Informed Consent: Still Far from Ideal?

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In modern health care, paternalism has given place to shared information, shared decision making and shared responsibilities between doctors and patients [1]. To achieve these goals, doctors must give full and unbiased information to patients, provide adequate time for discussion, and encourage them to participate in the process of decision making. Informed consent is not a momentary action of getting patient's signature on a form. It is a dynamic process of events which rests upon mutual respect and honors the doctor–patient relationship.

Informed consent derives from the principle of respecting the patient's autonomy, i.e., the patient has the right to decide about proposed treatment or procedure. The process of informed consent requires that the doctor explains to the patient the benefits and risks of any suggested test or treatment and obtains the patient's deliberate agreement to proceed [2, 3].

Focusing this article on diagnostic endoscopy, informing a patient and obtaining written informed consent is not that simple because endoscopies are invasive procedures. What would a 'reasonable patient' wish to know so that he/she will be appropriately informed and make a deliberate decision [4]? The elements of adequate disclosure should include: (1) the reason that gastroscopy is indicated; (2) the nature (description) of gastroscopy, i.e., what will happen before, during and after the procedure; (3) diagnostic benefits, including therapeutic options; (4) possible risks, complications and mortality rates; (5) alternative diagnostic tests and their advantages and disadvantages, as compared to gastroscopy, and (6) a clear explanation that the patient may withdraw consent at any time prior to endoscopy.

This information should be given to patients in clear understandable language, adapted to the patients' needs and intelligence [5]. The competence of patients to understand this information should be assessed by the endoscopist. A crucial unresolved issue is the amount of information that the endoscopist should provide the patient about the complication and mortality rates of diagnostic gastroscopy. A published survey concluded that most patients wish to be informed of a risk greater than 1:1,000 [6]. On the contrary, another survey showed that 19% of gastroscopy patients wanted to know all possible complications [7], and a third survey reported that 16% of clinical negligence specialists suggested that patients should be told of risks of 1:1,000,000 [4].

Additional important issues in the process of informed consent include: (1) who should be the responsible person to provide the information and obtain the consent form – endoscopist, referring physician, nurse assistant or another doctor of the staff [8, 9], and (2) what is the best way to inform patients – verbally, leaflet, videotape, postal or e-mail letter [10]. Written information is undoubtedly useful and advisable, but cannot replace the need for doctor–patient verbal communication and discussion. Not least the timing of information is mandatory. Was information given at a counseling session with the patient a month before the examination or just before the patient was sedated for the procedure? Furthermore, nowadays several patients would wish to know the name of doctor who will be in charge or will perform the examination – consultant, trainee (supervised?) or a trained nurse. They would also like to know the years of experience and technical skills of the endoscopist [6, 11], including personal success and complication rates [12].

In this issue of *Digestion* Woodrow and Jenkins [13] investigated the completeness of the consent process in outpatients undergoing gastroscopy. They have shown that about 10% of the patients did not understand why they were having a gastroscopy and about 50% were not told the risks of the procedure and were not given the opportunity to decline. Even more important 40% did not read the consent form before signing it [13]. Two studies from the UK also showed that only 25–50% of the patients had carefully read the consent form before signing it [14, 15] and 51% were dissatisfied because they wished to have more information about risks (42%) and alternative tests (49%) to gastroscopy [15]. Despite published recommendations and guidelines in several countries by endoscopy societies [8, 9, 16], there is growing evidence that there are many deficiencies in the process of obtaining a valid informed consent. A survey assessing the current practice of doctors obtaining informed consent for outpatient endoscopy in the north-west of England showed a wide variation in practice among doctors regarding information given to patients about procedure risks and the person who will perform the endoscopic

procedure [17]. Variation in practice was recently confirmed in a survey among presidents or secretaries of European endoscopy societies, where 23% of the endoscopists did not provide sufficient time for discussion with their patients and only 23% reported related mortality rates [18]. Even worse, another unpublished survey by the European Society of Gastrointestinal Endoscopy among its member societies, with a high response rate, showed that patients do not sign a consent form before gastroscopy in more than half of the responders' endoscopy units.

