Communication from the Standards of Practice Committee

GUIDELINE

Informed consent for GI endoscopy

This is one of a series of statements discussing the utilization of GI endoscopy in common clinical situations. The American Society for Gastrointestinal Endoscopy (ASGE) Standards of Practice Committee the prepared this text. In preparing this guideline, MEDLINE and PubMed databases were used to search publications through February 2006 that related to the topic of "informed consent for gastrointestinal endoscopy" by using the keyword(s) "informed consent," "patient information," "risk," "gastrointestinal endoscopy," "endoscopy," "endoscopic procedures," and "procedures." The search was supplemented by accessing the "related articles" feature of PubMed, with articles identified on MEDLINE and PubMed as the references. Pertinent studies published in English were reviewed. Studies or reports that described fewer than 10 patients were excluded from the analysis if multiple series with more than 10 patients that addressed the same issue were available. The strength of reported evidence and the recommendations based on reviewed studies were graded on the strength of the supporting evidence (Table 1).[1]

Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus. Further controlled clinical studies may be needed to clarify aspects of this statement, and revision may be necessary as new data appear. Clinical consideration may justify a course of action at variance to these recommendations.

Over the last 50 years, informed consent has undergone a transformation from an ethical concept to a legal doctrine. It is based on the ethical principles of self determination and autonomy.[2] Courts and juries may find physician liability based on the failure to obtain adequate informed consent.[3-5] Historically, physicians have had the primary responsibility to disclose to patients the patient's diagnosis, the nature of a proposed procedure or treatment, material risks and benefits, and reasonably available alternatives in obtaining consent.[6] Properly obtaining informed consent can guard against legal claims for medical battery and negligence.

All 50 states have adopted the legal notion of informed consent through state statutes or court decisions. The duty of all GI endoscopists is to obtain legally adequate informed consent before performing any endoscopic procedure. Although there is no one absolute prescribed way to obtain adequate informed consent, the purpose of this guideline is to present to endoscopists a reasonable and effective method of obtaining it. This review updates the 1988 ASGE guideline on informed consent for gastrointestinal endoscopy.[7,8]

DEFINITION OF INFORMED CONSENT

Consent is defined as 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.[9] Informed consent is defined as 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.[9] The crux of informed consent is a combination of disclosure of the substantive information necessary to make a reasoned decision and voluntary decision making by the patient. The disclosure requirements as defined legally are of 2 types and differ based on the measure used to determine the scope of the disclosure.[3,10]

One or the other is applied in each state, and it is recommended that the endoscopist learn the applicable standard in his or her state.[3] The first standard of disclosure is the "professional disclosure" or "physician-based" standard, which requires that the GI endoscopist disclose to the patient that amount of information that a reasonable, similarly situated physician would provide. The second disclosure standard is the "reasonable patient" standard. Under this standard, the endoscopist must provide information that a reasonable lay person would consider material and significant in consenting to a proposed procedure. States are almost evenly split as to which standard is followed. The recent trend seems to be moving toward adoption of the reasonable patient standard.[11]

INFORMATION TO BE DISCLOSED

The essential elements of disclosure under either standard include the following:

1. The patient's pertinent medical diagnosis and test results.

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TABLE 1. Grades of recommendation

Grade of recommendation	Clarity of benefit	Methodologic strength supporting evidence	Implications
1A	Clear	Randomized trials without important limitations	Strong recommendation; can be applied to most clinical settings
1B	Clear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Strong recommendation; likely to apply to most practice settings
1C+	Clear	Overwhelming evidence from observational studies	Strong recommendation; can apply to most practice settings in most situations
1C	Clear	Observational studies	Intermediate-strength recommendation; may change when stronger evidence is available
2A	Unclear	Randomized trials without important limitations	Intermediate-strength recommendation; best action may differ, depending on circumstances or patient or societal values
2B	Unclear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Weak recommendation; alternative approaches may be better under some circumstances
2C	Unclear	Observational studies	Very weak recommendation; alternative approaches likely to be better under some circumstances
3	Unclear	Expert opinion only	Weak recommendation; likely to change as data become available

