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Quality Indicators for Colonoscopy

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Colonoscopy is widely used for the diagnosis and treatment of colonic disorders. Properly performed, colonoscopy is generally safe, accurate, and well tolerated by most patients. Visualization of the mucosa of the entire large intestine and distal terminal ileum is usually possible at colonoscopy. In patients with chronic diarrhea, biopsy specimens can help diagnose the underlying condition. Polyps can be identified and removed during colonoscopy, thereby reducing the risk of colon cancer. Colonoscopy is the preferred method to evaluate the colon in most adult patients with bowel symptoms, iron deficiency anemia, abnormal radiographic studies of the colon, positive colorectal cancer screening tests, postpolypectomy and postcancer resection surveillance, surveillance in inflammatory bowel disease, and in those with suspected masses.

The use of colonoscopy has become accepted as the most effective method of screening the colon for neoplasia in patients over the age of 50 years and in younger patients at increased risk (1). The effectiveness of colonoscopy in reducing colon cancer incidence depends on adequate visualization of the entire colon, diligence in examining the mucosa, and patient acceptance of the procedure. Preparation quality affects the ability to perform a complete examination, the duration the procedure, and the need to cancel or reschedule procedures (2, 3). Ineffective preparation is a major contributor to costs (4). Longer withdrawal times have been demonstrated to improve polyp detection rates, (5–7) and conversely, rapid withdrawal may miss lesions and reduce the effectiveness of colon cancer prevention by colonoscopy. The miss rates of colonoscopy for large (≥1 cm) adenomas may be higher than previously thought (8, 9) Thus, careful examinations are necessary to optimize the effectiveness of recommended intervals between screening and surveillance examinations. Finally, technical expertise will help prevent complications that can offset any cost benefit ratio gained by removing neoplastic lesions.

The following quality indicators have been selected to establish competence in performing colonoscopy and help define areas for continuous quality improvement. The levels of evidence supporting these quality indicators were graded according to Table 1.

PREPROCEDURE

The preprocedure period encompasses the time from first contact by the patient until administration of sedation or instrument insertion. The aspects of patient care addressed in prior documents apply here as well, including timely scheduling, patient preparation, identification, history and physical examination, appropriate choice of sedation and analgesia, evaluation of bleeding risk, etc. Because many examinations are currently being performed for colon cancer screening and are elective, care must be taken to be certain that all potential risks have been reduced to as low as practically achievable.

The American Society for Gastrointestinal Endoscopy (ASGE) (10) and the U.S. Multi-Society Task Force on Colon Cancer have published appropriate indications for colonoscopy (11) (Tables 2 and 3).

SPECIFIC QUALITY INDICATORS

1. Appropriate indication. The ASGE and the U.S. Multi Society Task Force on Colon Cancer have published appropriate indications for colonoscopy (Tables 2 and 3). An indication should be documented for each procedure, and when it is a nonstandard indication it should be justified in the documentation.

Discussion. The ASGE in 2000 published a list of accepted indications for endoscopic procedures (10). This list was determined by a review of published literature and expert consensus. Studies have shown that when esophago gastroduodenoscopy and colonoscopy are done for appropriate reasons significantly more clinically relevant diagnoses are made (12–14). In these studies, which divided indications into appropriate, uncertain, and inappropriate, and looked at high-volume European centers, 21% to 39% were classified as inappropriate. It is likely that this can be improved to less than a 20% inappropriate rate (15). The European Panel of Appropriateness of Gastrointestinal Endoscopy (EPAGE) Internet guideline is a useful decision support tool for determining the appropriateness of colonoscopy (15). The goal is

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 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, et al. 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. pp. 599–608.

