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Assessment of Quality of Colonoscopy Reports: Results from a multi-center consortium

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Abstract

Background—In order to improve colonoscopy quality, reports must include key quality indicators which can be monitored.

Objective—To determine the quality of colonoscopy reports in diverse practice settings.

Setting—The consortium of the Clinical Outcomes Research Initiative (CORI), which includes 73 gastroenterology practice sites in the United States which use a structured computerized endoscopy report generator, which includes fields for specific quality indicators.

Design—Prospective data collection from 2004 to 2006.

Dr. Lieberman is the executive director of the Clinical Outcomes Research Initiative (CORI), a non-profit organization that receives funding from federal and industry sources. The CORI database is used in this study. This relationship has been reviewed and managed by the OHSU Conflict of Interest in Research Committee and the VA Conflict of Interest in Research committee.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

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Main Outcomes Measurements—Reports were queried to determine if specific quality indicators were recorded. Specific endpoints, including quality of bowel prep, cecal intubation rate and detection of polyp(s) >9mm in screening exams were compared in 53 practices with more than 100 colonoscopy procedures per year.

Results—Of the 438,521 reports received during the study period, 13.9% did not include bowel prep quality and 10.1% did not include co-morbidity classification. The overall cecal intubation rate was 96.3%, but cecal landmarks were not recorded in 14% of reports. Missing polyp descriptors included polyp size (4.9%) and morphology (14.7%). Report of interventions for adverse events during the procedure varied from 0 to 6.5%. Among average-risk patients receiving screening exams, the detection rate of polyps >9mm, adjusted for age, gender and race, was between 4 and 10% in 81% of practices.

Limitation—Bias toward high rates of reporting because of standard use of a computerized report generator.

Conclusion—There is significant variation in quality of colonoscopy reports across diverse practices, despite the use of a computerized report generator. Measurement of quality indicators in clinical practice can identify areas for quality improvement.

Introduction

Colonoscopy is used for primary colorectal cancer (CRC) screening, surveillance of patients with prior colon neoplasia or cancer and for diagnosis in patients with lower gastrointestinal (GI) tract symptoms. Colonoscopy is also used to evaluate patients with positive CRC screening with fecal occult blood test (FOBT), sigmoidoscopy, fecal DNA or imaging. There is evidence that utilization of colonoscopy has increased dramatically in the past few years, largely due to increased rates of CRC screening (1–3). The effectiveness and safety of colonoscopy depend on the quality of examination, and a growing body of evidence suggests that the quality of colonoscopy in clinical practice varies (4,5).

In 2002, the Multi-Society Task Force on colorectal cancer (MSTF-CRC) published specific recommendations to improve the quality and effectiveness of colonoscopy (4). This important contribution highlighted key indicators for continuous quality improvement (CQI), and suggested targets for specific indicators. In 2006, Rex et al (5) added background data with identification of levels of evidence that supported key quality indicators and proposed targets in the earlier document. In 2007, the Quality Assurance Task Force of the National Colorectal Cancer Roundtable developed a reporting and data system for colonoscopy (CO-RADS) to assist endoscopists in monitoring quality indicators in their practice (6).

Structured, computerized endoscopic reporting systems provide an ideal tool for monitoring quality indicators. The Clinical Outcomes Research Initiative (CORI) developed a computerized endoscopic reporting system to study outcomes of endoscopy in the United States. Data are transmitted electronically to a central data repository for analysis. The CORI consortium includes 73 diverse practice sites in 24 states, and receives about 350,000 endoscopic reports annually.

Quality of colonoscopy cannot be measured or improved if reports do not include key quality indicators. Therefore, the aims of the current study are to determine 1) if the colonoscopy reports include key quality indicators and 2) to measure actual performance relative to specific targets for bowel prep quality, cecal intubation and detection of polyps >9mm on screening exams within each practice in the CORI consortium. A secondary aim is to assess the degree of variation in these measured quality indicators among practices that use the same computerized report generator.

Methods

Clinical Outcomes Research Initiative (CORI)

The CORI consortium includes 73 gastroenterology practice sites in 24 states. Practice sites include private practice (79% of colonoscopy reports), academic sites (10%) and VA sites (11%). Practice sites were selected to represent a complete spectrum of GI practices and include both urban and rural sites in each region of the country. Participating physicians use a structured, computerized endoscopic report generator to produce their endoscopic reports. The data file from that report is transmitted electronically to a central data repository (National Endoscopic Database: CORI-NED). All colonoscopy reports received between January 1, 2004 and December 31, 2006 were included in this analysis. The study period was selected to represent a time period of greater than one year after the publication of the MSTF-CRC paper (4) on colonoscopy quality indicators and one year after the publication of the 2003 screening and surveillance guideline (7). We excluded reports in patients less than 20 years old.

