Development of Quality Indicators for Patients Undergoing Colorectal Cancer Surgery

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Background: **Colorectal cancer is the second most common cancer type among new cancer diagnoses in the United States. Attention to the quality of surgical care for colorectal cancer is of particular importance given the increasing numbers of colorectal cancer resections performed in the aging population. A National Cancer Institute–sponsored consensus panel produced guidelines for colorectal cancer surgery in 2000. We have updated and extended that work by using a formal process to identify and rate quality indicators as valid for care during the preoperative, intraoperative, and postoperative periods.** ***Methods:*** **Using a modification of the RAND/UCLA Appropriateness Methodology, we carried out structured interviews with leaders in the field of colorectal cancer surgery and systematic reviews of the literature to identify candidate quality indicators addressing perioperative care for patients undergoing surgery for colorectal cancer. A panel of 14 colorectal surgeons, general surgeons, and surgical oncologists then evaluated and formally rated the indicators using the modified Delphi method to identify valid indicators.** ***Results:*** **A total of 142 candidate indicators were identified in six broad domains: privileging (which addresses surgical credentials), preoperative evaluation, patient–provider discussions, medication use, intraoperative care, and postoperative management. The expert panel rated 92 indicators as valid. These indicators address all domains of perioperative care for patients undergoing surgery for colorectal cancer.** ***Conclusions:*** **The RAND/UCLA Appropriateness Methodology can be used to identify and rate indicators of high-quality perioperative care for patients undergoing surgery for colorectal cancer. The indicators can be used as quality performance measures and for quality-improvement programs. [J Natl Cancer Inst 2006;98:1623–33]**

Measures of the quality of care for diseases other than cancer are being developed and employed by numerous groups and agencies, including the Centers for Medicare and Medicaid Services (CMS) *(1)*, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) *(2)*, and the National Quality Forum (NQF) *(3)*. Quality measures are also being used as tools in pay-for-performance demonstration projects, such as the CMS's Hospital Quality Initiative, which requires all eligible hospitals to submit data on adherence to an initial set of 10 quality indicators for the conditions of acute myocardial infarction (five indicators), heart failure (two indicators), and pneumonia (three indicators) *(4)*. Measures and indicators of the quality of care will be needed for evaluating and improving the quality of cancer care as well.

Colorectal cancer is the second most common cancer type among both estimated new cancer cases and cancer deaths in 2005 in the United States *(5)*. The importance of quality care for cancer patients, including those with colorectal cancer, was highlighted by the Institute of Medicine (IOM) report on Ensuring Quality Cancer Care *(6)*, which recommended that the quality of cancer care be monitored and measured using a core set of quality measures. However, the IOM report also noted that specific quality measures for cancer care require further development and testing.

Although regulatory agencies have not yet adopted quality measures for colorectal cancer surgery, quality measures for colorectal cancer care have been recently identified by the NQF *(3)* and the American Society of Clinical Oncologists/National Comprehensive Cancer Network (NCCN) *(7)*. Although these groups used different methodologies, they developed similar groups of three to four measures each. The identification of these measures raises a number of issues. Can these measures be used for detailed programmatic quality improvement? Is this number of quality measures sufficient or representative for the topic of colorectal cancer surgery? If not, there are potential sources for additional quality indicators including clinical practice guidelines for colorectal cancer surgery, developed by the NCCN *(8)*, the Standards Practice Task Force of the American Society of Colon & Rectal Surgeons (ASCRS) *(9,10)*, and a prior National Cancer Institute (NCI)–sponsored consensus panel *(11)*. This panel developed guidelines for colon and rectal surgery and addressed important issues such as anatomic definitions (e.g., colon versus rectum), staging, surgical techniques, and surgical documentation *(11)*. Since these NCI-sponsored guidelines were developed, however, advances in colorectal cancer treatment (e.g., laparoscopic colectomy) have occurred. In addition, it is important to note that the intended conceptual and clinical purposes of guidelines differ from those of quality measures. Whereas clinical practice guidelines are useful for internal improvement and are open to clinical judgment, quality measures represent the most basic level of quality and thus are useful for both internal improvement and external reporting; they also provide specific indicators of the quality of care *(12)*.

Here we report the results of our effort to both update and expand on the NCI-sponsored work through the use of a formal, non–consensus-based rating methodology that combined expert opinion with a formal systematic review of the best evidence in the literature of what constitutes high-quality care for colorectal cancer surgery. We also expanded the scope beyond operative measures to measures that encompass the entire perioperative

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time period. Our goal was to develop a set of process-based quality indicators for colorectal cancer surgery that are applicable to the health care system, to the hospital, or to the teams of providers caring for patients undergoing colorectal cancer surgery. This is the first time, to our knowledge, that formal, independently rated (i.e., non-consensus) quality indicators have been developed that identify ways to improve care across the preoperative, intraoperative, and postoperative time periods for patients undergoing colorectal cancer surgery.

Methods

Identification of Candidate Quality Indicators

A process-based quality indicator is a process that, if performed, results in or signifies higher quality. Conceptually, quality indicators represent the basic level of care, and they set a standard that, if not met, identifies poor quality of care *(13)*. We initially identified candidate quality indicators for colorectal cancer surgery through literature reviews and semistructured interviews with nationally recognized leaders in the fields of colorectal surgery, general surgery, and surgical oncology. During the semistructured interviews, candidate process indicators were identified that were viewed as indicating high-quality care for patients undergoing colorectal cancer surgery.

Systematic Literature Review

For each of the identified candidate indicators, we performed a systematic literature review to identify the highest level of evidence supporting the validity of that quality indicator. As part of this review, we accessed the Web sites of relevant professional societies (e.g., ASCRS), cancer networks (e.g., NCCN), and organizations and associations that monitor quality of medical care (e.g., NQF) to identify currently available clinical practice guidelines and quality measures relating to each of the indicators. In addition, we searched the Medline database for articles published from January 1966 through November 2004 using combinations of search terms relevant to each quality indicator. For example, to identify articles relevant to the quality indicator that addresses pretreatment carcinoembryonic antigen level, we used the search algorithm "colorectal cancer" AND "carcinoembryonic antigen" AND "preoperative." The reference lists of the included articles were also examined to identify any additional articles that had not been identified in the Medline search.

For candidate indicators that concern effectiveness of treatment (e.g., laparoscopic colorectal cancer resection), the highest level of evidence is the randomized controlled trial, whereas for candidate indicators concerning risk or prognosis (e.g., performance of preoperative carcinoembryonic antigen level), the highest level of evidence is generally considered to be the prospective cohort study. If evidence at the highest level were limited or absent, then lower levels of evidence were evaluated. For example, if data were not available from randomized controlled trials, then data from controlled clinical trials, cohort or case–control studies, case series, and expert opinion or clinical guidelines were reviewed. A list of definitions for all terms used in the candidate indicators (Table 1) was also developed to standardize terminology.

