Communication from the ASGE Standards of Practice Committee

GUIDELINE

ASGE American Society for Gastrointestinal Endoscopy

American Society for Gastrointestinal Endoscopy guideline on informed consent for GI endoscopic procedures

Andrew C. Storm, MD,[1] Douglas S. Fishman, MD, FAAP, FASGE,[2] James L. Buxbaum, MD, FASGE,[3] Nayantara Coelho-Prabhu, MD, FASGE,[1] Mohammad A. Al-Haddad, MD, FASGE,[4] Stuart K. Amateau, MD, PhD, FASGE,[5] Audrey H. Calderwood, MD, MS, FASGE,[6] Christopher J. DiMaio, MD, FASGE,[7] Sherif E. Elhanafi, MD,[8] Nauzer Forbes, MD, MSc,[9] Larissa L. Fujii-Lau, MD,[10] Terry L. Jue, MD, FASGE,[11] Divyanshoo R. Kohli, MD,[12] Richard S. Kwon, MD,[13] Joanna K. Law, MD,[14] Swati Pawa, MD, FASGE,[15] Nirav C. Thosani, MD, MHA,[16] Sachin Wani, MD, FASGE,[17] Bashar J. Qumseya, MD, MPH,[18] (ASGE Standards of Practice Committee Chair)

Prepared: ASGE STANDARDS OF PRACTICE COMMITTEE

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

Informed consent is the cornerstone of the ethical practice of procedures and treatments in medicine. The purpose of this document from the American Society for Gastrointestinal Endoscopy (ASGE) Standards of Practice Committee is to provide an update on best practice of the informed consent process and other issues around informed consent and shared decision-making for endoscopic procedures. The principles of informed consent are based on longstanding legal doctrine. Several new concepts and clinical trials addressing the best practice of informed consent will help guide practitioners of the burgeoning field of GI endoscopic procedures. After a literature review and an iterative discussion and voting process by the ASGE Standards of Practice Committee, this document was produced to update our guidance on informed consent for the practicing endoscopist. Because this document was designed by considering the laws and broad practice of endoscopy in the United States, legal requirements may differ by state and region, and it is the responsibility of the endoscopist, practice managers, and other healthcare organizations to be aware of local laws. Our recommendations are designed to improve the informed consent experience for both physicians and patients as they work together to diagnose and treat GI diseases with endoscopy. (Gastrointest Endosc 2022;95:207-15.)

(footnotes appear on last page of article)

This guideline document was prepared by the Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy using the best available scientific evidence and considering a multitude of variables including, but not limited to, adverse events, patients' values, and cost implications. The purpose of these guidelines is to provide the best practice recommendations, which may help standardize patient care, improve patient outcomes, and reduce variability in practice. We recognize that clinical decision-making is complex. Guidelines, therefore, are not a substitute for a clinician's judgment. Such judgements may, at times, seem contradictory to our guidance because of many factors that are impossible to fully consider by guideline developers. Any clinical decisions should be based on the clinician's experience, local expertise, resource availability, and patient values and preferences. This document is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating for, mandating, or discouraging any particular treatment. Our guidelines should not be used in support of medical complaints, legal proceedings, and/or litigation, as they were not designed for this purpose.

Informed consent is the basis of practice of any medical treatment or procedure, including GI endoscopy. Informed consent is rooted in the ethical principles of self-determination and autonomy. All 50 states require, through state statute or court decisions, that providers obtain legally adequate informed consent from patients before performing any endoscopic procedure.[1] From a medicolegal perspective, courts may find physician liability based on the failure to obtain informed consent.[2] Additionally, properly obtaining informed consent can guard against legal claims for medical battery and negligence.[3]

TABLE 1. Summary and strength of recommendations

Recommendation	Strength of recommendation
Endoscopists and practitioners should learn the applicable standard of informed consent in the state(s) where they practice.	*Strong recommendation, low quality of evidence*
Informed consent may be obtained by any member of the GI team (including nurse, advanced practice provider, or trainee) who are thoroughly knowledgeable of and able to communicate the indication(s), risks, benefits, and alternatives of that procedure.	*Strong recommendation, low quality of evidence*
Routine informed consent should be performed and documented before the performance of a procedure, including in direct-access endoscopy practice.	*Conditional recommendation, low quality of evidence*
When available, video and other electronic supplemental educational materials can be used to supplement informed consent.	*Strong recommendation, moderate quality of evidence*
A discussion of non–FDA–approved and off-label techniques and devices should be included in the informed consent process.	*Conditional recommendation, low quality of evidence*
In an emergency situation, effort should be made (and documented) to obtain written consent before a procedure as the situation allows.	*Strong recommendation, high quality of evidence*
In pediatric patients undergoing GI procedures we recommend age-appropriate consent and assent processes that are developmentally appropriate for patients and their families	*Strong recommendation, low quality of evidence*

Adequate informed consent primarily involves a discussion between the physician and patient aimed at educating the patient regarding the indication for and potential benefits to gain from performing the proposed procedure, the potential risks of the proposed procedure and of foregoing the procedure, and the alternatives to the proposed procedure. After completion of this discussion, the patient legally acknowledges this dialogue and his or her consent to proceed with the treatment or procedure by signing a consent form.