Quality Indicators

We queried the database to identify specific quality indicators to the extent possible (Table 1). Data were compiled and analyzed for the entire consortium (CORI-NED), and analyzed for individual practices with more than 100 colonoscopies per year during the study period ($n = 53$) to measure practice variation. Practices with fewer than 100 colonoscopies per year were not included in the practice site analysis. Unplanned intervention(s) for adverse events included only those interventions which were reported at the time of colonoscopy.

Data were collected prospectively in the CORI consortium. We used the proportion of patients with polyp(s) > 9 mm or suspected malignant tumor as a surrogate endpoint for advanced neoplasia since we did not have pathology data from all sites. We analyzed data from more than 13,609 subjects undergoing colon screening from 22 sites which provide pathology to determine if the prevalence of the surrogate was representative of actual proportion of patients with histologically proven advanced neoplasia. In this sub-analysis, 7.0% subjects had histologically advanced neoplasia, including polyps of all sizes. If we used the presence of one of more polyps greater than 9mm as a surrogate, the "surrogate" rate was 6.8%. Based on this close association, we have used the surrogate in the current analysis.

To measure the prevalence of polyp(s) > 9 mm among screening patients we identified patients for whom the indication for colonoscopy was average-risk screening. We also identified cohorts with a family history of CRC and positive fecal occult blood test (FOBT) for comparison. Patients were excluded from this analysis if there were any other indications listed for colonoscopy, such as pain or change in bowel habits. If a patient had more than one screening exam during the time period, only the first was considered. We employed multivariate regression analysis to statistically construct standardized polyp(s) > 9 mm detection rates among average risk patients adjusted for the population age (dichotomized as < 65 years vs ≥ 65 years), gender and race (white vs non-white) distribution. All analyses were performed using SAS software version 9.1 (SAS Institute, Inc., Cary, NC).

Results

From 2004 to 2006, CORI received 438,521 colonoscopy reports. Patient demographics and procedure indications are described in Table 2.

Pre-Procedure Indicators

ASA Classification field was not completed in 10.1% of reports. In 10 of 53 sites, completion rates were less than 90% (Fig 1a). When completed, 7.0% of exams were performed in high-risk individuals with ASA class 3 or higher.

The quality of the bowel prep was not recorded in 13.9% of reports. In 14 of 53 practices, more than 20% of exams did not have a recorded bowel prep quality (Fig 2a). When reported, the quality was described as excellent, good or fair in 94.3% (range 84–100%) excluding one outlier site (Fig 2b).

Table 2 presents the overall patient demographics and procedure indications for all colonoscopy reports received. Polyp surveillance accounts for 16.5% of exams. In order to determine if surveillance was performed at an appropriate interval, the report would need to include information from the last colonoscopy. These data would include the date and endoscopic and histologic findings of the previous colonoscopy. This information was absent in 66.1% of patients undergoing polyp surveillance (Fig 1b). Therefore, in most cases, the colonoscopy report lacked sufficient information to determine if the surveillance interval was consistent with published guidelines.

Procedure-related indicators

All reports included information about cecal intubation because it is a required field. The cecum or ileum was reached in 94.8% of exams (range 88–99%). In some cases, cecal intubation was not intended such as exams for colitis or obstruction. When cecal intubation was intended, the cecum was reached in 96.3% of exams. Four of 53 sites reported rates less than 90% (Fig 3). Cecal landmarks (appendiceal orifice and/or ileocecal valve) were reported in 85.9% of the reports when the cecum was reached. The CORI database has a field for total procedure time, and does not have separate fields for insertion and withdrawal times in the software version used for this analysis. Procedure time was recorded in 65.2% of exams, with wide variation in reporting among sites (Fig 4). When recorded, only 1.6% of exams were less than 10 minutes, and nearly 38% of exams were 10–20 minutes in duration. All other exams exceeded 20 minutes.