RAND/UCLA Appropriateness Methodology—First- and Second-Round Ratings

We assessed the validity of the candidate indicators using a modification of the RAND/UCLA Appropriateness Methodology,

Table 1. Definitions of terms for colorectal cancer surgery

Amsterdam II criteria—patient must meet all of the following:
- Three or more relatives with histologically verified cancer of a type associated with hereditary nonpolyposis colorectal cancer (colorectal cancer or cancer of the endometrium, small bowel, ureter, or renal pelvis), one relative should be a first-degree relative of the other two; individuals with familial adenomatous polyposis should be excluded
- Colorectal cancer must involve at least two generations
- Either the patient or a relative must have been diagnosed with colorectal cancer before age 50

Bowel function—assessment by history of patient's bowel movement habits and ability; includes stool incontinence (and severity), urgency, diarrhea, and constipation

En bloc resection—when the tumor has invaded surrounding structures or organs (e.g., abdominal wall, bladder, spleen), the surrounding tissues must be resected in continuity with the primary lesion; this resection must include the entire organ (e.g., spleen) or portion of an organ (e.g., distal pancreas), as appropriate

High ligation—ligation of the major feeding arteries at their origin during colon or rectal cancer resection; most commonly discussed in the context of the inferior mesenteric artery

Intracorporeal ligation—complete dissection and ligation of the vessels within the confines of the intraabdominal cavity during laparoscopic resection

Mechanical bowel preparation—the process of mechanical cleansing to reduce fecal mass and decrease the risk of postoperative infectious complications in surgery involving the gastrointestinal tract; methods may include one or more of the following: use of cathartics (magnesium citrate, enemas, and bisacodyl tablets or suppositories) to stimulate bowel activity, gut lavage methods (polyethylene glycol), or oral sodium phosphate

Multidisciplinary tumor board—group meeting that includes simultaneous discussion and input by surgeon, medical oncologist, radiation oncologist, and pathologist to discuss workup and treatment recommendations for the colorectal cancer patient

Total abdominal colectomy—removal of the entire colon, including sigmoid colon, with anastomosis created between ileum and upper rectum

Total colonic examination—radiologic imaging studies that evaluate the colon for synchronous lesions or polyps; includes colonoscopy, barium enema, and virtual colonoscopy

Tumor characteristics for local excision—a rectal tumor that is T1 (invades submucosa), well differentiated, without lymphovascular invasion, <4 cm in diameter, and within 3 cm of dentate line

Total mesorectal excision—technique of rectal resection that specifically involves sharp dissection and extirpation of the mesorectum by dissecting outside of the investing fascia of the mesorectum; removes draining lymph nodes and maximizes lateral margins; dissection includes high ligation of the inferior mesenteric artery at its origin

Transanal endoscopic microsurgery—indicated for tumors >5 cm from anal verge if they meet all other criteria for local excision except for location; this minimally invasive technique is performed through an endoscope placed in the anal canal; a smaller telescope is used to magnify the tumor. This technique also dilates the rectum with gas to perform the surgery through the anus. Optimal excision requires 1 cm of margin circumferentially, a full-thickness excision, and an excision that is not piecemeal

Wound protector—separates edges of the incision from contact with visceral contents, instruments, and gloves during the procedure; allows for visualization of the wound edges

which is a modified Delphi method *(14)*. In brief, the method entails two rounds of independent ratings by a group of panelists, with a face-to-face group discussion between rounds. Each panelist has equal weight in determining the final ratings. The RAND/UCLA Appropriateness Methodology includes an explicit synthesis of findings from the literature and iterative panel ratings and has been shown to produce appropriateness criteria and quality indicators that have face, construct, and predictive validity *(15–20)*. The list of candidate indicators, a summary of the supporting literature from the systematic review, and definitions of terms were sent to all 14 members of a panel that included seven colorectal surgeons, five surgical oncologists, and two general surgeons. The 14 panelists individually rated the validity of each candidate indicator on a 1–9 validity scale, defined as follows: 1 = definitely not valid, 5 = of uncertain or equivocal validity, and 9 = definitely valid. In general, when using the RAND/UCLA Appropriateness Methodology, ratings of 1–3 signify that the indicator is not a valid criterion of good quality, ratings of 4–6 signify uncertain or equivocal validity, and ratings of 7–9 signify that the indicator is clearly valid *(14,21)*. Panelists were instructed to consider the following definition of validity when rating the candidate indicators. An indicator would be defined as valid if the following two conditions were met: adequate scientific evidence or professional consensus exists to support a link between the performance of care specified by the indicator and the accrual of health benefits to the patient and a physician or facility with higher rates of adherence to the indicator would be considered a higher quality provider (and those with lower rates of adherence would be considered poorer quality providers) *(21)*.

The rating sheets were returned by mail and tabulated, and the results of the first-round ratings were used to guide a subsequent face-to-face meeting of all panelists. At the face-to-face meeting, each panelist was provided with a confidential reminder of his or her own first-round ratings as well as the median and range of scores from the other panelists (each individual panelist's ratings were kept confidential). Each candidate indicator was discussed to identify areas of disagreement, highlight evidence not cited in the systematic review, and clarify specific definitions or wording of the indicators. In addition, panelists could revise existing indicators to better fit their clinical judgment as well as propose new indicators. During the meeting, each panelist then rerated all the indicators on the 1–9 validity scale.

The validity scores from the second round of ratings were used to generate a median score and standard error for each indicator. For each indicator, the extent of agreement in scores among the panelists (i.e., agreement, disagreement, and indeterminate) was determined based on the spread of ratings between panelists in a manner equivalent to that used in other expert panels utilizing the RAND/UCLA Appropriateness Methodology *(14,22,23)*. Specifically, we examined how many ratings for an indicator were within the same three-point region (i.e., 1–3, 4–6, or 7–9) as the observed median. If no more than two ratings were outside the three-point range that included the median, then scores were said to be in agreement. If three or more ratings for an indicator were in the 1–3 region and three or more ratings were in the 7–9 region, the scores for that indicator were said to be in disagreement. All other score distributions were defined as indeterminate. An indicator was described as "valid" if it had a median score of at least 7.0 without disagreement in the second-round ratings. An indicator was described as showing movement toward agreement between the first- and second-round ratings if it changed from indeterminate to agreement or from disagreement to indeterminate or agreement.