Table 2. Colonoscopy Indications*

A. Evaluation on barium enema or other imaging study of an abnormality that is likely to be clinically significant, such as a filling defect or stricture
B. Evaluation of unexplained gastrointestinal bleeding
   1. Hematochezia
   2. Melena after an upper gastrointestinal source has been excluded
   3. Presence of fecal occult blood
C. Unexplained iron deficiency anemia
D. Screening and surveillance for colonic neoplasia
   1. Screening of asymptomatic, average-risk patients for colonic neoplasia
   2. Examination to evaluate the entire colon for synchronous cancer or neoplastic polyps in a patient with treatable cancer or neoplastic polyp
   3. Colonoscopy to remove synchronous neoplastic lesions at or around time of curative resection of cancer followed by Colonoscopy at 3 years and 3-5 years thereafter to detect metachronous cancer
   4. After adequate clearance of neoplastic polyp(s) survey at 3- to 5-year intervals
   5. Patients with significant family history
      a. Hereditary nonpolyposis colorectal cancer: Colonoscopy every 2 years beginning at the earlier of age 25 years or 5 years younger than the earliest age of diagnosis of colorectal cancer. Annual Colonoscopy should begin at age 40 years.
      b. Sporadic colorectal cancer before age 60 years: Colonoscopy every 5 years beginning at age 10 years earlier than the affected relative or every 3 years if adenoma is found
   6. In patients with ulcerative or Crohn's pancolitis 8 or more years' duration or left-sided colitis 15 or more years' duration every 1-2 years with systematic biopsies to detect dysplasia
E. Chronic inflammatory bowel disease of the colon if more precise diagnosis or determination of the extent of activity of disease will influence immediate management
F. Clinically significant diarrhea of unexplained origin
G. Intraoperative identification of a lesion not apparent at surgery (e.g., polypectomy site, location of a bleeding site)
H. Treatment of bleeding from such lesions as vascular malformation, ulceration, neoplasia, and polypectomy site (e.g., electrocoagulation, heater probe, laser or injection therapy)
I. Foreign body removal
J. Excision of colonic polyp
K. Decompression of acute nontoxic megacolon or sigmoid volvulus
L. Balloon dilation of stenotic lesions (e.g., anastomotic strictures)
M. Palliative treatment of stenosing or bleeding neoplasms (e.g., laser, electrocoagulation, stenting)
N. Marking a neoplasm for localization

*ASGE. Appropriate use of gastrointestinal endoscopy. Gastrointest Endosc 2000:52:831–7.

Table 3. Indications for Colonoscopy and Appropriate Intervals*

Indication	Interval*
Bleeding	
Positive FOBT	NR
Hematochezia	NR
Iron deficiency anemia	NR
Melena with negative esophagogastroduodenoscopy	NR
Screening	
Average risk	10 y (begin at age 50 y)
Single FDR with cancer (or adenomas) at age ≥60 y	10 y (begin at age 40 y)
≥2 FDRs with cancer (or adenomas) or 1 FDR diagnosed at age <60 y	5 y (begin at age 40 y or 10 y younger, whichever is earlier)
Prior endometrial or ovarian cancer diagnosed at age <50 y	5 y
HNPCC (begin age 20-25 y)	1-2 y
Abdominal pain, altered bowel habitf†	
Positive sigmoidoscopy (large polyp or polyp of <1 cm shown to be an adenoma)‡	
Postadenoma resection	
1-2 tubular adenomas of <1 cm	5-10 y
3-10 adenomas or adenoma with villous features, ≥1 cm or with HGD	3 y
>10 adenomas	<3 y
Sessile adenoma of ≥2 cm, removed piecemeal§	2-6 m
Postcancer resection	Clear colon, then in 1 y, then 3 y, then 5 y
Ulcerative colitis, Crohn's colitis surveillance after 8 y of pancolitis or 15 y of left-sided colitis	2-3 y until 20 y after onset of symptoms, then 1 y

FOBT = Fecal occult blood test; NR = interval not recommended; FDR = first-degree relative; *HNPCC* = hereditary nonpolyposis colorectal cancer; *HGD,* high-grade dysplasia.
*From: Rex DK, Bond JH, Winawer S, et al. Quality in the technical performance of colonoscopy and the continuous quality improvement process for colonoscopy: recommendations of the U.S. Multi-Society Task
Force on Colorectal Cancer. Am J Gastroenterol 2002;97:1296–308. Updated based on guideline revisions in press. Used with permission.
†If colonoscopy has negative results and symptoms are stable, repeat examination should be done according to screening recommendations.
‡See postadenoma resection recommendation.
§The goal is to reexamine the site for residual polyp; repeating a flexible sigmoidoscopy is adequate for a distal polyp.

to minimize as much as possible the number of inappropriate procedures (16–19).

In the average-risk population, colonoscopic screening is recommended in all current guidelines at 10-year intervals (20–22). Direct observational data to support this interval are lacking. However, in a cohort of average-risk persons who underwent an initial colonoscopy with negative results, a repeat colonoscopy 5 years later had a very low yield (23). Two studies of flexible sigmoidoscopy showed that the protective effect of endoscopy with polypectomy was present for intervals of 10 years and 16 years and could not exclude longer durations of effect (24, 25). Thus, although colonoscopy is not perfectly protective, its protective effect is prolonged. These data support the continued use of the 10-year interval.

2. Informed consent is obtained, including specific discussions of risks associated with colonoscopy.

Discussion. As with all other endoscopic procedures, consent must be obtained before the procedure from the patient or guardian on the same day (or as required by local law or per policy of the institution) as the procedure. Consent may be obtained in the procedure room. It must include a discussion of the risks, benefits, and alternatives to the procedure. The risks of endoscopy include bleeding, perforation, infection, sedation adverse events, missed diagnosis, missed lesions, and intravenous site complications.

