understands as far as possible in a situation in which trust has been established between the patient and the doctor [2]

The need for patient informed consent in any invasive procedure and specifically in gastrointestinal endoscopy is based on various statements of “Patient’s Rights” [3,4] and on principle-based ethics, as developed and described by Beauchamp and Childress. These principles are based on the idea that any individual, regardless of personal philosophy, political or moral beliefs, religion or nationality, will have no difficulty finding in them a simple, accessible and culturally neutral approach to such biomedical ethical issues as patient’s informed consent and physician’s rights.

### Respect for autonomy

Autonomy, or the capacity for self-determination, refers in this context to the right to make a decision after due deliberation without external pressure. In healthcare, respecting a patient’s autonomy requires that the doctor consult his or her patient and obtain his/her agreement before taking action that affects him/her. Hence, there is an obligation to obtain informed consent.

Medical confidentiality is another implication of respect for a patient’s autonomy. If the doctor respects this autonomy, it follows that the doctor should never deceive a patient about his/her diagnosis or prognosis, unless the patient clearly wishes to be deceived. To exercise such respect for autonomy requires communication skills, so as to provide patients with adequate information in a way they can understand and assimilate, as well as skills in sympathetic listening and understanding.

### Beneficence and non-maleficence

Whenever we try to help others, we inevitably risk harming them. Therefore, the aim of the doctor should be to produce net benefit

over harm. To achieve this, what is required is a continuing medical education that encourages the provision of good. This obligation also requires doctors to be clear about the risks involved in producing a net benefit. In the field of gastroenterology, this might translate into a need to give explicit information about the probabilities of the harm and benefit of endoscopic intervention.

### Justice

In medical practice, this means treating the patient with fairness and equality, using consideration with respect to the distribution of scarce resources and respecting morally acceptable laws. Practical examples of the application of justice include avoiding the pursuit of self-interest over the interest of the patient and avoiding discrimination against patients who the doctor might not like personally or feel prejudiced against [5,6]

What is regarded as ethically imperative today is certainly not the same as it was 20 years ago and undoubtedly will change with time. Consent always arises from an informed decision on the part of the patient and is only valid if it reflects a reasonable understanding of the procedure, its implications, risks and alternatives on the part of the patient. Some patients make it clear that they do not wish to receive information, and this is ethically acceptable, provided some basic information is given. One major problem is judging what is reasonable to tell the patient as there is an unavoidable information gap between doctor and patient. Too much information may frighten patients and too little can leave the doctor open to claims that consent is invalid [7,8]. Information given should be based on evidence from the literature and from local experience from a particular gastroenterology unit.

The relationship between law and ethics is notoriously difficult and complex. However, any person or group of persons needs very compelling ethical reasons to justify departure from legally accepted norms. The law is seen as the important guarantor of the rights and duties of both patients and physicians. In many published guidelines for informed consent an important aspect is the problem of protecting clinicians from malpractice.

### How should informed consent be obtained in practice?

It is essential that informed consent be obtained in advance of any procedure, with adequate time to allow for unpressured agreement. A suggested step-by-step protocol is as follows:

- The clinician suggesting the procedure, whether the family physician – in a health maintenance organization, hospital or private clinic, or the doctor on the hospital ward – whether it be the intern, junior or senior physician or the gastroenterologist, should describe the essential elements of the procedure. If possible, this explanation should take place during the office consultation or on the ward.
- The patient should receive understandable pre-prepared information sheets on the appropriate procedures [9], which should include the purpose of the procedure, details of the procedure, options for treatment during the procedure, explanation of benefits, risks, complications and alternatives to the procedure. In addition, the patient should be advised whom to contact for further information.
- On arrival at the endoscopy unit, the receiving nurse should check whether the patient has understood the information given and provide further information and reassurance.
- The ultimate responsibility for the information given to the patient lies with the physician who will be carrying out the endoscopic procedure.
- If the patient is being seen by the endoscopist for the first time, as in open-access endoscopy, the physician must personally give the patient a full explanation. (However, this should have been preceded by the primary physician having given basic information, and the patient at the time of receiving the appointment should have received information sheets as mentioned above.)
- At this time, a formal, standardized consent form (as prepared by medical insurance firms) should be signed.

#### **How should a patient be informed about the risks of a procedure?**

Obviously, the patient must be given information that is truthful regarding the complication rates. But at the same time, information about the benefits of the procedure should also be given. All this information should be presented in a reassuring way, and the patient should be given the opportunity to ask further questions. If the risk is greater than 1 in 1,000 [10], most patients will wish to be informed. A minority of patients wish to be informed about the risk of death. Patients should be told that they may experience discomfort during the procedure and that sedation is usually offered before the procedure, but they may choose not to have it.

#### **What are the exceptions to informed consent?**

Incompetence or inability on the part of the patient to understand or communicate at the time of the procedure requires consent from a legal representative.

In case of an emergency, the physician is allowed to perform an endoscopy even if the patient is not in a physical or mental state to give consent. This requires three physicians to sign the consent form except in an acute emergency that does not allow for this.

In the case of a minor under the age of 18, the legal guardians, usually the family, need to give consent. Where parents appear not to be acting in the child's interest, the physician must act according to the patient's best interest, within the framework of the law.

Withdrawal of consent during a procedure is within a patient's rights, up to a certain point. If the patient is under sedation when requesting a procedure to be stopped, the physician must make a judgment based on the patient's best interests.

#### **Completion of responsibility**

The obligation to give the patient information continues after the procedure. A careful discussion with the patient is necessary after the patient recovers from the sedation. Providing the patient and the family physician with a report, including a histology report if a biopsy is taken, is essential.

#### **Conclusion**

Informed consent is a continual process of providing the patient with understandable information, to allow him/her to make an informed decision about undergoing an endoscopic procedure. This process starts when the first physician proposes the endoscopic procedure and only ends when the patient has received all the information on the findings at endoscopy and biopsy (if taken). All this information should be communicated to the patient in an empathetic and compassionate way.

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*If anyone has conducted a Beethoven performance, and then doesn't have to go to an osteopath, then there's something wrong*

(Sir) Simon Rattle (1995- ), British conductor