Results

Candidate Quality Indicators

A total of 142 candidate indicators for colorectal cancer surgery were identified through literature reviews and interviews with leading specialists in colorectal surgery, general surgery, and surgical oncology. These candidate indicators fell into six domains that spanned the entire perioperative period: privileging (i.e., surgical credentialing) for laparoscopic colorectal cancer surgery (six candidate indicators); preoperative evaluation, including evaluating comorbidities and staging (38 candidate indicators); patient–provider discussions, including treatment options and advance directives (nine candidate indicators); medication use, including antibiotics, beta blockade, and deep venous thrombosis prophylaxis (16 candidate indicators); intraoperative care, including criteria for intraoperative staging and oncologic resection (50 candidate indicators); and postoperative management, including infection prevention and referral for adjuvant therapy (23 candidate indicators). Each domain relates to one of the periods of care for patients undergoing colorectal cancer surgery—the preoperative, intraoperative, or postoperative period (Fig. 1). (The entire list of candidate indicators with supporting references from the systematic literature review are provided in the Supplementary Data, available at: http://jncicancerspectrum.oxfordjournals.org/jnci/content/vol98/issue22).

Definitions

During the systematic literature review and identification of candidate indicators, an explicit list of definitions of terms related to colorectal cancer surgery was generated (Table 1). The definitions of terms used in the candidate indicators were discussed and revised at the face-to-face panel meeting. The purpose of these definitions was to provide the expert panelists with a common ground to understand the terms used in each of the candidate indicators. For example, the term "colorectal cancer surgery" is used in each of the candidate indicators and determines the scope of colorectal cancer operations to which the quality indicators are applicable. For the purposes of this

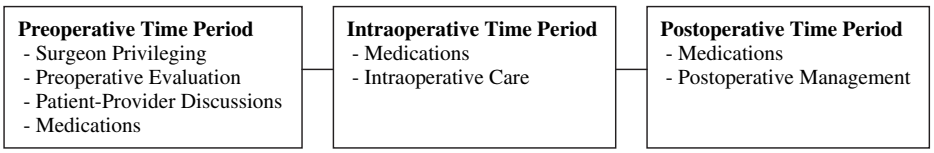

Fig. 1. The six domains of care for patients undergoing colorectal cancer surgery by preoperative, intraoperative, and postoperative time periods. The domains include privileging, preoperative evaluation, patient–provider discussions, medication use, intraoperative care, and postoperative management. Each domain relates to one of the periods of care for patients undergoing colorectal cancer surgery—the preoperative, intraoperative, or postoperative period.

project, colorectal cancer surgery was defined as an elective operation that includes major resections of colon or rectal cancers (open or laparoscopic), including hemicolectomy, low anterior resection/sphincter-preserving cancer operations, abdominal perineal resection, and procedures where an ostomy is used in conjunction with resection. The definition excludes intestinal bypass, use of diverting ostomy only, and emergent operations.

Quality Indicators Rated as Valid

Through the formal rating process (summarized in Fig. 2), a total of 92 (65%) of the 142 candidate indicators were rated as valid. This proportion is similar to what has been seen in other studies *(21)*. The quality indicators that were rated as valid in each of the six domains are shown in Table 2. The number of quality indicators rated as valid for each of the six domains of care were as follows: privileging (three of six candidate indicators rated as valid), preoperative evaluation (29 of 38), patient–provider discussions (five of nine), medication use (nine of 16), intraoperative care (28 of 50), and postoperative management (18 of 23). Of the 92 indicators rated as valid, 61 (66%) were applicable to all patients undergoing colorectal cancer surgery. Of the rest, 19 (21%) were restricted to rectal cancer, three (3%) to colon cancer, and nine (10%) to laparoscopic surgery.

Emphasis Within Domains

Although the 92 indicators rated as valid were initially divided in only six domains of care, additional areas of emphasis within most domains emerged as a result of the expert panel rating process. The privileging domain includes only three indicators, all of which relate to credentialing for surgeons performing laparoscopic colon and rectal cancer surgery. The indicators in the preoperative evaluation domain could be further divided into those that address preoperative history, physical examination, and evaluation of preoperative comorbidities (11 indicators) and those that address preoperative diagnosis and staging (18 indicators). The indicators in the patient–provider discussions domain address issues that are unique to colorectal cancer surgery, such as genetic counseling for hereditary colorectal cancer (two indicators), and a specific type of rectal cancer treatment (transanal endoscopic microsurgery), as well as issues that are applicable to most surgical procedures, including informed consent and preoperative smoking cessation. The intraoperative care domain could be further divided into indicators addressing patient safety (three indicators), intraoperative staging (six indicators), prevention of complications such as ureteral injury or anastomotic leak (five indicators), criteria necessary for an oncologic resection (10 indicators), and issues unique to laparoscopic colorectal cancer surgery (four indicators). Finally, the postoperative management domain indicators were found to address both areas unique to colorectal cancer surgery (seven indicators) as well as standard postoperative care items (11 indicators).

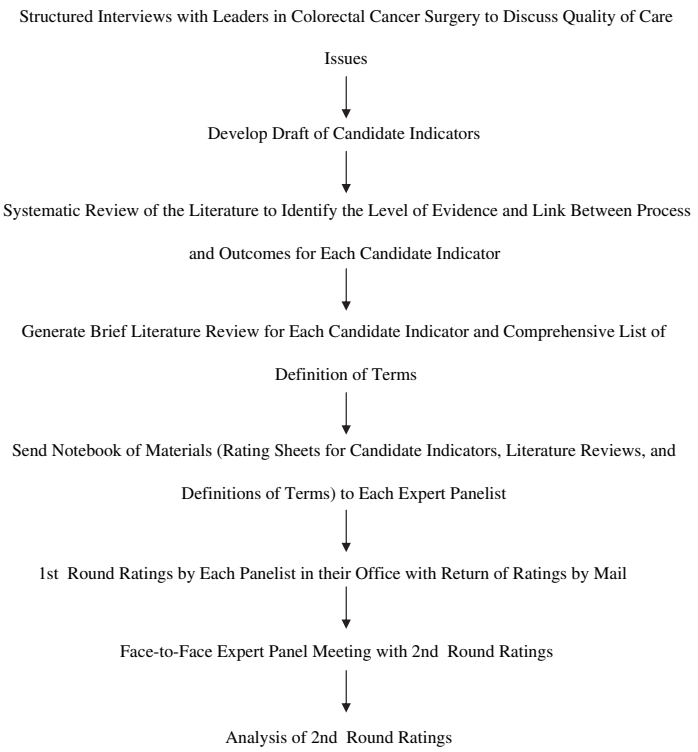

Fig. 2. Overview of process to identify and rate quality indicators for colorectal cancer surgery. The RAND/UCLA Appropriateness Methodology identifies quality indicators through a combination of expert opinion with an explicit synthesis of findings in the literature. The method uses two rounds of independent ratings by a group of panelists, with a face-to-face group discussion between rounds. See text for details.

