The Quality of Colonoscopy Services—Responsibilities of Referring Clinicians

A Consensus Statement of the Quality Assurance Task Group, National Colorectal Cancer Roundtable

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Primary care clinicians initiate and oversee colorectal screening for their patients, but colonoscopy, a central component of screening programs, is usually performed by consultants. The accuracy and safety of colonoscopy varies among endoscopists, even those with mainstream training and certification. Therefore, it is a primary care responsibility to choose the best available colonoscopy services. A working group of the National Colorectal Cancer Roundtable identified a set of indicators that primary care clinicians can use to assess the quality of colonoscopy services. Quality measures are of actual performance, not training, specialty, or experience alone. The main elements of quality are a complete report, technical competence, and a safe setting for the procedure. We provide explicit criteria that primary care physicians can use when choosing a colonoscopist. Information on quality indicators will be increasingly available with quality improvement efforts within the colonoscopy community and growth in the use of electronic medical records.

 $\ensuremath{\mathit{KEYWORDS}}$ primary care clinicians; colorectal screening; endoscopist; colonoscopist.

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S creening for colorectal cancer can prevent cancer incidence and death and is recommended in clinical practice guidelines^{1,2}. Primary care clinicians initiate and oversee colorectal cancer screening programs for their patients³. However, colonoscopy, which is usually not performed by the primary care clinicians themselves, is a central part of such

programs—for screening, for diagnostic evaluation of positive test results regardless of the initial screening test, and for surveillance of patients at increased risk. Most colonoscopies in the U.S. are performed by gastroenterologists and colorectal surgeons, although other specialists also do this procedure⁴. Thus, primary care clinicians and referral endoscopists share responsibility for successful colorectal cancer screening.

The accuracy and safety of colonoscopy vary from clinician to clinician, even among those with extensive experience 5,6 . In a study of 12 full-time, board-certified gastroenterologists with formal training, each of whom had performed at least 3,000 colonoscopies, adenoma detection rates ranged from 9.4% to $32.7\%^5$. Withdrawal times ranged from 3.1 to 16.8 minutes in patients in whom no polyps were found and endoscopists with longer withdrawal times had higher adenoma detection rates. Rates of cancer detection and perforation also vary among examiners 7 .

Given this variation in performance of colonoscopy, primary care clinicians should be in a position to identify endoscopists who meet high standards for quality. We have identified a set of indicators that primary care clinicians can use to assess quality of colonoscopy procedures. This work is part of a larger effort to improve the quality of colonoscopy. In 2002, the U.S. Multi-Society Task Force on Colorectal Cancer published recommendations for indicators that should be measured by colonoscopy practices as part of ongoing quality improvement⁸. The Quality Assurance Task Group of the National Colorectal Cancer Roundtable then developed a standardized reporting system (CO-RADS) that specifies the elements that should be included in colonoscopy reports and a standard method for reporting them⁸. That documentation system should also serve to improve communication with referring clinicians and patients by providing reports that use standard terms and include specific, evidence-based recommendations for follow-up.

PROCESS

These recommendations were developed by members of the National Colorectal Cancer Roundtable, a coalition of nearly 60 public, private, and voluntary organizations who work together, with support from the American Cancer Society and the Centers for Disease Control and Prevention, to advance colorectal cancer control through screening9. The Quality Assurance Task Group, a working group of the Roundtable, identified the importance of colonoscopy quality from the primary care perspective at a meeting on November 5, 2007. A panel of the Task Group, including three primary care physicians (two family physicians and one general internist), one preventive medicine specialist, six gastroenterologists, two epidemiologists, and one nurse volunteered to prepare this statement. This panel met by conference call and exchanged views by email and telephone. Drafts of the statement were revised and circulated until all members of the Panel approved the recommendations. We based our recommendations on existing research evidence and clinical practice guidelines. While there is not strong, direct research evidence that these recommendations change outcomes, all reflect the kinds of performance measures-such as completeness of examination, adenoma detection rates, and safety-that matter to patients and have been shown to be achievable. They also reflect the information that clinicians need to have to make evidence-based decisions about screening in individual patients. For example, recommendations for surveillance intervals depend on the number, size, and histology of adenomas found on the preceding examination ¹⁰.