3. Use of recommended postpolypectomy and post-cancer resection surveillance intervals (Tables 2 and 3).

Discussion. For colonoscopy to be both effective and cost-effective and to minimize risk, the intervals between examinations should be optimized. Intervals between examinations can only be effective in prevention of incident colorectal cancer when the colon is effectively cleared of neoplasia. Therefore, detailed and effective examination of the colon, as discussed below, is critical to the effectiveness of recommended intervals between colonoscopies. The recommended intervals assume cecal intubation, adequate bowel preparation, and careful examination.

Colonoscopy, even when performed carefully, is not expected to prevent all incident colorectal cancers. Some colorectal cancers arise because of genetic factors that make the adenoma-to-carcinoma sequence faster (26). In addition, in some instances, colonoscopic polypectomy may not be effective in eradicating polyps (27). Because colonoscopy can be an expensive procedure and is associated with a low risk of serious consequences, intervals between examinations are recommended on the basis of the best available evidence and experience that indicates a balance between the protective effect of high-quality clearing colonoscopy with the risks and cost of colonoscopy

Recent evidence from 4 surveys indicated that post-polypectomy surveillance colonoscopy in the United States is frequently performed at intervals that are shorter than those recommended in guidelines (28–31) These surveys underscore the importance of measuring intervals between examinations in continuous quality improvement programs. Some

endoscopists in these studies performed colonoscopy in patients with only small hyperplastic polyps or a single tubular adenoma at 1 year, an interval abandoned in guidelines after publication of the National Polyp Study randomized trial in 1993 (32). Surgeons were more likely than gastroenterologists to use short intervals (28). These data underscore the need for endoscopic leaders to promote continuous quality improvement among all specialties practicing colonoscopy in a given community.

Diminutive hyperplastic polyps, when found only in the rectosigmoid colon, can be considered normal. The presence of small distal hyperplastic polyps only should not alter the recommended interval for surveillance. Appropriate intervals in patients with large hyperplastic polyps located in the proximal colon, or in patients who have many hyperplastic polyps (30 or more) are not yet established, but close follow-up may be appropriate (33–34).

Patients who have evidence of colonic bleeding that occurs after a colonoscopy with negative results may need repeat examinations at intervals shorter than those recommended in Tables 2 and 3. However, the use of fecal occult blood testing for the first 5 years after a colonoscopy is discouraged because the positive predictive value of guaiac-based fecal occult blood testing during that interval is extremely low (35). Additional study of fecal immunochemical testing for blood in this setting as an adjunct to colonoscopy is warranted (36).

4. The use of recommended ulcerative colitis and Crohn's colitis surveillance.

Discussion. In ulcerative colitis and Crohn's colitis, surveillance refers to interval examinations of patients with long-standing disease who have undergone an initial examination in which dysplasia is not detected. The term is also used when patients who are asymptomatic are prospectively entered into interval colonoscopy programs on the basis of their duration of disease. Surveillance does not refer to diagnostic examinations or examinations in previously diagnosed patients to assess symptoms. Both ulcerative colitis and Crohn's colitis of long duration are associated with an increased risk of colorectal cancer (37, 38).

There are no randomized trials to support the effectiveness of surveillance colonoscopy in ulcerative colitis or Crohn's colitis, but case control studies in ulcerative colitis suggest a survival benefit for patients who participate in surveillance (39, 40). Surveys of practitioners in the United States (41) and the United Kingdom (42) demonstrate that many practitioners are not familiar with surveillance recommendations, have a poor understanding of dysplasia, and make inappropriate recommendations in response to findings of dysplasia (41, 42).

Patients should be encouraged to undergo surveillance colonoscopy, and surveillance has emerged as a standard of medical care in the United States. The onset of disease is timed to the onset of symptoms for the purpose of timing the initiation of surveillance in both ulcerative colitis and Crohn's colitis. Because the yield of ulcerative colitis in surveillance for cancer and severe dysplasia is relatively low, (43, 44) it is important to not overuse surveillance colonoscopy during the first 20 years because overuse is not cost-effective (45). Shorter intervals between examinations are indicated for patients with long-duration disease and may be initiated earlier in the course of disease in patients with established risk modifiers, such as a family history of colorectal cancer or a personal history of primary sclerosing cholangitis (46, 47). Persons with primary sclerosing cholangitis who are discovered to have asymptomatic ulcerative colitis should begin surveillance at the time ulcerative colitis is diagnosed.

5. Preparation: in every case the procedure note should document the quality of preparation.

Discussion. In each colonoscopy, the colonoscopist should document the quality of the bowel preparation. In clinical trials of bowel preparation, terms used to commonly characterize bowel preparation include "excellent," "good," "fair," and "poor." In clinical practice, these terms do not have standardized definitions. In clinical trials on the effectiveness of various laxative regimens for bowel preparation, excellent is typically defined as no or minimal solid stool and only small amounts of clear fluid requiring suctioning. "Good" is typically no or minimal solid stool with large amounts of clear fluid requiring suctioning. "Fair" refers to collections of semisolid debris that are cleared with difficulty. "Poor" refers to solid or semisolid debris that cannot be effectively cleared. These terms can be interpreted as having more to do with retained intraluminal contents that often can be removed by suctioning rather than the quality of inspection allowed after suctionable material has been fully removed; however, these terms are probably reasonable guides to the appropriate use of bowel descriptors.