Discussion

The goal of the current work was to develop process-based quality indicators for colorectal cancer surgery. Such indicators are needed because colorectal cancer is a common malignancy, the risk of which increases with age. Given the aging of the US population, surgeons will need to develop methods to ensure delivery of high-quality surgical care for patients with colorectal cancer. In addition, the foreseeable future in quality evaluation and improvement for health care will likely involve the use of quality indicators of processes of care by regulatory and accrediting agencies such as CMS, JCAHO, and others.

The current project represents a unique contribution to the literature for several reasons. One way in which it is unique is that we have developed quality indicators rather than practice guidelines. To date, several practice guidelines for colorectal cancer surgery have been developed, including the NCCN practice guidelines in oncology *(8)*, the ASCRS practice parameters *(9,10)*, and the Guidelines 2000 for colon and rectal cancer surgery *(11)*. However, the quality indicators developed in this project differ in several ways from the existing practice guidelines for colorectal cancer surgery. First, quality indicators are measurable and define the most basic level of care that, if not performed, would indicate poor quality care. In addition, the majority of the quality indicators identified in the current project (except the three quality indicators in the privileging domain) are process measures, which reflect interpersonal, diagnostic, and therapeutic aspects of the encounter between patient and provider. Process measures are generally more specific and representative of the delivered quality of care than structural (e.g., hospital volume) or outcome (e.g., mortality) measures. In contrast, practice guidelines are generally not measurable and present a framework for optimal care in the context of complex medical decision

Table 2. Quality indicators rated as valid for colorectal cancer surgery with median score ≥ 7.0 and without disagreement among panelists during the first and second rounds of ratings*

Domain	Median rating, agreement, and range	
	First round	Second round
Privileging		
1. IF a patient undergoes laparoscopic colon cancer surgery, THEN to be credentialed for these procedures the operating surgeon must have completed:		
(a) experience in 20 laparoscopic colon resections during training	7.0, D, 1–9	7.0, D, 1–9
(b) 20 proctored laparoscopic colon resection cases	7.0, I, 1–9	6.5, D, 1–9
(c) 20 laparoscopic colon cases for benign disease	8.0, I, 1–9	8.0, I, 1–9
(f) a, b, or c	Not Rated	8.0, A, 1–9
2. IF a patient undergoes laparoscopic colon cancer surgery, THEN the surgeon should complete a minimum annual volume of these cases:		
(b) at least 12	6.5, I, 1–9	8.0, I, 1–9
4. IF a patient undergoes laparoscopic rectal cancer surgery, THEN to be credentialed for these procedures the operating surgeon must have completed five open rectal cancer cases and:		
(a) credentialing criteria for laparoscopic colon cancer surgery	9.0, I, 2–9	9.0, I, 2–9
Preoperative evaluation		
7. IF a patient is undergoing colorectal cancer surgery, THEN a history of present illness should be documented before operation including:		
(a) presenting symptoms	9.0, A, 2–9	9.0, A, 7–9
(b) diagnostic tests and results	9.0, A, 6–9	9.0, A, 6–9
(c) receipt of neoadjuvant therapy (for rectal cancer), with date of completion	9.0, A, 5–9	9.0, A, 8–9
8. IF a patient is undergoing colon cancer surgery, THEN a history of current functional status should be documented before operation including:		
(a) bowel function	8.0, A, 1–9	8.0, I, 1–9
9. IF a patient is undergoing rectal cancer surgery, THEN a history of current functional status should be documented before operation including:		
(a) bowel function	9.0, A, 5–9	9.0, A, 1–9
(c) sexual function in males	Not rated	8.5, I, 1–9
(d) urinary function	8.5, I, 5–9	8.0, I, 1–9
10. IF a patient is undergoing colorectal cancer surgery, THEN the following additional history should be documented before operation including the following:		
(a) past medical history (including presence or absence of cardiac disease, pulmonary disease, and diabetes)	9.0, A, 8–9	9.0, A, 8–9
(b) past surgical history	9.0, A, 7–9	9.0, A, 7–9
(c) medications/allergies (including most recent list of outpatient medications and dosages)	9.0, A, 8–9	9.0, A, 8–9
(d) tobacco use (current or previous smoker)	8.0, A, 3–9	8.0, A, 7–9
(e) alcohol use	8.0, A, 6–9	8.0, A, 7–9
(g) any family history of cancer	8.5, A, 6–9	9.0, A, 1–9
(h) if family history of cancer positive, then include details of cancer history, age of patients, and type of cancer	Not rated	9.0, A, 5–9
(i) evaluation for bleeding disorders	Not rated	7.5, I, 5–9
11. IF a patient is undergoing colorectal cancer surgery, THEN a panel of preoperative studies should be performed within 8 weeks before surgery and the results documented in the chart. The panel should include:		
(a) hemoglobin or hematocrit	9.0, A, 1–9	9.0, A, 8–9
(c) platelet count	**8.0, I, 1–9**	**8.0, A, 1–9**
(e) electrolytes (Na, K, Cl, CO_2, glucose)	7.5, A, 1–9	7.5, A, 1–9
(g) renal function (blood urea nitrogen, Cr)	8.0, A, 1–9	8.0, A, 1–9
(k) chest radiograph	**8.0, I, 1–9**	**8.0, A, 1–9**
(l) height and weight	7.0, I, 1–9	7.0, I, 5–9
12. IF a patient is undergoing colorectal cancer surgery without neoadjuvant therapy, THEN a carcinoembryonic antigen (CEA) level should be obtained preoperatively (between diagnosis and surgery)	8.0, I, 1–9	8.0, I, 1–9
13. IF a patient is undergoing colorectal cancer surgery with neoadjuvant therapy, THEN a CEA level should be obtained preoperatively:		
(a) before neoadjuvant therapy	9.0, I, 1–9	8.5, I, 1–9
14. IF a patient is undergoing colorectal cancer surgery and the patient is not anemic, THEN the following should be performed preoperatively:		
(b) type and screen in rectal cancer	Not rated	7.0, I, 1–9
16. IF a patient is undergoing colorectal cancer surgery, THEN there should be documentation of cardiac evaluation performed, if necessary	Not rated	8.0, A, 6–9
19. IF a patient is undergoing colorectal cancer surgery, THEN in addition to the surgeon, a baseline preoperative risk assessment should be obtained by:		
(b) anesthesiologist or equivalent	8.0, A, 5–9	8.0, A, 1–9
20. IF a patient is undergoing colorectal cancer surgery and had a diagnostic endoscopy performed by another provider, THEN there should be a note describing the details of the endoscopy including the following:		
(a) location	9.0, A, 9	9.0, A, 9
(b) size of tumor—includes descriptive terms (e.g., small, medium, large, circumferential) or measured size	**8.5, I, 1–9**	**9.0, A, 7–9**

(Table continues)

Table 2 (continued).