This document attempts to provide guidance for several important situations that may be encountered in legal consent for the practicing endoscopist. Several novel concepts and clinical trials have been performed to enhance how we may think about, obtain, and provide informed consent for the growing range of GI endoscopic procedures. Although no single absolute method is prescribed, this guideline aims to present to endoscopists a reasonable and effective approach for obtaining informed consent. Further controlled clinical studies may be needed to clarify aspects of these statements, and revision may be necessary as new data appear. Additionally, real-time clinical considerations may require variation from these recommendations. This review updates the 2007 American Society for Gastrointestinal Endoscopy (ASGE) guideline on informed consent for GI endoscopy.[4]

COMPREHENSIVE LITERATURE SEARCH

A comprehensive search of the medical literature was performed using the strategy described in Appendix 1 (available online at www.giejournal.org). In collaboration with an information specialist, MEDLINE and Embase were searched from inception through February 2020. Search terms included "informed consent," "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 Embase as the references.

In total, 720 pertinent studies published in English were reviewed, and 102 were selected for data review through a 2-member selection process using Covidence (Melbourne, Australia). Studies were included if they discussed issues pertaining to informed consent in endoscopy. Studies were excluded if the topic did not address endoscopic procedures. Additionally, meeting abstracts and case reviews were excluded.

Our final guideline statements are based on our critical review of the available data and expert consensus. The strength of a recommendation was based on the ASGE Standards of Practice Committee panel vote. The level of evidence was determined according to standard GRADE (Grading of Recommendation Assessment, Development and Evaluation) terminology adopted by the ASGE Standards of Practice (SOP) Committee, which is based on various factors including quality of evidence among other considerations (Table 1).[5] Due to the nature of this document, the GRADE methodology was not used in developing the recommendations.

DEFINITION OF INFORMED CONSENT

Consent is a voluntary agreement by a person with the capacity to make an informed choice about a proposed action upon them by another person.[6] Informed consent carries a legal mandate to disclose information about a proposed procedure that must enable the individual to understand, consider, and voluntarily authorize that procedure. The disclosure requirements as defined legally are of 2 types and differ based on the measure used to determine the scope of the disclosure. The first standard of disclosure is the "professional disclosure" or "physician-based" standard, which

requires that a medical team disclose to the patient an amount of information that a reasonable, similarly situated physician would provide.[7-10] The second disclosure standard is the "reasonable patient" standard. Under this standard, the medical team 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, with the most recent trend moving toward adoption of the reasonable patient standard.[9] Regardless of the legal standard of disclosure, the informed consent process is ideally a patient-centered discussion of a proposed treatment that includes the medical provider's expertise and the patient's individual values to decide on a diagnostic or therapeutic plan of action, also called *shared decision-making*.

Recommendation: **Endoscopists and practitioners should learn the applicable standard of informed consent in the state(s) where they practice.**

(Strong recommendation, low quality of evidence)

PERSONNEL TO OBTAIN INFORMED CONSENT

Historically, it has been considered ideal that informed consent should be obtained by the clinician performing the procedure; however, this has become controversial in modern team-based medical practice.[10] There are, as explored in Use of Electronic Resources for Consent, below, many ways to successfully fulfill the legal and ethical mandate of informed consent. An increasing clerical burden on medical professionals has resulted in the increasing use of physician extenders including physician assistants and nurse practitioners as well as situations where trainees including residents and fellows are involved in procedural workflow. These professionals often possess the skills and credentials necessary to supply patients with the information and support that is required to make an informed decision regarding a proposed treatment, including procedural treatments. The ethical mandate of high-quality informed consent may be fulfilled regardless of who among the treating care team obtains the consent. As such, consideration must be given to other members of the team for their role in providing informed consent.

Several studies have addressed trainee performance of informed consent in endoscopic and surgical procedures.[11-15] These data suggest that with proper education, individuals who do not yet independently perform various procedures are able to become proficient in provision of high-quality informed consent for procedural therapy. The legal statutory language regarding this issue of who may obtain consent varies from state to state and is often not specific in nature but includes the following examples.[10] Some states specifically note that a "physician assistant" (Oregon) or "healthcare *provider* licensed to provide health care in the state" (Texas) may obtain consent. Others are more strict, dictating that a "physician" (Pennsylvania), "the person providing the professional treatment" (New York), or "any physician who treats a patient" (Wisconsin) should inform the consent process.

To satisfy both the workflow of a modern medical team and the patient's right to a complete and high-quality informed consent process, the following recommendation is made based on expert committee consensus, with the limitation that local and state mandate may restrict or allow otherwise:

Recommendation: **Informed consent may be obtained by any member of the GI team (including nurse, advanced practice provider, or trainee) who are thoroughly knowledgeable of and able to communicate the indication(s), risks, benefits, and alternatives of that procedure.**

(Strong recommendation, low quality of evidence)

INFORMATION TO BE INCLUDED

As previously mentioned, informed consent requires disclosure of key pieces of information:

1. Review of the patient's relevant medical conditions and results (if not already done previously).
2. A description of the procedure to be performed, including any diagnostic or therapeutic interventions that may reasonably be anticipated to occur during the procedure (ie, tissue biopsy sampling, polypectomy, dilation).
3. Potential benefits of the procedure (ie, why it is being proposed).
4. Potential risks and adverse events (AEs) associated with this procedure, including an estimate of the frequency and severity of the most common and most severe AEs.
5. A discussion of the alternatives to the procedure, including the option to not do the procedure.
6. Potential harms of not proceeding with the proposed procedure.
7. A discussion regarding the potential needs for intubation, resuscitation, hospitalization, and blood transfusion; documenting a patient's preference.