Procedure outcomes

Polyps (n = 258,601 polyps) were found in 159,449 procedures (36.3%). Overall, polyp size was not recorded in 4.9% of reported polyps. However, in 15% of practices (8/53), size was not reported in more than 10% of polyps (Fig 5a). Polyp morphology (pedunculated, sessile, flat) was not reported in 14.7% of reported polyps. Whether or not the polyp was retrieved for pathology was not documented in 4.5%. Variation among practices is shown in Figures 5b and 5c.

We measured the proportion of exams in unique patients with one or more polyps >9mm in three different screening cohorts. If a patient had more than one screening exam during the time period, only the first was considered. Patients were excluded from this analysis if they had any other indication for colonoscopy. In the average-risk cohort, (n = 114,069), 6.3% had polyp(s) >9mm. Among patients with a family history of CRC (n = 33,428), 5.7% had polyp(s) >9mm. Patients with a positive fecal occult blood test were included for comparison if they had no other GI symptoms (n = 15,811). The rate of polyp(s) greater than 9mm was 12.1% in this group. Figure 5d displays the standardized polyp(s) >9mm detection rates among average risk exams in each practice, after adjusting for the population age, gender and race distribution. Based on published literature, the expected range for prevalence of polyp(s) >9mm in average risk individuals over 50 years would be 4–10%. We find that 10 of 53 practices (19.2%) are

either above or below this range, and that 9 of the 10 of outlier practices performed fewer than 8,000 procedures during the study period.

We determined the proportion of reports which included one or more unplanned interventions for an adverse event. The range of reporting of interventions was 0 to 6.5%. Seventy-four percent of sites reported interventions in $\leq 1.0\%$ of procedures (Fig 6).

Discussion

The increasing utilization of screening and diagnostic colonoscopy has focused attention on the quality of the performance of the procedure (4–6). Over the past few years, new data have emerged which highlight possible shortfalls in colonoscopy performance. Recent studies (8–12) have reported interval cancers (0.3–0.9%) within 2 to 3 years of colonoscopy in adenoma-bearing patients which could be due to missed lesions, incomplete removal (13) or new, fast growing lesions (14). The first two factors may be related to the quality of colonoscopy and polypectomy. The problem of missed lesions was highlighted by CT colonography studies which compared CT imaging with optical colonoscopy using a method of segmental unblinding. Optical colonoscopy missed 2–12% of polyps greater than 10mm (15–17). Other studies have highlighted variation in the rates of adenoma detection among physicians (18), and noted a relationship between endoscope withdrawal time and rate of adenomas in first-time screening exams. These studies suggest that the potential benefits of colonoscopy depend on the quality of the exam.

The Quality Assurance Task Group of the National Colorectal Cancer Roundtable published a standardized reporting system (CO-RADS) to enable every endoscopist to monitor quality indicators in their practice (6). Practices can utilize these data to initiate quality improvement measures. This effort was modeled after successful efforts in radiology to standardize reporting systems for mammography and CT colonography (19,20). The current study is the largest attempt to measure colonoscopy quality across different practice settings in the United States. We selected a time period for study one to two years after publication of quality indicators by the Multi-Society Task Force (4) so that it would be likely that endoscopists would be aware of the indicators. The CORI software captures most of the indicators proposed in CO-RADS (6). New versions of CORI will include all of the key indicators. An underlying principle of quality improvement is that quality indicators must be recorded, in order to monitor and improve quality. Therefore, our study focused on both the quality of the colonoscopy report, and a few specific quality indicators.

Our results reveal that even with a structured report generator, some key quality fields were often incomplete. Several of these fields are important in determining the quality of the exam, including bowel prep quality (absent in 13.9%) and specific mention of cecal landmarks (absent in 14.1%). The current guidelines suggest that endoscopists produce photographic documentation of cecal landmarks to establish confirmation that intubation was achieved (6). Without this information in the report, a careful reviewer could not confirm whether the exam was complete and adequate. The absence of these data could result in unnecessary repeat examinations.

A key element of exam quality is whether the procedure is indicated. There is evidence from physician surveys that colonoscopy for polyp surveillance is over-utilized, which may expose patients to unnecessary cost and risk (21,22). To determine if this is a problem in clinical practice based on the colonoscopy report, the report would need to include documentation of the prior colonoscopy exam and its findings. In most cases, we found this documentation was lacking, and therefore, it was not possible to determine if the interval was appropriate. Further study will be needed to monitor the appropriate use of colonoscopy for polyp surveillance.