Domain	Median rating, agreement, and range	
	First round	Second round
21. IF a patient is undergoing colorectal cancer surgery and had a biopsy specimen that was obtained preoperatively, THEN the surgeon should review and document the results	9.0, A, 3–9	9.0, A, 1–9
22. IF a patient is undergoing colorectal cancer surgery, THEN a total colonic examination should be performed preoperatively between 12 mo before initiation of treatment OR 12 mo after surgery OR document reason why not performed	Not rated	9.0, A, 8–9
23. IF a patient is undergoing colorectal cancer surgery and has a total colonic examination before surgery, THEN adequacy of the examination should be documented	9.0, A, 1–9	9.0, A, 9
26. IF a patient is undergoing laparoscopic colorectal cancer surgery, THEN the tumor site should be tattooed preoperatively if radiologic localization not performed for the following:		
(a) all tumors	**7.0, I, 1–9**	**7.5, A, 1–9**
27. IF a patient is undergoing colorectal cancer surgery, THEN a digital rectal examination by the operating surgeon must be performed and documented before surgery	9.0, A, 1–9	9.0, A, 5–9
28. IF a patient is undergoing rectal cancer surgery, THEN the tumor location relative to the anal sphincters must be determined and documented before surgery (or before neoadjuvant therapy, if given) by the:		
(a) operating surgeon	9.0, A, 8–9	9.0, A, 8–9
29. IF a patient is undergoing rectal cancer surgery and receives neoadjuvant therapy, THEN the tumor location relative to the anal sphincters must be determined and documented in the period after neoadjuvant therapy and before surgery by the:		
(a) operating surgeon	9.0, A, 1–9	9.0, A, 8–9
30a. IF a patient is undergoing rectal cancer surgery, THEN imaging of the abdomen/pelvis with CT or MRI should be performed	Not rated	9.0, A, 1–9
31. IF a patient is undergoing rectal cancer surgery and receives neoadjuvant therapy, THEN imaging of the abdomen/pelvis with CT or MRI should be performed:		
(a) before neoadjuvant therapy	8.5, A, 3–9	9.0, A, 5–9
32. IF a patient is undergoing rectal cancer surgery, THEN the depth of tumor invasion should be evaluated preoperatively or preneoadjuvant therapy (if neoadjuvant given)	9.0, A, 5–9	9.0, A, 7–9
33. IF a patient is undergoing rectal cancer surgery and CT does not show obvious wall invasion, THEN the depth of tumor invasion should be performed preoperatively or preneoadjuvant therapy (if neoadjuvant given) by the following:		
(a) TRUS or EUS	8.5, A, 7–9	8.5, A, 1–9
(b) MRI	6.5, I, 3–9	6.0, I, 1–9
(d) a or b (but not c)	**8.0, I, 2–9**	**9.0, A, 2–9**
34. IF a patient is undergoing rectal cancer surgery, THEN the characterization of perirectal lymph nodes should be performed preoperatively or preneoadjuvant therapy (if neoadjuvant given)	8.5, I, 1–9	8.0, I, 3–9
35. IF a patient is undergoing rectal cancer surgery, THEN the characterization of perirectal lymph nodes should be performed preoperatively or preneoadjuvant therapy (if neoadjuvant given) by the following:		
(a) TRUS or EUS	7.5, I, 1–9	7.0, I, 1–9
(b) MRI	6.0, I, 1–9	7.0, I, 1–9
(e) a or b	Not rated	9.0, I, 3–9
36. IF a patient is diagnosed with colorectal cancer, THEN treatment should be initiated within 10 weeks after biopsy or 6 weeks after seeing the surgeon for consultation or documented why performed later	**7.0, I, 1–9**	**8.0, A, 1–9**
37. IF a patient is undergoing rectal cancer surgery and creation of an ostomy is planned, THEN location of the ostomy should be marked preoperatively	8.5, A, 6–9	9.0, A, 7–9
38. IF a patient is undergoing colon cancer surgery and preoperative workup suggests metastatic disease, THEN in addition to the surgeon the patient should be offered evaluation preoperatively by:		
(a) medical oncologist	8.0, A, 1–9	9.0, A, 5–9
40. IF a patient is undergoing rectal cancer surgery and preoperative workup suggests stage IV disease, THEN in addition to the surgeon the patient should be evaluated preoperatively by:		
(a) medical oncologist	8.0, A, 1–9	8.0, A, 1–9
(b) radiation oncologist	**7.0, I, 1–9**	**8.5, A, 1–9**
(c) multidisciplinary tumor board	7.0, I, 1–9	7.0, I, 1–9
(d) a and b, or c	**7.0, I, 1–9**	**8.0, A, 3–9**
41. IF a patient is undergoing rectal cancer surgery and preoperative workup suggests stage II–III disease, THEN in addition to the surgeon the patient should be evaluated preoperatively by:		
(a) medical oncologist	8.5, A, 1–9	9.0, A, 1–9
(b) radiation oncologist	9.0, A, 1–9	9.0, A, 1–9
(c) multidisciplinary tumor board	7.0, I, 1–9	7.0, I, 1–9
(d) a and b, or c	8.0, A, 1–9	8.5, A, 5–9
Patient–provider discussions		
43. IF a patient is undergoing colorectal cancer surgery, THEN the following issues should be discussed and documented by the surgeon in the medical record:		
(a) treatment options with patient's priorities and preferences (including operative and nonoperative alternatives)	9.0, A, 5–9	9.0, A, 8–9
(b) operative risks, including complications and mortality	9.0, A, 5–9	9.0, A, 7–9
(c) functional outcome, including period of disability, time to resume normal function, likelihood of better or worse function, and ostomy issues (if appropriate)	7.5, A, 5–9	8.5, A, 7–9

(Table continues)

Table 2 (continued).

