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