The consenting provider should be certain to explain the procedure to the patient, including what will occur before, during, and after the procedure. Not every possible AE can reasonably be disclosed. Rather, 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, the more common AEs and most serious AEs should be discussed. Reasonable alternatives to the proposed procedure should be presented, including those that may be more or less

hazardous. Finally, the provider should inform the patient of the possible outcomes if the patient declines the proposed procedure. Appendix 2 (available online at www.giejournal.org) shows an example statement of consent for medical treatment.

DOCUMENTATION, TIMING, AND SETTING OF INFORMED CONSENT

With the mandate on hospitals to move toward portable electronic medical record systems, electronic aids to the written consent process are increasingly available. Although electronic medical records have been shown to reduce endoscopy staff satisfaction and increase clerical burden, patient safety may be improved by some components, including preprocedure reminders regarding collecting informed consent.[16,17]

In some circumstances, a provider may be required to obtain informed consent through the means of a telephone or other virtual discussion with the patient or their proxy rather than during an in-person discussion. In such cases, all the usual components of informed consent need to be discussed. Adequate time should be given to answer questions, and documentation of the conversation in the medical record is expected before initiation of the proposed procedure.

A challenge somewhat unique to GI endoscopy is that of direct access procedures, whereby patients may be referred for a procedure the same day they will be meeting the endoscopist performing their procedure.[18] Open-access endoscopy can detract from the preprocedure education and informed consent that would occur in the office setting before a patient prepares and presents for the procedure.[19] Although informed consent for GI endoscopy may sometimes necessarily be obtained the day of the procedure or even in the procedure room itself, the previously described aspects of informed consent are still required, and the patient should be given time to ask questions before the procedure. Given the interest of patients and providers alike in continuing to use direct-access procedures while also providing excellent patient-centered care, the provision of various preprocedure education materials has been studied.

Additionally, medical care and consultation are increasingly provided electronically.[20-23] Several studies have assessed quality improvement measures aimed at improving the informed consent process for patients presenting for consultation and same-day procedures. A prospective trial comparing patient recall of the consent process for sedated endoscopic procedures either 10 to 60 minutes before the procedure or 40 to 72 hours before the procedure showed no difference in recall at discharge from the endoscopy unit and again 2 to 3 days later.[24] That said, patient recall and satisfaction with the traditional written or oral informed consent process generally remains poor even among healthy volunteer subjects.[25]

> ***Recommendation:*** **Routine informed consent should be performed and documented before the performance of a procedure, including in direct access endoscopy practice.**
>
> *(Conditional recommendation, low quality of evidence)*

USE OF ELECTRONIC RESOURCES FOR CONSENT

A large systematic review and meta-analysis of 29 randomized controlled trials using video, computer program, electronic presentation, compact disc, or website to supplement medical informed consent demonstrated significantly improved recall of informed consent detail.[26] No consistent effects were seen on patient satisfaction or anxiety with these supplements to the informed consent process. Similarly, a systematic review including 8 studies of informed consent before trauma surgery reported significantly improved patient recall, comprehension, and satisfaction when verbal consent was supplemented by additional written or video education about their proposed procedure.[27] Finally, a randomized prospective trail comparing traditional informed consent versus an electronic interactive learning module in 101 parents of children undergoing diagnostic upper endoscopy revealed that informed consent as measured by their instrument was more often achieved using the electronic resource. At the same time, satisfaction, anxiety, or the number of questions asked by parents was not impacted.[28] Therefore, when available, video and other electronic supplemental educational materials can be used to supplement informed consent.

USE OF OFF-LABEL OR DEVICES AND TECHNIQUES NOT APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION

With rapidly changing technology and techniques, the practice of endoscopy often involves the use of tools and instruments in an off-label or investigational fashion. Off-label use of a device "when the intent is the practice of medicine" typically does not require Institutional Review Board review or an Investigational Device Exemption.[29] According to this guidance from the U.S. Food and Drug Administration (FDA), a physician is tasked with the responsibility to be "well-informed about the product, to base its use on firm scientific rationale and on sound medical evidence and to maintain records of the product's use and effects" (page 1).[29]

Although many endoscopic devices are FDA approved for a single application, clinical use for other indications

for the benefit of patients may precede further FDA indications for such use. For example, lumen-apposing metal stents are FDA approved for pseudocyst drainage; however, in practice, they are often used for therapy of walled-off necrosis, gallbladder drainage, gastrojejunostomy creation, and luminal stricture therapy.[30] The literature specifically relating to the ethics and consent process for off-label use of devices and techniques is scarce. This is also true for use of devices not approved by the FDA. Scoring tools are available to assist physicians in the ethical consideration of a specific device.[31] That said, it is the responsibility of the physician to consider the balance of risk and benefit of the proposed off-label use of a device, including their own experience, training, and abilities.