Finally, the omission of key polyp descriptors (size, morphology) may impact decisions for surveillance colonoscopy. Current guidelines call for a three year surveillance interval if adenomas are $\geq 10\text{mm}$. If size is omitted (5% of exams), it would be difficult to determine the appropriate timing for surveillance.

We note other deficiencies in reporting which are important, but do not directly impact exam quality. The ASA classification was absent in 10.1% of reports. While this indicator does not reflect exam quality, it is an important surrogate of co-morbidity (23). Prior work has shown an association between higher class and adverse events (24,25). Procedure duration was not recorded in 35% of exams. Our study period pre-dated a recent study showing a relationship between withdrawal time and adenoma detection rate (18). In addition, it is possible that other systems, such as nursing chart notes, may document the procedure duration. Physicians may not record the time if it is being noted elsewhere. When time was recorded, only a small proportion of exams were less than 10 minutes in duration (1.6%).

We report on performance of three key quality indicators: cecal intubation rate, polyp detection rate and unplanned interventions for adverse events. In most cases, endoscopists reached the cecum when this was intended (96.3%), although as noted above, reporting or photodocumentation of cecal landmarks were sometimes absent. It should be noted that most CORI physicians are board-certified gastroenterologists. In the United States, more than 18% of colonoscopy exams are performed by non-GI trained physicians (26,27), and it is possible that cecal intubation rates may not be as high in other clinical settings.

A primary goal of screening and surveillance is the detection and removal of neoplastic polyps. We note considerable variation in the rates of finding one or more polyps $> 9\text{mm}$ in screening examinations. In clinical studies (15,28–31), 4–10% of average-risk subjects have advanced neoplasia, defined by polyp size ($\geq 10\text{mm}$) or histology (villous or high-grade dysplasia). Our study uses size $> 9\text{mm}$ as a surrogate for advanced neoplasia. In our analysis of pathology from selected CORI sites, this rate is similar to the overall rate of advanced neoplasia. After adjusting for age, gender and race, we find that 81% of practices had detection rates of 4–10% for average-risk individuals (Fig 5d). Outliers (both high and low) tended to be low-volume sites. Higher volume sites may include more endoscopists so that the effect of an individual endoscopist with an unusually high or low adenoma detection rate will be diluted. Future analyses will include individual provider quality data. Variation in detection rates may also be due to variable patient demographics in the practice although our data were adjusted for patient demographics. Finally, such variation may be a reflection of exam quality.

The harms of colonoscopy in clinical practice are uncertain (32–37). Certain patient populations (elderly, ASA class 3 or higher) may have a higher risk of adverse events than other patients (24,25). Recent reports from various practice sites have suggested that rates may be higher than those observed in clinical trials performed by expert colonoscopists (35–37). We note wide practice variation in the rate of reporting adverse events (0.2–7.4%) which may reflect different reporting thresholds. For example, some practitioners may note every episode of oxygen desaturation to less than 90%. Others, may not record such events if they are transient. Therefore, we focused on unplanned interventions for adverse events, assuming that if the event was significant enough to require an intervention, it would be clinically important, and likely to be reported. CORI provides structured fields to indicate the type of event and the nature of any unplanned intervention. We note variation (0 to 6.5%) in reporting unplanned interventions, with 26% of sites reporting interventions in more than 1% of procedures. These differences among sites may be due to true variation in adverse event rates or may reflect reporting threshold practice. If the primary reason for variation is the threshold for reporting events, our data suggest the need for a more standard method of classification and reporting

of significant events and interventions so that meaningful quality improvement programs can be initiated.

Our study is biased toward finding high rates of completion of quality indicators because each physician used a structured report generator which provided a field for completion of the specific indicator. It is possible that physicians using unstructured reports, with dictation, may be less likely to record all of the indicators. Nevertheless, even using a structured report, areas for quality improvement are evident in some practices. CORI may be subject to self-selection bias, by including physicians who are comfortable sharing data about their practice, and may not reflect practice elsewhere.

In summary, this analysis provides a snapshot of quality of colonoscopy reporting in the United States. Quality improvement depends on monitoring quality indicators in daily practice. We observe considerable variation among 53 diverse practices. This study demonstrates that quality indicators of colonoscopy can be measured in the flow of clinical practice. Such measurement is facilitated by using a computerized report generator. Routine measurement of quality indicators could lead to a process of quality improvement in the practice of colonoscopy.

