Assessment of delivery methods used in the informed consent process at a safety-net hospital

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Background: Informed consent is legally and ethically required before a patient undergoes an endoscopic procedure, yet current literature suggests that patient comprehension of key components of informed consent is poor.

Objective: To evaluate specific aspects of and patient satisfaction with the informed consent process in patients who attended an endoscopy education class versus gastroenterology clinic.

Design: Prospective survey that examined all components of the informed consent process.

Setting: Safety-net hospital.

Patients: Outpatients undergoing endoscopy.

Intervention: Endoscopy education class versus gastroenterology clinic.

Main Outcome Measurements: Patient recall of the components of and satisfaction with the informed consent process.

Results: A total of 301 patients completed the survey, 52.0% of whom attended and were consented in an endoscopy education class. Patients who attended an endoscopy education class reported that a greater number of individual components of the informed consent process were explained to them as compared with patients who were consented in clinic. In multivariate analysis, patients who attended an education class were more likely to recall having had the alternatives (odds ratio [OR] 4.8; 95% confidence interval [CI], 2.0-11.8), details of the procedure (OR 3.0; 95% CI, 1.3-6.8), and what to expect after the procedure (OR 3.0; 95% CI, 1.5-5.6) explained to them by a provider. These patients were more likely to know they could refuse the procedure (OR 4.1; 95% CI, 1.0-16.8), compared with patients consented in the gastroenterology clinic.

Limitations: Non-randomized trial.

Conclusion: Patients from a diverse, urban population who attended a multilingual endoscopy education class reported having more elements of the informed consent process explained to them compared with patients who were consented in gastroenterology clinic. (Gastrointest Endosc 2014;80:61-8.)

Abbreviations: SFGH, San Francisco General Hospital and Trauma Center.

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See CME section; p. 152.

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Informed consent, defined as a process of communication between a patient and physician that results in the patient's agreement to undergo a specific medical intervention, is legally and ethically required.[1] Guidelines from the American Society for Gastrointestinal Endoscopy state that an endoscopist should obtain informed consent from the patient before any endoscopic procedure.[2] Informed consent should include the nature of the proposed procedure, the reason for the procedure, the benefits of the procedure, the risks, the adverse events of the procedure, and reasonable alternatives to the proposed procedure.

Patient comprehension of key components of informed consent is poor,[3] and the literature describing informed consent in regard to endoscopy is scarce. Additionally, patients with low health literacy (ie, patients with less ability to read, understand, and use healthcare information to make decisions and follow instructions for treatment) are less able to comprehend medical information and may have decreased understanding of the informed consent process.[4] At the same time, studies on interventions of how to improve informed consent for endoscopy, particularly in an ethnically diverse population with low health literacy, are extremely limited.[5-7] Moreover, the overwhelming majority of studies do not assess all of the components of informed consent.[6]

Consequently, we conducted a prospective study, comparing the effectiveness of a novel, multilingual, endoscopy education class to the usual gastroenterology clinic–based setting for obtaining informed consent in a large, urban hospital among patients scheduled for endoscopic procedures.

Take-home Message

- Patients from a diverse, urban population who attended a multilingual endoscopy education class report and/or recall having more elements of the informed consent process explained to them compared with patients who were counseled and consented in the usual manner in a gastroenterology clinic.
- Education classes can play an important and critical role in the education of patients before endoscopic procedures and can be an effective tool for ensuring that patients are properly and adequately informed about procedures.

METHODS

Study design

We conducted a prospective, cross-sectional survey of patients referred to the San Francisco General Hospital and Trauma Center (SFGH) Gastroenterology Division for an outpatient endoscopic procedure from December 1, 2012 to February 1, 2013 assessing patients' recall of and satisfaction with the informed consent process.

Patient population and setting

The study was conducted at SFGH, a safety-net institution (ie, provides a significant level of care to low income, uninsured, and vulnerable populations) affiliated with the University of California, San Francisco. Patients are ethnically diverse (20% African American, 20% Asian/Pacific Islander, 25% white, and 30% Hispanic), and many are immigrants, with more than 20 different languages spoken by patients. Approximately 36% of outpatients at SFGH lack insurance, 34% have MediCal (California's Medicaid program), 16% have Medicare, and 14% report commercial payers or other sources. The SFGH Gastroenterology Division receives 5300 referrals annually for a wide spectrum of GI-related conditions and performs over 3500 endoscopic procedures per year.

Patients who receive primary care at SFGH or its affiliated clinics are eligible to be referred for an endoscopic procedure through 2 mechanisms: (1) direct access endoscopy or (2) gastroenterology clinic. Direct access endoscopy is available for patients with a specific indication that requires an endoscopic procedure and includes patients with a positive fecal immunochemical test and/or fecal occult blood test, history of adenomatous polyps, personal or family history of colorectal cancer, rectal bleeding, and iron deficiency anemia. Patients referred through direct access endoscopy attend an initial group endoscopy education class before the scheduling of their endoscopic procedure. This class consists of 20 patients and is taught by a gastroenterology nurse practitioner using a PowerPoint (Microsoft, Redmond, WA, USA) presentation (Appendix 1, available online at www.giejournal.org). The class discusses various aspects of undergoing endoscopy including indications for the procedure, the informed consent process, preprocedure preparation, medication restrictions, and patient expectations with regard to endoscopy. The class is conducted in English, Spanish, and Cantonese (accounts for over 90% of the languages spoken by patients who are referred to the GI division). Patients provide informed consent at the end of the class after all questions are answered. All other gastroenterology referrals are evaluated in the gastroenterology clinic. If an endoscopic procedure is ordered at the clinic visit, the provider evaluating the patient discusses the proposed procedure and obtains informed consent from the patient at the end of the visit.

Survey development

A previous systematic review on interventions of how to improve informed consent for procedures identified significant variation across studies with respect to the elements of the informed consent assessed. The majority of the included studies assessed patient's self-reported understanding of procedural risk, but only 6 of 44 studies assessed benefits and/or indications, alternatives, and general knowledge (ie, what is the actual procedure being done).[6]