Many commonly used and FDA-cleared endoscopic devices are neither studied nor FDA cleared for use in children. Although off-label use in pediatric endoscopy is the accepted standard in this population, in some circumstances, among all age groups, documentation that acknowledges off-label use of devices as a part of consent can be considered.[32] Discussion of risk with off-label use of devices and techniques is often challenging because of the limited data available regarding AE rates during many off-label interventions, compared with those during off-label pharmaceutical use, which are better described.[33]

Recommendation: **A discussion of non–FDA–approved and off-label techniques and devices should be included in the informed consent process.**

(Conditional recommendation, low quality of evidence)

EXCEPTIONS TO INFORMED CONSENT

Informed consent in emergency situations

Medical situations necessitating emergency interventions occur commonly in endoscopic practice, ranging from GI hemorrhage, perforation, cholangitis, bowel obstruction, or foreign body and food impactions. In some situations, including life-threatening emergencies, full compliance with written consent may be impossible. Furthermore, the quality of the informed consent process is impacted by each unique emergency medical situation. A systematic review and meta-analysis of the informed consent process for emergency surgery including 11 observational studies concluded that patient recall and satisfaction are poorer in emergent than in elective situations.[34] Highlighted factors likely to interfere with the consent process were pain, analgesic medications, and fatigue. Furthermore, patient capacity to consent may be impacted by the medical emergency making verbal consent with the patient inadequate. Given these data suggesting that patients consenting for emergency procedures experience dissatisfaction with the consent process and that a standard written consent form increases compliance with informed consent in emergency procedures, it is imperative that every reasonable attempt should be made to provide a patient or his or her proxy a complete and thorough written informed consent when the situation permits. The following recommendation is therefore made based on expert committee consensus:

Recommendation: **In an emergency situation, effort should be made (and documented) to obtain written or verbal consent before a procedure as the situation allows.**

(Strong recommendation, high quality of evidence)

Therapeutic privilege

Therapeutic privilege is the intentional withholding of information that a physician believes would undermine the goals of informed consent or harm the patient.[35] This exception to informed consent is unlikely to be often invoked in the practice of GI endoscopy.

Waiver

Waiver of informed consent is a choice a patient makes to forego the informed consent process.[36] In this circumstance, the endoscopist must ensure the patient understands his or her right to informed consent and that he or she voluntarily relinquishes that right. A written acknowledgement of the waiver signed by the patient should be documented.

Legal mandate

In exceedingly rare circumstances, a judge's order or statute may supplant the process of informed consent. Under such a legal mandate, the patient and/or public's welfare supersedes the right to informed consent.

Informed consent for pediatric patients

Informed consent can be given by patients with the legal right, with qualifications varying by state, and appropriate decisional capacity.[37] In most cases, parents or surrogates can provide informed decision-making with the assent of the underaged pediatric patient. Children who are developmentally "able" to assent (ie, to agree to a proposed intervention) can provide this, knowing that assent should include the following: helping the patient achieve a developmentally appropriate awareness of the nature of his or her condition, explaining to the patient what he or she can expect with tests and treatments, make a clinical assessment of the patient's understanding of the situation, and finally to solicit an expression of the patient's willingness to accept the proposed care.[38] The American Academy of Pediatrics has recommended that "physicians involve pediatric patients in their health care decision-making

by providing information on their illness and options for diagnosis and treatment in a developmentally appropriate manner and seeking assent to medical care whenever appropriate" (page e6).[38]

The concept of shared decision-making in pediatrics takes this 1 step further to involve patients and their parents or guardians in medical decision-making as it relates to patient preferences and treatment goals. In a meta-analysis, various techniques using shared decision-making were shown to improve knowledge and decisional conflict without a clear impact on outcomes.[39] It is recommended that adolescents should be included in decisions about their care, and the endoscopist should assess patient understanding and gauge the patient's willingness for the proposed procedure.[38]

As in adults, understanding of the consent process is highly variable and may be poor in some circumstances. In a series of 88 pediatric patients undergoing informed consent for endoscopy, only 2 youth and 12 parents demonstrated comprehensive understanding of key informed consent elements.[40] Understanding by the pediatric patients varied by age, but the parental understanding varied by the physician obtaining consent, highlighting the important role our discussions play.

Legal age of consent varies by state and circumstances.[41] Specific categories allow for minor consent including cases of *emergency*, *emancipated minor*, and *mature minor* exceptions. Different requirements also exist for informed consent in pregnant minors. Most states recognize a mature minor exception, and allow consent to evaluation and treatment without parental consent for services including mental health, drug and alcohol addiction, reproductive health, and sexually transmitted disease related issues. As such, pregnant minors may generally consent to any medical treatment without parental involvement. This has unique relevance for endoscopists, given the increased mortality rates of gallstone pancreatitis in pregnancy, reported up to 37%.[41] Finally, an emergency situation in a minor, under the federal Emergency Medical Treatment and Active Labor Act, preempts conflicting or inconsistent state laws, essentially rendering the problem of obtaining consent for the emergency treatment of minors a nonissue at participating hospitals.[41,42]