All the above indicate that there are numerous deficiencies in the process of informed consent for gastrointestinal endoscopic procedures in many European countries. These violate patients' self-determination, have a negative influence on the doctor–patient relationship and could lead to malpractice claims by patients [12, 19, 20]. The workload of endoscopic procedures has very much increased over the past 30 years, but the lack of doctor's time is not an excuse for violating patient's rights and doctor's ethical obligations.

References

- Coulter A: paternalism or partnership? *BMJ* 1999;319:719–720.
- Kirsch M: The myth of informed consent. *Am J Gastroenterol* 2000;95:588–589.
- Feld AD: Informed consent: not just for procedures anymore. *Am J Gastroenterol* 2004;99:977–980.
- Mayberry MK, Mayberry JF: Towards better informed consent in endoscopy: a study of information and consent processes in gastroscopy and flexible sigmoidoscopy. *Eur J Gastroenterol Hepatol* 2001;13:1467–1476.
- Lavelle-Jones C, Byrne DJ, Rice P, Cuschieri A: Factors affecting quality of informed consent. *BMJ* 1993;306:885–890.
- Newton-Howes PA, Bedford ND, Dobbs BR, Frizelle FA: Informed consent: what do patients want to know? *NZ Med J* 1998;111:340–342.
- Brooks AJ, Hurlstone DP, Fotheringham J, Gane J, Sanders DS, McAlindon ME: Information required to provide informed consent for endoscopy: an observational study of patients' expectations. *Endoscopy* 2005;37:1136–1139.
- Stanciu C, Novis B, Ladas S, Sommerville A, Zabovowski P, Isaacs P, Papatheodoridis G, James T: Recommendations of the ESGE workshop on Informed Consent for Digestive Endoscopy. First European Symposium on Ethics in Gastroenterology and Digestive Endoscopy, Kos, Greece, June 2003. *Endoscopy* 2003;35:772–774.
- British Society of Gastroenterology: Guidelines for Informed Consent for Endoscopic Procedures. Guidelines in Gastroenterology, London, British Society of Gastroenterology, 1999, <http://www.bsg.org.uk>
- Plumeri PA: Informed consent and the gastrointestinal endoscopist. *Gastrointest Endosc* 1985;31:218–221.
- Yacavone RF, Locke GR 3rd, Gostout CJ, Rockwood TH, Thieling S, Zinsmeister AR: Factors influencing patient satisfaction with GI endoscopy. *Gastrointest Endosc* 2001;53:703–710.
- Cotton PB: Analysis of 59 ERCP lawsuits; mainly about indications. *Gastrointest Endosc* 2006;63:378–382.
- Woodrow SR, Jenkins AP: How thorough is the process of informed consent prior to outpatient gastroscopy? A study of practice in a United Kingdom district hospital. *Digestion* 2006;73:189–197.
- Pereira SP, Hussaini SH, Wilkinson ML: Informed consent for upper gastrointestinal endoscopy. *Gut* 1995;37:151–153.
- Basi E, Brown E, Kapoor N, Bodger K: Dissatisfaction with consent for diagnostic gastrointestinal endoscopy. *Dig Dis* 2002;20:275–279.
- American Society for Gastrointestinal Endoscopy: Informed consent for gastrointestinal endoscopy. *Gastrointest Endosc* 1988;34(suppl 3):26s–27s.
- Thuraisingam AI: Survey of informed consent for endoscopy. *Gut* 2001;49:874.
- Triantafyllou K, Stanciu C, Kruse A, Malfertheiner P, Axon A, Ladas SD, European Society of Gastrointestinal Endoscopy: Informed consent for gastrointestinal endoscopy: a 2002 ESGE survey. *Dig Dis* 2002;20:280–283.
- Neale G: Reducing risks in gastroenterological practice. *Gut* 1998;42:139–142.
- Levine EG, Brandt LJ, Plumeri PA: Informed consent: a survey of physician outcomes and practices. *Gastrointest Endosc* 1995;41:448–452.