My best advise for consent in GI endoscopy

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Disclosure

- I’ve never been in the court except for a traffic court
- Following this advise, I can not guarantee you from being sued
- The purpose of this lecture and discussion is to get you and your patients for the best relationship and hopefully…. It may save you from some avoidable legal conditions

Consent

- The voluntary agreement by a person with the functional capacity for decision making to make an informed choice about allowing an action proposed by another person (eg, performance of a procedure) to be performed on himself or herself.

Informed consent

- A physician's legal requirement to disclose information to his or her patient and enables the patient to understand, evaluate, and authorize a specific surgical or medical intervention
- Informed consent is a process of disclosure and deliberation, not merely the signing of a form.

- Informed consent should be the result of a collaborative effort between the patient and the doctor that honors the patient’s autonomy

Material risks

- Risk that a reasonable patient would wish to know in order to make an appropriate decision

Four elements of material risk

- The nature of the risk
- The magnitude of the risk (seriousness)
- The probability that the risk may occur
- The imminence of the risk (Immediately post procedure or later)

Documentation

- A signed consent form
- A brief note in the chart states in general term that the consent has been obtained
- A longer note states all the risks, benefits, alternatives, and limitations
- Tape or video.. Do not recommend

Standard format

- Medical diagnosis and results
- The nature of the proposed procedure.
- The reason the procedure is being suggested.
- The benefits of the procedure.
- The risks and complications of the procedure, including the relative incidence and severity, that would be material to the patient's decision-making process.
- Reasonable alternatives to the proposed procedure.
- The patient's prognosis if the treatment or test is decline

Personnel to obtain the consent

- The endoscopist is best advised to obtain the patient's informed consent personally.
- The purpose of the informed consent process is not simply the acquisition of a patient's or family member's signature but to provide information and ensure that the patient consents, based on meaningfuldiscussion and mutual understanding of all parties involved.

Tips for though

- Specific form is needed for particular invasive procedure; liver biopsy, ERCP
- Asymptomatic indication (screening idea) requires more through explanation than the sick one
- Use simple lay language and explain to them do not just say “let them read!”
- Obtain it a reasonable time
- Should be legibly dated, timed and signed
- It is also advisable that the endoscopist have a third party witness the informed consent interview
- Videotaping of informed consent is generally not recommended.

Interesting questions

- Do you obtain informed consent on patients whom you first meet on a gurney after they have been prepped,stripped, gowned, and poked?
- Which is more important to you, the signed consent form or the consent discussion? Which would you be willing to omit?

- Do your patients sign a consent form *before* you have discussed the procedure with them?
- Have you ever invoked a diagnosis of cancer, even if unlikely, to persuade a vacillating patient to consent to a procedure?
- Do you routinely include *foregoing* diagnostic testing as an option?

- Do you create hypothetical scenarios such as, “if I were you, I’d have a colonoscopy done,” or respond to patient inquires on what your advice would be if the patient were your mother, etc?
- Do you routinely present barium contrast studies as reasonable options when recommending endoscopic procedures?

- Have you ever assumed consent when you have performed the identical procedure on a patient previously?
- Have you ever performed endoscopy on a patient whom, deep down, you were not fully certain comprehended the risks, benefits, and alternatives?
- Does your consent process change if the patient is an attorney?

Exceptions to the informed consent process

- Emergency situation
- Therapeutic privilege (rare)
- Waiver
- Legal mandate (judge’s order)

Incompetent patients

- Very elderly
- Below-average IQ
- Impaired cognitive function
- Alcohol or drug influence

Withdrawal of consent

- A patient who is not sedated can withdraw consent at any time
- Consent can be withdrawn after administration of sedation but it should be carefully evaluated by the endoscopist, including listening to the patient and the nursing staff

Pitfall in informed consent process

- Majority do not read consent forms carefully, and many do not even understand them[1,2]
- Patients were not advised of alternative treatment options, and nearly 10% were not aware that they had a right to refuse treatment[3]

1. Lavelle-Jones Br Med J 1993
2. Agre P Cancer Prac 1997
3. Sulmasy DP J Clin Ethics 1994

What is your experience on Lawsuits?

Lawsuits for years in practice

Years in practice	Total	Lawsuits	
		No.	%
0-1	65	2	3.1
2-3	56	5	8.9
4-5	95	6	6.3
6-10	248	36	14.5
11-15	274	70	25.5
16-20	251	56	22.3
>20	243	80	32.9
Total	1232	255	20.7

Levine EG GIE 1995

Indication for the procedure is the most important issue

While serious complications can occur in patients with good indications, most patients and relatives are more understanding when things do not go according to plan in those circumstances.

Cotton PB GIE 2006

Analysis of 59 ERCP lawsuits; mainly about indications

Peter B. Cotton, MD, FRCP, FRCS

Charleston, South Carolina, USA

	Primary issue	Secondary issue
Indications	32	16
ERCP	15	11
Sphincterotomy	8	5
Pre-cutting	9	0
Technique	19	4
Assumed	11	
Documented	8	
Post-ERCP care	5	10
Declined ERCP	2	
Delayed ERCP	1	
Consent	0	15
Credentialing	0	1
Training	0	2

Cotton PB GIE 2006

The myth of informed consent

For gastroenterologists and surgeons who practice endoscopy, informed consent discussions are built-in opportunities for "quality time" with our patients.

The consent discussion should be a forum for patients and doctors to discuss, and even debate, various options in the context of their illness or overall health. This improved communication will help to invigorate our relationships with our patients. Thanks to midazolam, our patients will not remember us for our technical wizardry, but they will recall the content and manner of our discussions with them.

Kirsch M AJG 2000