Thus, as discussed earlier in this document, electronic resources should be considered when possible as supplements to informed consent.[28] In a questionnaire-based pediatric study, 89% of respondents remembered receiving an explanation from the doctor performing the procedure, and 94% believed the information received was adequate. The authors also reported 30% of families were unhappy with the time spent in the GI unit, 8% received inadequate discharge information, and 39% of children did not attend school the following day. These quality determinants may offer some opportunities in the process of the procedure as it relates to consent.[43]

Recommendation: **In pediatric patients undergoing GI procedures we recommend age-appropriate consent and assent processes that are developmentally appropriate for patients and their families.**

(Strong recommendation, low quality of evidence)

Other issues

Incompetent or incapacitated patients. A patient's cognitive facilities may impact the quality of informed consent. As such, patients who have either temporary or durable impairment of their ability to understand and execute an informed consent require an alternative route for informed consent, which generally means obtaining informed consent from a patient's proxy, depending on state and local law.

Withdrawal of consent. An unsedated patient may withdraw his or her consent for a proposed therapy at any time. More controversial and applicable to the endoscopist is the situation of a sedated patient who declines or requests to prematurely terminate a procedure that is underway.[44] In these situations, case-by-case decision-making on the part of the endoscopist with the input of the supporting nursing staff is prudent.

Refusal. As discussed previously, informed refusal occurs when a patient refuses a proposed therapy after fully performing the informed consent process.[45] In this situation, the informed consent discussion, the patient's capacity, and his or her understanding of the risks of declining the therapy should be documented.

Limited English proficiency. Federal antidiscrimination law requires that healthcare facilities receiving federal funding provide professional interpreter services for non– and limited English-speaking patients.[46] Fortunately, increasing access to over the phone and virtual interpreter services have made this mandate more readily achievable.

TRAINEES, IMAGES, AND VIDEO IN ENDOSCOPIC PROCEDURES

Although the legal mandate remains murky, disclosure of the participation of a trainee in a patient's procedure or of the potential use of patient data (images or video) for educational purposes is considered best practice and should be a universal part of informed consent when applicable.[47]

CONCLUSIONS

Achieving high-quality informed consent is complex but remains the foundation of ethical medical practice and is especially important in the endoscopic field given its procedural emphasis. Aside from the legal mandate of informed consent and resulting legal risk for providers when it is not performed adequately, patient

understanding and satisfaction is improved when high-quality informed consent is achieved.

The recommendations in this guideline are designed to help improve the informed consent process and experience for both physicians and patients as they work together to diagnose and treat GI diseases with endoscopy. Because this document was designed considering the laws and broad practice of endoscopy in the United States, legal requirements and precedents may differ by state, region, and hospital; therefore, it is the responsibility of the individual endoscopist to be aware of his or her local laws and regulations.

DISCLOSURE

The following authors disclosed financial relationships: A. C. Storm is a consultant for and has received travel compensation and food and beverage from Apollo Endo Surgery US Inc; is a consultant for Endo-TAGSS and Enterasense; receives data/safety monitoring from Erbe USA Inc and GI Dynamics; and has received research support and food and beverage from Boston Scientific Corporation. D. S. Fishman has received food and beverage from AbbVie, Inc and Boston Scientific Corporation. M. A. Al-Haddad has received a grant, research/teaching support, and food and beverage from Boston Scientific Corporation. S. K. Amateau is a consultant for and has received travel and lodging and food and beverage from Boston Scientific Corporation and Olympus America Inc; is a consultant for and has received food and beverage from Cook Medical LLC; and is a consultant for Endo-Therapeutics, Hemostasis LLC, Merit Medical Systems Inc, and Steris Corporation. J. L. Buxbaum is a consultant for and has received a grant, traveling and lodging, and food and beverage from Olympus America Inc; is a consultant for and received travel and lodging and food and beverage from Boston Scientific Corporation; is a consultant for Eagle Pharmaceuticals, Inc and Cook Incorporated; has received a grant from Medtronic USA, Inc; and has received food and beverage from Covidien LP and AbbVie, Inc. N. Coelho-Prabhu has received food and beverage from Boston Scientific Corporation. C. J. DiMaio is a consultant for and has received travel and lodging and food and beverage from Boston Scientific Corporation; is a consultant for Covidien LP and AbbVie, Inc; has received food and beverage from Cook Medical LLC. S. E. Elhanafi has received food and beverage from Gilead Sciences, Inc, Pfizer Inc, Salix Pharmaceuticals, Olympus America Inc, Lumendi LLC, and Covidien LP. N. Forbes is a consultant for Boston Scientific Corporation, Pentax Medical, and Pendopharm Inc; is on the speaker bureau for and has received research support from Pentax Medical. L. L. Fujii-Lau has received a grant from Cook Medical LLC; has received travel and lodging from Ovesco; and has received food and beverage from Covidien LP and Boston Scientific Corporation. T. L. Jue has received food and beverage from Boston Scientific Corporation. D. R. Kohli has received a grant from Olympus Corporation of the Americas and has received food and beverage from Boston Scientific Corporation. R. S. Kwon has received travel compensation from C2 Therapeutics, Inc and has received food and beverage from Covidien LP. J. K. Law has received food and beverage from Cook Medical LLC. S. Pawa has received educational support from Alexion Pharmaceuticals, Inc and has received food and beverage from Cook Medical LLC. C. N. Thosani is a consultant for and has received travel compensation and food and beverage from Boston Scientific Corporation; is a consultant for TaeWoong Medical; is a consultant and has received research support, travel and lodging, and food and beverage from Pentax of America, Inc; receives royalties from UpToDate; has received research support and food and beverage from Endogastric Solutions; is a speaker for and has received food and beverage from Abbie; has received food and beverage from Covidien, LP; and is on the advisory board for ColubrisMX Inc. S. Wani is a consultant for and has received food and beverage from Boston Scientific Corporation; is a consultant for Medtronic, Exact Sciences, and Interpace; received a grant from Cook Medical LLC; has received food and beverage from Olympus America Inc; and is on the advisory board for Cernostics. B. J. Qumseya has received food and beverage from Boston Scientific Corporation and GlaxoSmithKline, LLC.