Domain	Median rating, agreement, and range: First round	Median rating, agreement, and range: Second round
(d) advance directive or living will	7.0, I, 1–9	7.0, I, 1–9
(e) advance directive or durable power of attorney for health care indicating the patient's surrogate decision maker	7.5, I, 1–9	7.0, I, 1–9
(f) need for possible chemotherapy or radiation (if appropriate)	7.5, I, 5–9	7.0, I, 5–9
46. IF a patient is undergoing rectal cancer surgery for a tumor that is a distal, T1, and well differentiated without lymphovascular invasion, THEN a transanal local excision should be discussed including possible role of adjuvant therapy	8.0, A, 5–9	8.0, A, 5–9
47. IF a patient is undergoing colorectal cancer surgery and meets Amsterdam I or II criteria, THEN genetic counseling should be recommended	9.0, A, 7–9	9.0, A, 7–9
49. IF a patient is undergoing colorectal cancer surgery and genetic testing is positive, THEN the following should be performed:		
(a) discussion of subtotal colectomy with males and females	9.0, A, 5–9	9.0, A, 8–9
(b) discussion of hysterectomy and oophorectomy with females	9.0, A, 5–9	9.0, A, 7–9
(c) discussion regarding follow-up surveillance for other cancers	9.0, A, 5–9	9.0, A, 8–9
50. IF a patient who smokes is undergoing colorectal cancer surgery, THEN the patient should be encouraged to stop smoking and the discussion documented in the chart	7.5, I, 2–9	7.0, I, 1–9
Medications		
55. IF a patient is undergoing colorectal cancer surgery and requires a mechanical bowel preparation, THEN the patient should be admitted for the mechanical bowel preparation if they have no social support at home and have any of the following:		
(c) inability to ambulate	7.5, I, 1–9	8.0, I, 1–9
56. IF a patient is undergoing colorectal cancer surgery, THEN intravenous antibiotic prophylaxis should be given within 1 h of surgical incision	9.0, A, 8–9	9.0, A, 8–9
57. IF a patient undergoes colorectal cancer surgery, THEN intravenous antibiotic prophylaxis should be discontinued within 24 h postoperatively	9.0, A, 6–9	9.0, A, 7–9
58. IF a patient is undergoing colorectal cancer surgery and has valvular or congenital heart disease, an intracardiac valvular prosthesis, hypertrophic cardiomyopathy, mitral valve prolapse with regurgitation, or a previous episode of endocarditis, THEN endocarditis prophylaxis should be given	9.0, A, 7–9	9.0, A, 7–9
59. IF a patient is undergoing colorectal cancer surgery and meets criteria for perioperative beta blockade, THEN unless contraindicated, beta blocker therapy should be initiated before surgery	9.0, A, 7–9	9.0, A, 8–9
60. IF a patient undergoes colorectal cancer surgery and meets criteria for perioperative beta blockade, THEN unless contraindicated, beta blocker therapy should be continued postoperatively at least until discharge from the hospital	8.5, A, 7–9	9.0, A, 7–9
62. IF a patient is undergoing colorectal cancer surgery and is taking one of the following classes of medications, THEN specific instructions regarding preoperative management of the following classes of medications should be given to the patient:		
(a) antiplatelet medications	9.0, A, 7–9	9.0, A, 7–9
(b) diabetes medications	9.0, A, 7–9	9.0, A, 7–9
(c) cardiovascular medications	9.0, A, 7–9	9.0, A, 7–9
63. IF a patient taking warfarin is undergoing colorectal cancer surgery, THEN withdrawal of warfarin before surgery should be managed according to recommendations from the Seventh ACCP Conference on Antithrombotic Therapy	9.0, A, 5–9	9.0, A, 7–9
65. IF a patient undergoes colorectal cancer surgery, THEN postoperative deep venous thrombosis prophylaxis should be provided with low-dose unfractionated heparin or low–molecular weight heparin, in addition to mechanical prophylaxis (intermittent pneumatic compression and/or graduated compression stockings) according to the Seventh ACCP Conference on Antithrombotic Therapy	7.5, I, 5–9	7.0, I, 1–9
Intraoperative care		
68. IF a patient undergoes colorectal cancer surgery, THEN the following should be performed before skin incision:		
(a) time-out	8.0, A, 5–9	8.5, A, 5–9
69. IF a patient undergoes colorectal cancer surgery and requires the lithotomy position, THEN proper positioning of the lower extremities should be performed and documented	7.5, I, 1–9	7.5, I, 1–9
71. IF a patient undergoes colorectal cancer surgery, THEN the abdomen should be explored (or reason exploration could not be done documented) including the following:		
(a) liver	9.0, A, 1–9	9.0, A, 5–9
(b) peritoneal lining	9.0, A, 1–9	9.0, I, 3–9
(h) ovaries and uterus (if present)	8.5, A, 1–9	8.5, A, 5–9
73. IF a patient undergoes colorectal cancer surgery and a liver lesion suspicious for metastatic disease is present, THEN the lesion should be biopsied or a reason provided for not performing the biopsy	8.0, A, 5–9	8.5, A, 7–9
75. IF a patient undergoes colorectal cancer surgery that is in the rectosigmoid area, THEN the surgeon should specify whether the tumor should be treated as a colon versus a rectal cancer	9.0, A, 6–9	9.0, A, 1–9
76. IF a patient undergoes colon cancer surgery, THEN the ureter(s) should be identified intraoperatively including the following:		
(b) on side where the lesion is located during left-sided procedure	Not rated	8.0, A, 5–9
77. IF a patient undergoes rectal cancer surgery, THEN the ureter(s) should be identified intraoperatively including the following:		
(b) both ureters	8.0, I, 1–9	8.5, I, 1–9

(Table continues)

Table 2 (continued).