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Acronyms

CRC	Colorectal cancer
GI	Gastrointestinal
FOBT	Fecal occult blood test
MSTF-CRC	Multi-Society Task Force on Colorectal Cancer
CQI	Continuous Quality Improvement
CO-RADS	Colonoscopy reporting and data system
CORI	Clinical Outcomes Research Initiative
CORI-NED	CORI National Endoscopic Database
ASA	American Society of Anesthesiology classification
CT Colonography	Computerized Tomographic Colonography

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Figure 1. Pre-Procedure Indicators based on patient history

Figure 1a: Percentage of reports with ASA Classification field documented, for each practice site

Figure 1b: Percentage of reports with information on prior colon exam in patients receiving polyp surveillance, for each practice site.

Figure 2. Bowel Prep indicators

Figure 2a: Percentage of reports with adequacy of bowel preparation documented, for each practice site

Figure 2b: Percentage of reports with bowel preparation quality described as adequate*, for each practice site

* Includes excellent, good or fair bowel prep quality.

Figure 3.
Rate of cecal intubation when intended, for each practice site

Figure 4.
Percentage of reports with procedure duration documented for each practice site

Figure 5. Polyp Indicators

Figure 5a. Percentage of polyps with polyp size documented, for each practice site

Figure 5b. Percentage of polyps with polyp morphology documented, for each practice site

Figure 5c. Percentage of polyps for which polyp retrieval documented, for each practice site

Figure 5d. Percentage of average-risk subjects with one or more polyps >9mm documented, adjusted for age, gender and race, for each practice site.

Figure 6. Percentage of reports documenting intervention(s) for immediate adverse event(s), for each practice site.

Table 1
Colonoscopy Quality Indicators*

Bowel Prep quality

Field Completed (yes/no)

Prep quality (if reported): Proportion with prep described as excellent, good or fair-adequate

American Society of Anesthesiology (ASA) Classification of Physical Status (proxy for co-morbidity)

Field Completed (yes/no)

Rates of each classification in outpatient setting

Extent of exam

Cecal intubation rate (when reaching cecum was intended)

Documentation of cecal landmarks

Total Procedure time

Time recorded (yes/no)

Total procedure time

Procedure Indication: Polyp Surveillance

Documented date and findings of prior exam (yes/no)

Polyp Descriptors

- Polyp Size recorded (yes/no)
- Polyp morphology recorded (yes/no)
- Polyp retrieval and submission to pathology recorded (yes/no)

Unplanned events and interventions

Rate of reported intervention(s) for immediate adverse event

In first time screening exams; rates of polyp >9mm**

Average-risk screening

* adapted from CO-RADS (6)

** polyp > 9mm is used as a surrogate of advanced neoplasia; adjusted for age, gender and race.

Table 2
Patient Demographics (n = 438,521)

	N	%
<u>Age (years)</u>		
20–29	7183	1.6%
30–39	15795	3.6%
40–49	46615	10.6%
50–59	150,642	34.4%
60–69	115,025	26.2%
70–79	77409	17.7%
>79	25852	5.9%
<u>Gender</u>		
Female	215016	49%
Male *	223505	51%
<u>Race/Ethnicity</u> **		
White, non-Hispanic	374019	85.6%
Black non-Hispanic	25238	5.8%
Asian/PI	6674	1.5%
Native American	2949	0.7%
Multi-racial, non-Hispanic	714	0.2%
Hispanic	27586	6.3%
<u>Site Type</u>		
Community/HMO	344,989	79%
VA/Military	49,691	11%
Academic	43,841	10%
<u>Procedure Indications</u> ***		
<u>Screening</u>		
Average-risk	129970	29.6%
Family history of CRC	47091	10.7%
Family history of polyps	11830	2.7%
Positive FOBT	22,974	5.2%
<u>Surveillance of:</u>		
Polyps	72163	16.5%
CRC	11104	2.5%
Ulcerative colitis	5360	1.2%
Crohns	3081	0.7%
<u>Evaluation of Symptoms</u>		
Hematochezia	67105	15.3%
Anemia	22627	5.2%
Weight loss	5839	1.3%
IBS cluster ****	91978	21.0%

* includes VA patients

**
Reports with missing or unknown race are excluded

Patients may have more than one indication

defined as one or more: diarrhea, constipation, abdominal pain/bloating or change in bowel habits