ACKNOWLEDGMENT

We thank ASGE librarian consultant Ms Kellee Kaulback for her assistance in performing the literature search used in this document as well as Dr Prateek Sharma, Dr Ramzi Mulki, and Dr Jenifer Lightdale for their review of this document.

REFERENCES

1. Millum J, Bromwich D. Informed consent: what must be disclosed and what must be understood? Am J Bioeth 2021;21:46-58.
2. Gerstenberger PD, Plumeri PA. Malpractice claims in gastrointestinal endoscopy: analysis of an insurance industry data base. Gastrointest Endosc 1993;39:132-8.
3. Hernandez LV, Klyve D, Regenbogen SE. Malpractice claims for endoscopy. World J Gastrointest Endosc 2013;5:169-73.
4. Standards of Practice Committee; Zuckerman MJ, Shen B, et al. Informed consent for GI endoscopy. Gastrointest Endosc 2007;66:213-8.
5. ASGE Standards of Practice Committee; Qumseya B, Sultan S, Bain P, et al. ASGE guideline on screening and surveillance of Barrett's esophagus. Gastrointest Endosc 2019;90:335-9.
6. Sprung CL, Winick BJ. Informed consent in theory and practice: legal and medical perspectives on the informed consent doctrine and a proposed reconceptualization. Crit Care Med 1989;17:1346-54.