Domain	Median rating, agreement, and range: First round	Second round
78. IF a patient undergoes colorectal cancer surgery, THEN ureteral stents should be placed preoperatively for the following:		
(b) recurrent rectal tumors	Not rated	7.5, A, 1–9
(f) presence of ureteral obstruction and/or hydronephrosis	8.0, A, 3–9	8.5, A, 5–9
79. IF a patient undergoes laparoscopic colorectal cancer surgery and the ipsilateral ureter is not identified, THEN the case should be converted to open		
(b) left-sided procedure	Not rated	8.0, I, 5–9
81. IF a patient undergoes colorectal cancer surgery, THEN ligation of major vessels (at their origin) to the specimen should be performed and documented, including naming the major vessels ligated (i.e., ileocolic, right colic branch of midcolic, left colic, sigmoid vessels)	**8.0, I, 2–9**	**8.0, A, 1–9**
84. IF a patient undergoes colorectal cancer surgery and an iatrogenic perforation occurs, THEN this should be documented in the operative report	9.0, A, 1–9	9.0, A, 7–9
88. IF a patient undergoes colorectal cancer surgery that involves the transverse colon, THEN the omentum of the resected colon should be removed	7.0, I, 3–9	7.5, I, 4–9
90. IF a patient undergoes colorectal cancer surgery and has tumor adherent to local structures, THEN en bloc resection should be performed	9.0, A, 8–9	9.0, A, 8–9
91. IF a patient undergoes colorectal cancer surgery and en bloc resection is performed, THEN the surgeon should document (in the operative report) the specimen margins by the following method:		
(a) gross evaluation	9.0, A, 5–9	9.0, A, 7–9
93. IF a patient undergoes rectal cancer surgery for a low rectal tumor, THEN a total mesorectal excision should be performed	Not rated	9.0, A, 5–9
94. IF a patient undergoes rectal cancer surgery for a mid or high rectal tumor, THEN the following procedure should be performed:		
(b) tumor-specific mesorectal excision (with at least a 2-cm margin mesentery)	Not rated	7.0, A, 5–9
95. IF a patient undergoes rectal cancer surgery and the radial/circumferential margin is grossly positive, THEN the reason should be documented	Not rated	8.5, I, 1–9
97. IF a patient undergoes rectal cancer surgery, THEN the distal margin should be documented in the operative report and be:		
(a) at least 1 cm	9.0, A, 5–9	9.0, A, 8–9
98. IF a patient undergoes colorectal cancer surgery, THEN the completeness of resection should be documented in the operative report	Not rated	9.0, A, 5–9
99. IF a patient undergoes colorectal cancer surgery and there is known tumor left behind (i.e., the primary), THEN the location should be marked with a radio-opaque guide (e.g., surgical clips)	7.0, A, 5–9	7.0, A, 5–9
102. IF a patient undergoes rectal cancer surgery with a low rectal–coloanal anastomosis and no defunctioning stoma, THEN the anastomosis should be tested intraoperatively	8.5, A, 5–9	8.0, A, 7–9
104a. IF a patient undergoes colorectal cancer surgery and <12 lymph nodes are obtained, THEN the pathologist should be asked to look again	Not rated	7.5, I, 1–9
104b. IF a patient undergoes colorectal cancer surgery and <12 lymph nodes are obtained, THEN the patient should be referred to a medical oncologist	Not rated	8.0, A, 3–9
111. IF a patient undergoes laparoscopic colorectal cancer surgery, THEN intracorporeal ligation of the vessels should be performed		
(b) left-sided procedure	Not rated	7.0, I, 1–9
112. IF a patient undergoes laparoscopic colorectal cancer surgery, THEN the following should be used to remove the specimen:		
(a) wound protector	7.0, I, 1–9	7.0, I, 1–9
(b) specimen bag	7.0, I, 1–9	7.0, I, 1–9
(c) either of the above	**6.0, D, 1–9**	**7.0, I, 3–9**
113. IF a patient undergoes laparoscopic colorectal cancer surgery, THEN the fascial layer should be closed for all bladed trocar sites 10 mm or larger	7.0, A, 5–9	7.0, A, 1–9
114. IF a patient undergoes colon cancer surgery (specifically hemicolectomy) and the procedure is started laparoscopically, THEN the procedure should be completed in <6 h even if converted to an open approach	7.0, A, 1–9	7.0, A, 6–9
115. IF a patient undergoes colorectal cancer surgery, THEN a correct lap/instrument count should be documented or an intraoperative plain film should show no retained lap/instruments	9.0, A, 7–9	9.0, A, 7–9
Postoperative management		
116. IF a patient undergoes colorectal cancer surgery, THEN a nasogastric tube should not be used postoperatively, unless the patient has signs/symptoms of obstruction	7.5, A, 1–9	8.0, A, 1–9
119. IF a patient undergoes colorectal cancer surgery, THEN the patient's fluid status needs to be monitored while the patient is receiving intravenous fluids:		
(a) daily input and output	8.0, A, 1–9	8.5, A, 6–9
(b) daily weights	7.0, I, 1–9	7.0, I, 1–9
121. IF a patient with diabetes undergoes colorectal cancer surgery, THEN postoperative blood glucose control should be monitored at least daily and if >150 then treatment should be initiated	Not rated	8.0, A, 7–9
122. IF a patient undergoes colorectal cancer surgery, THEN pain assessments should be performed and documented with each set of vital signs	7.5, A, 6–9	7.5, A, 6–9
123. IF a patient undergoes colorectal cancer surgery and was able to ambulate preoperatively, THEN ambulation should be performed within 2 days after surgery, or documented why the patient cannot ambulate	8.5, A, 1–9	8.0, A, 7–9

(Table continues)

Table 2 (continued).

Domain	Median rating, agreement, and range	
	First round	Second round
124. IF a patient undergoes colorectal cancer surgery and cannot ambulate by postoperative day 2, THEN mobilization should be performed by postoperative day 2, or documented why the patient cannot be mobilized.	8.0, A, 1–9	8.5, A, 1–9
125. IF a patient undergoes colorectal cancer surgery and is discharged home and was able to ambulate preoperatively, THEN the patient should be able to ambulate before discharge OR the reason why the patient is unable to ambulate is addressed and a treatment plan outlined	8.5, A, 5–9	9.0, A, 7–9
126. IF a patient undergoes colorectal cancer surgery and has a new fever (greater than 38.5 °C) after postoperative day 2, THEN evaluation of the wound(s) should be documented including erythema, warmth, and presence of drainage	9.0, A, 1–9	9.0, A, 7–9
127. IF a patient undergoes colorectal cancer surgery and has a new fever (greater than 38.5 °C) after postoperative day 2 and there is no obvious source of infection, THEN the following should be performed within 8 h (unless fever workup completed within the past 24 h):		
(f) history and physical examination linked to the fever	Not rated	9.0, A, 7–9
128. IF a patient undergoes colorectal cancer surgery and has a foley catheter placed during the operation, THEN the catheter should be removed (or documented why not removed) by postoperative day 5	**7.0, I, 1–9**	**7.5, A, 5–9**
130. IF a patient undergoes colorectal cancer surgery, THEN the patient should be able to tolerate an adequate diet before discharge	8.5, A, 1–9	8.5, A, 7–9
131. IF a patient undergoes colorectal cancer surgery, THEN pain should be controlled with oral or other nonparenteral medications before discharge	9.0, A, 7–9	8.5, A, 5–9
132. IF a patient undergoes colorectal cancer surgery, THEN the surgeon should document details of the pathology report including TNM stage, number of lymph nodes obtained, and margin status	9.0, A, 1–9	9.0, A, 9
133. IF a patient undergoes colorectal cancer surgery, THEN the surgeon should discuss the final pathology with the patient and document discussion in chart	9.0, A, 3–9	9.0, A, 8–9
134. IF a patient undergoes colorectal cancer surgery and has a tumor requiring chemotherapy, THEN the patient should be offered referral to a medical oncologist	9.0, A, 1–9	9.0, A, 8–9
135. IF a patient undergoes colorectal cancer surgery and has a tumor requiring radiation therapy, THEN the patient should be offered referral to a radiation oncologist	9.0, A, 1–9	9.0, A, 8–9
136. IF a patient undergoes colorectal cancer surgery and follows up with the surgeon, THEN the functional status should be assessed at least once in the first year after surgery including the following:		
(a) bowel function	9.0, A, 1–9	9.0, A, 7–9
(b) sexual function in males	Not rated	7.5, I, 1–9
(d) urinary function in males	Not rated	7.0, I, 1–9
137. IF a patient undergoes colorectal cancer surgery and the surgical treatment is completed, THEN there should be documentation of who will perform colorectal cancer surveillance	8.5, A, 5–9	8.5, A, 7–9

