Complete Summary

GUIDELINE TITLE

Informed consent for GI endoscopy.

BIBLIOGRAPHIC SOURCE(S)

Standards of Practice Committee, Zuckerman MJ, Shen B, Harrison ME 3rd, Baron TH, Adler DG, Davila RE, Gan SI, Lichtenstein DR, Qureshi WA, Rajan E, Fanelli RD, Van Guilder T. Informed consent for GI endoscopy. Gastrointest Endosc 2007 Aug;66(2):213-8. [38 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Society for Gastrointestinal Endoscopy. Guideline: informed consent for gastrointestinal endoscopy. Gastrointest Endosc 1988;34(Suppl):26S-7S.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Any disease or condition requiring gastrointestinal endoscopy

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To present to endoscopists a reasonable and effective method of obtaining adequate informed consent

TARGET POPULATION

Patients undergoing endoscopy

INTERVENTIONS AND PRACTICES CONSIDERED

Obtaining and documenting informed consent from patients undergoing gastrointestinal endoscopy

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

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.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

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	Strong

Grade of Recommendation	Clarity of Benefit	Methodologic Strength/ Supporting Evidence	Implications
		evidence from observational studies	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 patients' 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

*Adapted from Guyatt G, Sinclair J, Cook D, Jaeschke R, Schunemann H, Pauker S. Moving from evidence to action: grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, eds. Users' guides to the medical literature. Chicago: AMA Press; 2002. p. 599-608.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendations were graded on the strength of the supporting evidence (Grades 1A-3). Definitions of the recommendation grades are presented at the end of the "Major Recommendations" field.

Summary

- 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**).

Definitions:

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	Strong recommendation; likely to apply to

Grade of Recommendation	Clarity of Benefit	Methodologic Strength/ Supporting Evidence	Implications
		limitations (inconsistent results, nonfatal methodologic flaws)	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 patients' 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
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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate obtaining and documentation of adequate informed consent in patients undergoing an endoscopic procedure.
- Informed consent can enhance patient understanding and protect physicians from liability in medical battery or other malpractice lawsuits.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Further controlled clinical studies are 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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1988 (revised 2007 Aug)

GUIDELINE DEVELOPER(S)

American Society for Gastrointestinal Endoscopy - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society for Gastrointestinal Endoscopy

GUIDELINE COMMITTEE

Standards of Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Marc J. Zuckerman, MD; Bo Shen, MD; M. Edwyn Harrison III, MD; Todd H. Baron, MD, *Chair*; Douglas G. Adler, MD; Raquel E. Davila, MD; S. Ian Gan, MD; David R. Lichtenstein, MD; Waqar A. Qureshi, MD; Elizabeth Rajan, MD; Robert D. Fanelli, MD, SAGES Representative; Trina Van Guilder, RN, SGNA Representative

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available from the American Society for Gastrointestinal Endoscopy Web site.

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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