7. Sugarman J, Barker RA, Charo RA. A professional standard for informed consent for stem cell therapies. JAMA 2019;322:1651-2.
8. Johnson JD, Connell KM. Informed consent to HIV antibody testing: toward a standard of professional practice. Indiana Med 1989;82:538-43.
9. Spatz ES, Krumholz HM, Moulton BW. The new era of informed consent: getting to a reasonable-patient standard through shared decision making. JAMA 2016;315:2063-4.
10. Fernandez Lynch H, Joffe S, Feldman EA. Informed consent and the role of the treating physician. N Engl J Med 2018;378:2433-8.
11. Arumugam PJ, Harikrishnan AB, Carr ND, et al. A study on surgical knowledge of house officers and their role in consent. Hosp Med 2003;64:108-10.
12. Huntley JS, Shields DA, Stallworthy NK. Consent obtained by the junior house officer—Is it informed? J R Soc Med 1998;91:528-30.
13. Sherman HB, McGaghie WC, Unti SM, et al. Teaching pediatrics residents how to obtain informed consent. Acad Med 2005;80(10 Suppl):S10-3.
14. Paice E, Aitken M, Moss F. Informed consent and the preregistration house officer. Hosp Med 2001;62:699-701.
15. McClean KL, Card SE. Informed consent skills in internal medicine residency: How are residents taught, and what do they learn? Acad Med 2004;79:128-33.
16. Storm AC, Ryou M, Thompson CC. Multicenter implementation of a new electronic medical record system leads to longer procedure times and poor staff satisfaction. Clin Endosc 2019;52:87-9.
17. Zlabek JA, Wickus JW, Mathiason MA. Early cost and safety benefits of an inpatient electronic health record. J Am Med Inform Assoc 2011;18:169-72.
18. Eisen GM, Baron TH, Dominitz JA, et al. Open access endoscopy. Gastrointest Endosc 2002;56:793-5.
19. 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;73:189-97.
20. Humphrey LL, Shannon J, Partin MR, et al. Improving the follow-up of positive hemoccult screening tests: an electronic intervention. J Gen Intern Med 2011;26:691-7.
21. Nutalapati V, Tokala KT, Desai M, et al. Development and validation of a web-based electronic application in managing antithrombotic agents in patients undergoing GI endoscopy. Gastrointest Endosc 2019;90:906-12.
22. Venkatesh RD, Campbell EJ, Thiim M, et al. e-Consults in gastroenterology: an opportunity for innovative care. J Telemed Telecare 2019;25:499-505.
23. Lahat A, Shatz Z. Telemedicine in clinical gastroenterology practice: What do patients prefer? Therap Adv Gastroenterol 2021;14:1-9.
24. Proctor DD, Price J, Minhas BS, et al. Patient recall and appropriate timing for obtaining informed consent for endoscopic procedures. Am J Gastroenterol 1999;94:967-71.
25. Fortun P, West J, Chalkley L, et al. Recall of informed consent information by healthy volunteers in clinical trials. Q J Med 2008;101:625-9.
26. Farrell EH, Whistance RN, Phillips K, et al. Systematic review and meta-analysis of audio-visual information aids for informed consent for invasive healthcare procedures in clinical practice. Patient Educ Couns 2014;94:20-32.
27. Lin YK, Liu KT, Chen CW, et al. How to effectively obtain informed consent in trauma patients: a systematic review. BMC Med Ethics 2019;20:8.
28. Friedlander JA, Loeben GS, Finnegan PK, et al. A novel method to enhance informed consent: a prospective and randomised trial of form-based versus electronic assisted informed consent in paediatric endoscopy. J Med Ethics 2011;37:194-200.
29. U.S. Food and Drug Administration. FDA information sheet: "off-label" and investigational use of marketed drugs, biologics, and medical devices 1998 [updated May 6, 2020]. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices. Accessed November 22, 2021.
30. Kozarek RA. Integration of research into endoscopic practice. Gastrointest Endosc 2018;88:390-2.
31. Paull DE, Uhlig PN. How should risk managers respond to cases for which no risk profile exists? AMA J Ethics 2020;22:E911-8.
32. Martin-Kerry JM, Knapp P, Atkin K, et al. Supporting children and young people when making decisions about joining clinical trials: qualitative study to inform multimedia website development. BMJ Open 2019;9:e023984.
33. Eguale T, Buckeridge DL, Verma A, et al. Association of off-label drug use and adverse drug events in an adult population. JAMA Intern Med 2016;176:55-63.
34. D'Souza RS, Johnson RL, Bettini L, et al. Room for improvement: a systematic review and meta-analysis on the informed consent process for emergency surgery. Mayo Clin Proc 2019;94:1786-98.
35. Grignoli N, Wullschleger R, Di Bernardo V, et al. Hope and therapeutic privilege: time for shared prognosis communication. J Med Ethics. Epub 2020 Oct 14.
36. Klein L, Moore J, Biros M. A 20-year review: the use of exception from informed consent and waiver of informed consent in emergency research. Acad Emerg Med 2018;25:1169-77.
37. Committee on Bioethics, American Academy of Pediatrics. Informed consent, parental permission, and assent in pediatric practice. Pediatrics 1995;95:314-7.
38. Katz AL, Webb SA, Committee on Bioethics. Informed consent in decision-making in pediatric practice. Pediatrics 2016;138:e1-16.
39. Wyatt KD, List B, Brinkman WB, et al. Shared decision making in pediatrics: a systematic review and meta-analysis. Acad Pediatr 2015;15:573-83.
40. Jubbal K, Chun S, Chang J, et al. Parental and youth understanding of the informed consent process for pediatric endoscopy. J Pediatr Gastroenterol Nutr 2015;60:769-75.
41. Committee on Pediatric Emergency Medicine. Consent for emergency medical services for children and adolescents. Pediatrics 2003;111:703-6.
42. Bitterman RA. EMTALA and the ethical delivery of hospital emergency services. Emerg Med Clin North Am 2006;24:557-77.
43. Jimenez SG, Catto-Smith AG. Impact of day-case gastroscopy on children and their families. J Gastroenterol Hepatol 2008;23:379-84.
44. Ward B, Shah S, Kirwan P, et al. Issues of consent in colonoscopy: If a patient says "stop" should we continue? J R Soc Med 1999;92:132-3.
45. Vilanilam GC, Sasidharan GM. Informed refusal—a gray area in informed consent. Neurol India 2016;64:1393-5.
46. The U.S. Department of Justice. Executive Order 13166: Improving access to services for persons with limited English proficiency. Available at: https://www.justice.gov/crt/executive-order-13166. Accessed November 22, 2021.
47. Dutta S, Dunnington G, Blanchard MC, et al. "And doctor, no residents please!" J Am Coll Surg 2003;197:1012-7.

Abbreviations: AE, adverse event; ASGE, American Society for Gastrointestinal Endoscopy; FDA, U.S. Food and Drug Administration.

guidance document does not create an attorney–client relationship between the reader or user and the guidance document's authors, contributors, contributing law firms, or committee members and their respective employers.

0016-5107/$36.00
https://doi.org/10.1016/j.gie.2021.10.022

Received October 22, 2021. Accepted October 24, 2021.