2. The nature of the proposed procedure.
3. The reason the procedure is being suggested.
4. The benefits of the procedure.
5. The risks and complications of the procedure, including the relative incidence and severity, that would be material to the patient's decision-making process.
6. Reasonable alternatives to the proposed procedure.
7. The patient's prognosis if the treatment or test is declined.[11]

In short, information must be disclosed regarding risks, benefits, alternatives, and personnel involved in the medical or surgical intervention. The endoscopist should be certain to explain the procedure to the patient, including what will occur before, during, and after the procedure. The nature of the procedure should be described and the anticipated benefits outlined. The risks and possible complications of the procedure must be detailed. Not every possible risk or complication need be disclosed, but the substantive risks that would influence a reasonable person when making a choice are required, including the probability and severity of possible outcomes. In general, risks with significant frequency and risks that may be less frequent but of a serious nature should be presented. The description of risks should be tailored to the patient, taking into account the particular situation and physical vulnerabilities of the patient.[11] If drugs, including sedation, are to be used, the endoscopist should include their hazards and risks. All reasonable alternatives to the proposed procedure should be presented, including ones that may be more hazardous. If no clinical alternatives exist, the patient should be so informed. Finally, the endoscopist should inform the patient of the possible outcomes if the patient declines the proposed procedure.

PERSONNEL TO OBTAIN INFORMED CONSENT

The endoscopist is best advised to obtain the patient's informed consent personally.[10-12] In general, this duty should not be delegated to health care providers not directly involved with the procedure, although policies may vary from state to state and from hospital to hospital. It must be emphasized that 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 meaningful discussion and mutual understanding of all parties involved. Only true informed consent can enhance patient understanding and protect physicians from liability in medical battery or other malpractice lawsuits. In a national

survey of ASGE members, informed consent was obtained in 98.5% of endoscopic cases; however, 30% of physicians left the task of obtaining consent to other hospital or office personnel. Twenty-one percent of respondents had been sued, and, in 42% of these instances, the informed consent process was an issue. Being involved in a lawsuit appears to change one's approach to obtaining informed consent, especially when this process was an issue in the suit.[13] A questionnaire study showed that trainees involved in surgical procedures were often not able to correctly list all risks, benefits, and alternatives of procedures when they sought informed consent.[14] There is considerable international variation in the procedure of obtaining informed consent, as found in a survey of members of the European Society of Gastrointestinal Endoscopy.[15] Appropriate institution of informed consent and risk management should be part of the curriculum in GI fellowship training.[16] Preprinted materials; diagrams; and other audiovisual materials, videos, or ''postal consent'' (specifically designed information booklet with an integral consent form mailed to patients before their procedure) can be useful adjuncts to the patient's decision making but are not substitutes for the physician–patient interaction.[17-20] The patient should be given adequate time to deliberate and the endoscopist should solicit and answer questions.[10,11]

DOCUMENTATION OF INFORMED CONSENT

Most hospitals require written documentation of consent (eg, a consent form) to satisfy their informed consent policies, although such documentation is required by law in only a few states. The endoscopist must be mindful of the fact that informed consent is a process of disclosure and deliberation, not merely the signing of a form. The typical generic consent form serves little useful purpose other than to provide evidence that the patient signed it. To document the informed consent process, there may be a role for specific consent forms for each procedure that defines the nature, benefits, risks, and alternatives to that procedure.[10,11] Specific forms could include the particular and specific data for the procedure for which it is designed. For example, variability between which risks were discussed and the severity of each risk suggests the need for specific consent forms for high-risk endoscopic procedures, such as ERCP and PEG-tube placement.[21-23] Disputes about the quality of the process of informed consent were found to be present in the majority of cases in an analysis of ERCP lawsuits. Specifically, these disputes focused upon the indication for the procedure in 48 of 59 of cases (80%).[24] Patients commonly received their information only immediately before the procedure, often without significant documented physician involvement.