RECOMMENDATIONS AND RATIONALE

Recommendations for the quality of colonoscopy services are summarized in Table 1. The following describes the basis for these recommendations.

- 1. Elements of the Colonoscopy Report. We listed six basic descriptors of what was done and what was found during the colonoscopy based on earlier work by Task Group⁸. Each of these descriptors is necessary to interpret the clinical significance of findings and plans for follow-up.
- a. <u>Depth of insertion</u> is related to the proportion of the colon examined and thus the percent of adenomas and cancers that could have been found. Confidence in a report that the cecum was reached should be supported by a clear description of anatomic landmarks (appendiceal orifice and ileocecal valve) and photo documentation if it is available.
- b. Quality of bowel preparation. Poor bowel preparation results in missed lesions and follow-up examinations scheduled sooner than the usually recommended interval. The quality of bowel cleansing is a subjective measure, but efforts are under way to increase reproducibility and validity by establishing a common measure across endoscopists⁸ and to anchor judgments in an objective phenomenon such as "adequate to detect polyps >5 mm"⁸.
- c. Patient tolerance of the procedure is important information for the clinician who coordinates the patient's care over time. For example, syncope during the bowel preparation or procedure may signal cardiovascular risk

- and require evaluation; bleeding from the procedure may cause anemia, which should be diagnosed and treated.
- d. <u>Description of polyps.</u> The number, size, location, morphology (pedunculated, sessile, or flat) and histology of adenomas has been related to recurrence rate and this, plus <u>completeness of polyp removal and biopsy results</u> are the basis for planning surveillance intervals¹⁰.
- e. Pathology results for any biopsies. Recommendations for follow-up and surveillance depend on information from both the procedure itself and the pathology report. Despite logistic challenges in obtaining pathology reports promptly, referring clinicians should expect that the colonoscopist will promptly communicate findings from the procedure itself, the pathology, as well as recommendations both to them an directly to the patient.
- need to be explicit so that referring clinician, as well as the patient, know what the endoscopist has recommended. Recent, evidence-based guidelines, relating surveillance interval to risk factors for subsequent advanced neoplasia, are summarized in Table 2¹¹. If the recommended interval differs from guidelines, the reasons should be made explicit.

Physicians in practice say they often choose shorter surveillance intervals¹¹ than recommended in clinical practice guidelines. Because some risks and substantial costs (measured both in financial and human terms) are at stake, and the clinical benefit of short-interval colonoscopy surveillance after initial polypectomy is low for most patients¹², the surveillance interval is an important decision for everyone involved with the patient's care

Family history information gathered at the time of screening as well as some colonoscopy findings (such as a malignancy or advanced adenomas at a young age) may suggest that other family members are at increased risk and should have earlier than usual screening with colonoscopy. In the case of Lynch Syndrome, they are at increased risk for other cancers as well. The endoscopy report should include recommendations for colorectal cancer screening in family members when appropriate. The endoscopist and the primary care clinician have a collective responsibility for encouraging patients to notify family members if they are at increased risk, and for recommending that these family members talk with their own primary care clinician about colorectal cancer screening.

2. Cecal Intubation Rate. Clinically-important adenomas and cancers occur throughout the colon and will be missed to the extent that the entire colon is not examined. Reports of consecutive screening colonoscopies have established that cecal intubation rates of over 90% are achievable 13-18, especially in patients without clinical reasons for incomplete colonoscopies such as severe colitis, poor preparation, severe diverticulosis, vital sign instability during the procedure 17. Several expert groups have set a quality target of 90% or higher for cecal intubation rate 7.19. Screening guidelines recommend that if the cecum cannot be reached other imaging procedures (computed tomographic colonography or double contrast barium enema) should be used to complete the examination 1. We concluded that an average cecal intubation rate of at least