Current affiliations: Department of Gastroenterology and Hepatology, Mayo Clinic, Rochester, Minnesota, USA (1), Section of Pediatric Gastroenterology, Hepatology and Nutrition, Baylor College of Medicine, Texas Children's Hospital, Houston, Texas, USA (2), Division of Gastrointestinal and Liver Diseases, Keck School of Medicine of University of Southern California, Los Angeles, California, USA (3), Division of Gastroenterology and Hepatology, Indiana University School of Medicine, Indianapolis, Indiana, USA (4), Division of Gastroenterology Hepatology and Nutrition, University of Minnesota Medical Center, Minneapolis, Minnesota, USA (5), Section of Gastroenterology and Hepatology, Dartmouth-Hitchcock Medical Center, Dartmouth Geisel School of Medicine, Lebanon, New Hampshire, USA (6), Department of Gastroenterology, Mount Sinai School of Medicine, New York, New York, USA (7), Department of Gastroenterology, Texas Tech University, El Paso, Texas, USA (8), Department of Medicine, Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada (9), Department of Gastroenterology, The Queen's Medical Center, Honolulu, Hawaii, USA (10), Department of Gastroenterology, The Permanente Medical Group, San Francisco, California, USA (11), Department of Gastroenterology, Kansas City VA Medical Center, Kansas City, Missouri, USA (12), Division of Gastroenterology, Michigan Medicine, University of Michigan, Ann Arbor, Michigan, USA (13), Department of Gastroenterology and Hepatology, Digestive Disease Institute, Virginia Mason Medical Center, Seattle, Washington, USA (14), Department of Gastroenterology, Wake Forest School of Medicine, Winston Salem, North Carolina, USA (15), Center for Interventional Gastroenterology at UTHealth, McGovern Medical School, Houston, Texas, USA (16), Division of Gastroenterology and Hepatology, University of Colorado Anschutz Medical Campus, Aurora, Colorado, USA (17), Department of Gastroenterology, Hepatology, and Nutrition, University of Florida, Gainesville, Florida, USA (18).

Reprint requests: Bashar J. Qumseya, MD, MPH, FASGE, Chair–Standards of Practice Committee, Department of Gastroenterology, Hepatology and Nutrition, University of Florida, P.O. Box 100214, 1329 SW 16th St, Suite 5251, Gainesville, Florida 32610-0214 USA. T: (352) 273-9472.

APPENDIX 1

Search strategy

Search date: February 17, 2020

Databases searched: MEDLINE, Embase

Limits: English

Excluded: Letters, comments, editorials, notes, case reports, congresses/conference abstracts

Ovid MEDLINE(R), Embase

#	Searches	Results
1	exp Endoscopy, Gastrointestinal/ use ppez or exp Endoscopes, Gastrointestinal/ use ppez	90,042
2	exp digestive tract endoscopy/ use emczd or exp digestive endoscope/ use emczd	221,830
3	(Endoscop* or duodenoscop* or colonoscop* or enteroscop* or esophagoscop* or gastroscop* or proctoscop* or rectoscop* or sigmoidoscop* or esophagogastroduodenoscop*).ti,ab,kf,kw.	613,340
4	or/1-3	716,351
5	exp Informed Consent/	146,113
6	consent.ti,kf,kw.	33,510
7	5 or 6	152,893
8	4 and 7	2720
9	limit 8 to english language	2578
10	limit 9 to (case reports or comment or congress or editorial or letter or conference abstract or note) [Limit not valid in Ovid MEDLINE(R),Ovid MEDLINE(R) Daily Update,Ovid MEDLINE(R) In-Process,Ovid MEDLINE(R) Publisher, Embase; records were retained]	1555
11	Case Report/	4,624,123
12	9 not (10 or 11)	871
13	remove duplicates from 12	720

APPENDIX 2

Example statement of consent for medical treatment

Under [STATE] law my treating physician must inform me about the risks and benefits of the proposed treatment(s) and the availability of reasonable alternate medical modes of treatment, including the risks and benefits of the alternate modes of treatments. "Modes of treatment" means treatment, including diagnostic procedures, generally considered by the medical profession to be within the scope of current, acceptable standards of care.

My physician's duty to inform me about the proposed treatment and alternate modes of treatment and their risks and benefits does not require disclosure of (1) detailed technical information that in all probability I would not understand, (2) risks apparent or known to me, (3) extremely remote possibilities that might falsely or detrimentally alarm me, (4) information in emergencies where failure to provide treatment would be more harmful to me than treatment, (5) information in cases where I am incapable of consenting, and/or (6) information about alternate medical modes of treatment for any condition the physician has not included in his or her diagnosis at the time the physician informs me.

My physician has recommended that the treatment and/or procedure noted below be performed. The recommended treatment and/or procedure and reasonable alternate medical modes of treatment and their risks and benefits have been explained to me. The risks of the recommended treatment and/or procedure have also been explained to me and are also noted on this form. Any questions I have regarding the medical treatment and/or procedure, why it is necessary, its benefits and risks have been answered to my satisfaction. Therefore I, the undersigned, as the patient, do hereby voluntarily consent to and authorize medical care and treatment by [PRACTICE], through its individual physicians, employees, and/or agents. This care and treatment encompasses all diagnostic and therapeutic treatments considered necessary or advisable in the judgment of the physician and provided by [PRACTICE].

Treatment/procedure to be performed: _____

Potential significant risk(s): _____

I am aware that the practice of medicine is not an exact science and I acknowledge that no guarantees have been made to me as to the result of treatments, procedures, or examinations performed by the physician or [PRACTICE].

I have read this form, or had it read to me, and I certify that I fully understand and accept its contents.

Patient's signature _____ Date _____

Patient's name (printed) _____

Patient, _____, is a minor, or is unable to sign above because _____.

_____ _____

Person giving consent Relation to patient

This template statement of consent for medical treatment is provided for illustrative purposes only and may not satisfy the legal requirements of your jurisdiction. You should consult an independent attorney of your choosing to ensure your written authorization for medical consent satisfies the legal requirements where you practice.[32]