Informed consent information and acknowledgement forms should be written in simple lay language. To ensure that information can be understood, the text should be reviewed by an experienced education specialist (health educator).[25] If the form is to be used in a multicultural or multilingual setting, it is important to ensure that it can be understood by the patient who is undergoing the procedure.[25] Consent forms in foreign languages may be used in appropriate situations, depending upon demographics. Use of appropriate translators can be helpful, but caution should be taken not to use family members as translators, because this can introduce bias into the consent process. Endoscopists should be sensitive to potential physical barriers to the informed consent process for patients who were blind or deaf. Braille consent forms and sign language interpreters can be useful tools for conveying information and obtaining consent from these patients.

The endoscopist should be certain to document that he or she obtained the patient's informed consent within a reasonable time before the performance of a procedure. The informed consent document should be legibly dated, timed, and signed. An appropriate note should be entered into the patient's hospital or office record. The administration of sedation with midazolam and meperidine appears to not interfere with later patient recall of the preprocedure informed consent process. Pre-endoscopic informed consent can be obtained at any time before sedation.[26,27] It is also advisable that the endoscopist have a third party witness the informed consent interview.[10,11] This witness to the informed consent process may prove invaluable in the event that any questions arise concerning the validity or extent of disclosure. Although tape recording and videotaping of informed consent interviews may be useful in certain procedures or with high-risk patients, they are not generally recommended.[11]

TIMING AND SETTING OF INFORMED CONSENT

With few exceptions, noted below, informed consent must be obtained within a reasonable time before the procedure is performed, in outpatient or inpatient settings. The timing of the discussion with the patient and the patient's written acknowledgment will depend on the circumstances of each case. The use of open access endoscopy (OAE) is increasing.[28] OAE does not readily allow the provision of preprocedure education and informed consent during an office visit before the endoscopy. Studies that addressed the effect of OAE on the adequacy of patient informed consent found that patients reported being less adequately informed about their endoscopic procedure than patients referred from the GI subspecialty clinic.[29,30] Patient education may be improved through the aforementioned use of a mailed informed consent package or other preprocedural education.[17,18,20,28] The informed consent process is especially important for screening endoscopies, because these are

truly elective procedures, without symptoms or signs driving the study. The possibility of iatrogenic harm in this setting assumes greater ethical significance and suggests that the patient should understand not only the processes of the procedure but also its purpose and alternatives.[30,31] Iatrogenic injury from an elective procedure may include the harm resulting from false-positive findings with needless additional testing or from false-negative studies with missed lesions and failure to prevent interval cancers, as well as the direct complications of the procedure.[32,33] Informed consent for hospitalized patients undergoing endoscopic procedures has different challenges. Although these patients do not ordinarily undergo elective procedures, patients in the hospital are inherently compromised by their illness and may have impaired recall of the informed consent process.[31] Under certain circumstances, endoscopists may choose to conduct all or part of the patient education process over the telephone. The telephone consultation must incorporate the critical issues, including giving appropriate information regarding risks, benefits, and alternatives, as listed above. During the telephone call, the endoscopist should allow enough time to answer questions. The telephone consent process must be documented in the patient's medical record, and efforts should be taken to obtain signed consent forms when the patient presents for treatment. If the endoscopist has any reason to doubt the patient's decision-making capacity over the telephone, the endoscopist should not rely on the telephone conversation but should obtain consent in person.

Parents or guardians must provide consent before endoscopy for minors or patients who are incapacitated. State law should be consulted to determine the age of majority and other factors related to a person's capacity to consent to medical procedures.

EXCEPTIONS TO THE INFORMED CONSENT PROCESS

There are recognized exceptions to the informed consent process that affect an endoscopist's approach to informed consent. These include emergency, therapeutic privilege, waiver, and legal mandate.