Poor bowel preparation is a major impediment to the effectiveness of colonoscopy Poor preparation prolongs cecal intubation time and withdrawal time and reduces detection of both small (2) and large (2, 3) polyps. In every colonoscopic practice, some colonoscopies must be repeated at intervals shorter than those recommended in Table 3 because of inadequate preparation. The task force recommends that the procedure be considered adequate if it allows (within the technical limitations of the procedure) detection of polyps 5 mm or larger (11). The economic burden of repeating examinations because of inadequate bowel preparation is substantial (4). No thresholds are recommended by the committee for the percentage of examinations that are repeated for poor preparation because the percentage of patients requiring repeat examination may depend mostly on patient population characteristics. However, measurement of individual practitioners' percentage of examinations requiring repeat because of preparation is recommended. Individual endoscopists may compare their percentages to others within the same practice or to other endoscopists practicing in the same hospital. This can allow identification of outliers within that hospital for whom corrective measures should be taken.

Preprocedure Research Questions

- What are the most effective methods to disseminate guidelines and educate physicians on quality recommendations?
- Why do physicians fail to follow recommended guidelines for screening and surveillance intervals? Do they know the guidelines? Are they concerned about missed lesions?
- Which hyperplastic polyps in the proximal colon are clinically important? What are cost-effective intervals for follow-up after removal of large hyperplastic polyps?
- What is the current understanding among clinicians of surveillance guidelines for ulcerative colitis and Crohn's colitis?
- Can patients with ulcerative colitis be triaged on the basis of endoscopic findings into low- and high-risk groups for surveillance intervals?
- What method would allow same-day bowel preparation in the endoscopy unit in patients with poor preparation? Would this prevent patients with poor preparation from being lost to follow-up?
- What bowel preparation is the best combination of safety, effectiveness, and tolerability?

INTRAPROCEDURE

Quality evaluation of the colon consists of intubation of the entire colon and a detailed mucosal inspection. Cecal intubation improves sensitivity and reduces costs by eliminating the need for radiographic procedures or repeat colonoscopy to complete examination. Careful mucosal inspection is essential to effective colorectal cancer prevention and reduction of cancer mortality. The detection of neoplastic lesions is the primary goal of most colonoscopic examinations.

Cost-benefit analyses of colonoscopy for the detection of neoplastic lesions are well within acceptable rates (approximately $20,000 per year of life saved) (20–22). However, complications, repeat procedures, and inappropriate surgical intervention for endoscopically removable polyps can significantly reduce this benefit. It is incumbent on endoscopists to evaluate their practices and seek to make improvements wherever possible to reduce the costs associated with neoplasia detection.

6. Cecal intubation rates: visualization of the cecum by notation of landmarks and photodocumentation of landmarks should be documented in every procedure.

Discussion. In the United States, colonoscopy is generally undertaken with the intent to intubate the cecum. Cecal intubation is defined as passage of the colonoscope tip to a point proximal to the ileocecal valve so that the entire cecal caput, including the medial wall of the cecum between the ileocecal valve and appendiceal orifice, is visible. The need for cecal intubation is based on the persistent finding that a substantial fraction of colorectal neoplasms are located in the proximal colon, including the cecum (48). Techniques of cecal intubation are discussed elsewhere (49). Cecal intubation should be documented by naming the identified cecal landmarks. Most important, these include the appendiceal orifice and the ileocecal valve. In cases where there is uncertainty as to whether the cecum has been entered, visualization of the lips of the ileocecal valve (ie, the orifice) or intubation of the terminal ileum will be needed. Experienced colonoscopists can verify cecal intubation in real time in 100% of cases, (50) because there is no other portion of the gastrointestinal tract with a similar appearance. It can be helpful to document other landmarks, such as the cecal sling fold or intubation of the terminal ileum.

Photography of the cecum is also recommended. Still photography of the cecum may not be convincing in all cases because of variations in cecal anatomy (50) Thus, the ileocecal valve may not be notched or may not have a lipomatous appearance; however, still photography is convincing in a substantial majority of cases, and its use allows verification of cecal intubation rates of individual endoscopists in the continuous quality improvement program. The best photographs of the cecum to prove intubation are of the appendiceal orifice, taken from a distance sufficiently far away that the cecal strap fold is visible around the appendix, and a photograph of the cecum taken from distal to the ileocecal valve (50). Photographs of the terminal ileum are sometimes convincing if they s