Table 1. Elements of Quality of Colonoscopy Services with Operational Definitions

Element of Quality Operational Definition 1, Does the colonoscopy report include: Was the cecum reached? If so, were landmarks described? If the cecum was not reached, a) Depth of insertion what were the reasons? Was the bowel preparation adequate to detect polyps >5 mm? b) Bowel preparation quality c) Patient tolerance of the procedure What if any were the complications of the bowel preparation, sedation, and endoscopy? d) A description of polyps and whether they were removed For each polyp seen, what was the anatomic location, size (in mm), and morphology? or biopsied What was the method and completeness of removal? What was the histologic description of removed tissue? (Pathology reports may be sent e) Pathology results for any biopsies after the rest of the colonoscopy report, when they become available from the pathologist.) f) Clear recommendations for follow-up and/or surveillance When should the next colonoscopy be scheduled? If the recommended interval differs from (whether or not the examination was complete) national guidelines (see Table 2) the reasons should be stated. If family members are at increased risk, based on the patient's clinical presentation, how should they be screened? 2. Does the endoscopist have a high enough cecal Expert groups have suggested that a cecal intubation rate of > = 90% be a quality target. While intubation rate? there may be good reasons for not reaching the cecum in individual patients, average cecal intubation rates above 90% (after taking into account examinations that have been aborted because of poor bowel preparation, strictures, severe colitis, or when full colonoscopy was not the original intent) have been achieved by many experienced endoscopists 3. Does the endoscopist have a high enough adenoma Based on the known prevalence of adenomas by age and sex, endoscopists should detect detection rate? adenomas on initial screening examinations of adults 50 years old or older in at least 15% of women and 25% of men 4. Is the colonoscopy performed in a safe setting? Characteristics of a safe setting for colonoscopy are adequate cleaning and disinfection of equipment, well-maintained equipment, well-trained endoscopist and staff, and the ability to react to emergencies that might arise during the procedure. Some states and professional societies have in place guidelines for safe settings and requirements for accreditation but there is not a universally-accepted standard

90% was achievable after excluding examinations that were terminated for clinical reasons and those for which full colonoscopy was not the original intent. Rates are lower in some settings 6,20,21 , but there is evidence that rates can be improved by quality improvement programs 21 . We recommend that all endoscopists should aim to meet this target, regardless of specialty, training, or experience.

3. Adenoma Detection Rate. The prevalence of adenomas at age 50 years is estimated to be 15% in women and 25% in men, increases with age in both sexes⁷, and the majority of adenomas are detected by colonoscopy^{22,23}. It is not feasible to measure the proportion of adenomas found for individual colonoscopists against research standards, (a second colonoscopy and computed tomographic colonography) so we chose adenoma detection rates as a crude metric for the proportion of adenomas found at colonoscopy. Adenoma detection rate during screening colonoscopy has been shown to be inversely related to the risk of interval cancers²⁴. We confined this quality measure to first colonoscopies because prior polypectomies can

change the prevalence of adenomas, making polyp prevalence lower and detection rates more difficult to interpret.

4. Safe Setting. Colonoscopy can cause clinically-important complications such as bleeding, perforation, and cardiovascular events during bowel preparation or endoscopy. The procedure can also spread infection if equipment is improperly cleaned and disinfected. Although the great majority of colonoscopies occur without incident, complication rate is an important aspect of quality. However, we chose not to include complication rates in the quality measures because events occur too infrequently to allow stable estimates of rates for individual colonoscopists, unless he or she has performed an unusually high volume of procedures.

Instead, the panel recommended that safety be assessed by a surrogate measure, characteristics of the setting in which procedures are done. Among these are adequate cleaning and disinfection of equipment, well-maintained equipment, well-trained endoscopist and staff, and the ability to react to emergencies that might arise during the procedure²⁵.