Emergency

When there is inadequate time because of clinical exigency and there is a threat to a patient's life, the treating endoscopist may forgo obtaining the patient's informed consent. A physician may take that action necessary to save a patient's life by using the construct of implied consent. This exception only applies to emergencies in which the patient's condition is life threatening or the medical intervention is necessary to relieve pain and suffering. It is recommended that the circumstances surrounding the emergency be documented in the medical record.

Therapeutic privilege

Therapeutic privilege is the term for withholding information when the physician determines that providing the patient with information would harm the patient or otherwise undermine the goals of informed consent.[32] For endoscopic procedures, the likely incidence of this exception is small. In these cases, it may be appropriate to forgo informed consent. Although the degree of harm necessary to trigger this exception is unclear, an endoscopist may invoke it in selected clinical situations. Studies indicate that patients do not decline procedures and therapy because of disclosure, and they generally appreciate and want this information.[2]

Waiver

Withholding information from patients at their request is a legally recognized exception to informed consent and is referred to as a waiver.[32] A patient may elect to waive the right to informed consent. In this case, the endoscopist is not required to obtain informed consent. When the waiver exception is relied upon, the endoscopist should be certain that the patient has full knowledge and understanding of his or her right to informed consent and that he or she voluntarily relinquishes it. As with the application of any of the exceptions, appropriate documentation, including a written acknowledgment of the waiver signed by the patient, is essential.

Legal mandate

A judge's order or statute may supersede the process of informed consent. In these situations, the patient's and/or public welfare and interest overshadow the patient's right to informed consent.

OTHER ISSUES

Incompetent or incapacitated patients

The quality of informed consent can be affected by multiple factors. A systematic review of the published literature on informed consent found that older age and less formal education were associated with impaired understanding of informed consent information.[33] Elderly patients, patients with a below-average IQ, and those with impaired cognitive functions were shown, in a prospective survey of surgical patients, to have poor information recall. Written information given to patients before admission may be particularly useful for these groups of patients.[34] However, adequate cognitive function does not predict a high level of understanding of the informed consent process, whereas cognitive impairment precludes it.[35]

A patient's incompetence or lack of decision-making capacity by virtue of age, alcohol, or drugs, or by intellectual impairment is not an exception to the informed consent process. Special care must be taken in obtaining informed consent from patients who are incompetent. Obtaining

a signed consent form from a patient who is incompetent will not satisfy the legal requirements for informed consent. The endoscopist has a duty to obtain informed consent from a parent, legal guardian, or surrogate of a patient who is incompetent or incapacitated. State law should be consulted regarding patient capacity, guardian, and surrogate rules.

Withdrawal of consent

One unsettled area is the issue of withdrawal of consent.[36] A patient who is not sedated can withdraw consent at any time. However, the endoscopist and the staff should be aware that consent can be withdrawn after administration of sedation. A British survey of gastroenterologists found divergent views regarding stopping a colonoscopy under moderate sedation after requested by the patient.[37] Requests to stop a procedure should be carefully evaluated by the endoscopist, including listening to the patient and the nursing staff.[36]

Informed refusal

An issue related to informed consent is informed refusal.[38] The essence of this doctrine is that the patient who refuses a procedure or any medical treatment must have the opportunity to decline in a knowing way. One example of this is that of a patient who refuses colonoscopy for colorectal cancer screening. In the event that the patient declines the procedure, the physician's notes should reflect that the patient with decision-making capacity was informed of the indications for the procedure and understood the implications of declining the procedure so that it can be shown that the refusal was informed.

SUMMARY (LEVEL OF EVIDENCE)

- The crux of informed consent is a combination of disclosure and voluntary decision making (grade 3).
- The essential elements of adequate disclosure are the nature of a proposed procedure or treatment, the reason the procedure is suggested, the material risks and benefits, and the reasonable alternatives to the proposed procedure (grade 3).
- The endoscopist should be certain to document that the patient's informed consent has been obtained before the performance of a procedure (grade 3).
- All informed refusals should be documented (grade 3).
- Recognized exceptions to the informed consent process include emergency, therapeutic privilege, waiver, and legal mandate (grade 3).

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