Table 2. Recommended Surveillance Intervals After Polypectomy in Average Risk Patients (From 11)*

Colonoscopy Finding	Interval to Next Colonoscopy (Years)
Normal of hyperplastic polyp† 1–2 tubular adenomas <1 cm with only low-grade dysplasia	10 5–10
3-10 adenomas or at any adenoma $> = 1$ cm or any adenoma with villous features or high-grade dysplasia > 10 adenomas	3 < 3 years‡

^{*}These recommendations assume that the baseline colonoscopy was complete to the cecum, that bowel preparation was adequate, and that all polyps identified were completely removed. The recommendations do not apply to patients who have a high risk of colorectal cancer because of previous colorectal cancer, familial adenomatous polyposis, hereditary non-polyposis colon cancer (HNPCC < Lynch Syndrome), or inflammatory bowel disease.

[†] Since this table was published, there has been growing evidence that large or multiple hyperplastic polyps in the proximal colon may require earlier follow-up

[‡] Consider the possibility of a familial syndrome

While some states and professional societies have guidelines for safe settings and requirements for accreditation, primary care clinicians cannot always rely on external review to decide whether the colonoscopy setting is safe. At this time, there is no single, overall mechanism for credentialing that applies to all specialties that do colonoscopy and in all settings in which it is done.

DISCUSSION

We have identified a set of quality indicators that primary care clinicians can use when deciding where to send their patients for colonoscopy services. The need for a more rigorous approach to choosing among endoscopists is highlighted by reports of substantial variation in the quality of colonoscopy, even among clinicians generally considered to have appropriate training, experience, and credentials. The elements of quality are based on the information needed to follow screening and surveillance guidelines. The targets we set have been shown to be achievable in community settings.

We have recommended that primary care clinicians rely on the actual performance of colonoscopy, not just the background and specialty of those who do the procedures. Specialty societies have set standards for performance of colonoscopy but they have not been universally adopted or enforced. In one study of gastrointestinal endoscopy centers in the US, 60% required no minimum number of procedures before granting privileges, and two-thirds required no minimum number of procedures per year²⁶. Also, training, experience, and specialty do not in themselves assure high quality colonoscopy⁵.

Is it feasible for primary care clinicians to implement these recommendations? We would argue that primary care clinicians have always considered it a core responsibility to choose the best available consultants, and now, at least for colonoscopy, they are in a better position to meet that responsibility. They are also better able to care for their patients if the report of the procedure includes the information they need to explain plans for colorectal cancer screening and surveillance to their patients and judge the appropriateness of colonoscopy intervals for themselves. In the absence of performance information on individual endoscopists, it seems likely that consultants are chosen based on other considerations, such as availability, reputation, and congeniality. New models for how primary care can be organized and financed, which are now being tested as part of the patient-centered medical home movement²⁷, might foster, among many other improvements in care, ways to identify consultants by performance.

Will individual endoscopists be able and willing to provide information on their performance? Standardized reporting is being promoted within the endoscopy community as part of a larger set of quality improvement activities. We encourage clinicians to refer patients to endoscopists who use a standardized reporting mechanism such as the CO-RADS lexicon⁸, and to communicate with endoscopists that they value receiving reports that follow this standard. If electronic medical records become more widely implemented, information on quality of colonoscopies may be easier to monitor and share.

There has been a lively debate in the literature about the kind of training needed to perform high quality colonoscopy²⁸. The published literature is not yet robust enough to answer

this question with confidence. Whatever the answer, we thought that the performance of each endoscopist should stand on its own merits, as reflected in measurable quality indicators such as the quality of the colonoscopy report and cecal intubation and polyp detection rates. Choosing endoscopy services according to actual performance is becoming possible for the first time, as a result of efforts in the colonoscopy community to set measurable quality standards and the growing use of electronic medical records. With a better understanding of quality standards for colonoscopy, primary care clinicians can be better advocates for their patients.

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Conflict of Interest: None of the authors has a financial tie to entities that would stand to gain financially from implementation of the recommendations in this statement.

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