*The entire list of candidate quality indicators and supporting references identified during the systematic literature review are available as Supplementary Data at http://jncicancerspectrum.oxfordjournals.org/jnci/content/vol98/issue22. A = agreement (no more than two ratings were outside the three-point range that included the median); D = disagreement (three or more ratings for an indicator were in the 1–3 region and three or more ratings were in the 7–9 region); I = indeterminate (all other score distributions that were not categorized as agreement or disagreement); CT = computed tomography; MRI = magnetic resonance imaging; TRUS = transrectal ultrasound; EUS = endoscopic ultrasound; ACCP = American College of Chest Physicians; TNM = tumor, nodes, metastasis; not rated = indicators that were added to or modified from the proposed candidate indicators during the face-to-face expert panel meeting; scores given in boldface = movement toward agreement, defined as a change in the ratings from indeterminate to agreement or from disagreement to indeterminate/agreement; terms are underlined to highlight the eligible type of surgery for each quality indicator (e.g., colon cancer, rectal cancer, laparoscopic).

making *(13)*. Second, we used a formal iterative rating process, the RAND/UCLA Appropriateness Methodology, to develop the quality indicators; by contrast, the authors of the practice guidelines used consensus methodology to identify guidelines for care. Consensus panels have been criticized for the lack of a formal and transparent methodology *(24)*, which has the potential to bias the results toward the opinions of the most senior or most vocal member of the panel. The RAND/UCLA Appropriateness Methodology has been widely used within quality-of-care research to identify valid quality measures for other types of cancer [e.g., prostate *(23)*], to identify appropriateness criteria for procedures including colonoscopy and rectal cancer treatment *(25,26)*, and to evaluate the quality of health care delivered to adults in the United States *(27)*. This formal methodology combines the opinion of experts with the available literature using a modified Delphi method, in which two separate independent ratings are performed in combination with a face-to-face expert panel meeting for discussion of each proposed quality indicator. In this context, it is interesting to note that a recent study of quality indicators developed using a process identical to the current work demonstrated a statistically significant process-to-outcome relationship for care of vulnerable elders, defined as persons 65 years old or older who are at increased risk for death or functional decline (i.e., better performance on quality measures was associated with better survival) *(13,28)*.

A second unique aspect of the current work is that we addressed detailed issues in the entire perioperative period to encompass a longer duration of surgical care for a patient with colorectal cancer. Ninety-two of the candidate quality indicators were rated as valid by the expert panel. These quality indicators cover the preoperative, intraoperative, and postoperative time periods and include indicators that address the issues of surgeon credentialing for laparoscopic colorectal cancer surgery, preoperative assessment of comorbidities, preoperative staging, patient–provider discussions, medication use, and postoperative management. Like the Nelson 2000 Guidelines, which addressed intraoperative

techniques *(11)*, many of the quality indicators we identified are intraoperative quality indicators. However, additional topics such as prevention of ureteral damage as well as indicators unique to laparoscopic colorectal cancer surgery, for example, are also included in the current project.

A third unique aspect of the current work is that we emphasized noncancer quality indicators in both the preoperative and postoperative time periods. Given the aging of the population, increased attention to issues of comorbid disease, for example, are essential to ensure quality of care for all aspects of care of a patient with colorectal cancer. Although this is not a comprehensive list of measures addressing the elderly, it does encompass many of the important issues. A previous study identified a more complete list of measures addressing abdominal surgery in the elderly *(29)*.

A fourth unique aspect of the current work is that the quality indicators may be useful to regulatory and accrediting agencies as well as to individual hospitals and providers. First, the quality indicators may be translated into quality measures for pay-for-performance initiatives by CMS, for example. Given that CMS pay-for-performance initiatives generally use only three to seven quality measures per disease topic, a similar number of colorectal cancer measures may be selected by CMS from the 92 indicators rated as valid in the current project. Second, cancer registry databases such as the National Cancer Data Base (NCDB), which is housed by the American College of Surgeons, may potentially serve as a mechanism for collection as well as feedback of data regarding the quality of surgical care for patients with colorectal cancer. Specifically, the NCDB could provide information to each individual hospital or provider regarding its adherence to any number of quality measures (e.g., the percentage of colon cancer patients whose specimen contains at least 12 lymph nodes) to identify areas for improvement in colorectal cancer care at the level of the individual hospital. Third, because it may be difficult to comprehensively improve quality of health care with the small number of quality measures used in the current CMS pay-for-performance initiatives *(1)*, the larger list of quality indicators that we identified, along with the literature reviews performed for each candidate indicator, may also be used for teaching, comprehensive programmatic development, and standardization of care at all hospitals performing resections for colorectal cancer. Indeed, because the issue of regionalization based on hospital or surgeon volume remains controversial, an alternative approach may use the colorectal cancer surgery quality indicators identified in the current project to improve care regardless of the volume of colorectal cancer procedures performed.

In the process of developing the list of quality indicators for colorectal cancer surgery, a number of related issues and controversies arose. One controversial issue surrounds the candidate indicators in the privileging domain. The Clinical Outcomes of Surgical Therapy (COST) Study Group *(30)* carried out a trial comparing laparoscopically assisted with open colectomy for colon cancer and found similar rates of perioperative complications and recurrent colon cancer in the two groups. The results of this randomized controlled trial suggest that laparoscopically assisted colectomy is an acceptable alternative to open colectomy for colon cancer. Given that the COST Study Group used 20 prior laparoscopic cases as credentialing criteria for surgeons to be included in the study, the expert panelists relied heavily on this criterion when rating the privileging candidate indicators.

Another controversial issue relates to the legal implications of the quality indicators. Could quality indicators addressing the adequacy of oncologic resection (e.g., length of bowel margin during a colon resection) be grounds for legal action if a patient develops a cancer recurrence?

Another issue is whether the quality indicators rated as valid will be generalizable to different practice locations, especially those in rural areas. For example, one valid indicator for preoperative staging of rectal cancer requires radiologic imaging with transrectal ultrasound, endoscopic ultrasound, or magnetic resonance imaging—modalities that may not be readily available in some areas of the country or within smaller surgical practices. However, the rating of this indicator as "valid" was an explicit assessment of the trade-off between the importance of this process item in producing good outcomes versus the inconvenience of requiring patients to be referred to a hospital or medical center some distance away from where the patient lived. For some other proposed indicators, this trade-off was not judged to be sufficiently strong to justify rating the indicator as valid.

Finally, the relationship between documentation and measurement of quality raises questions about the amount of potential documentation that would be required to demonstrate adherence to these processes of care. The increased time required to document these items (e.g., in the progress notes or operative note) could take time away from direct patient care. However, it should be noted that the Veterans Affairs model of the National Surgical Quality Improvement Program *(31)* provides an example of a quality assessment program requiring documentation (including collection of preoperative, intraoperative, and 30-day outcome variables by a dedicated nurse) that has substantially reduced morbidity rates, which may justify the costs of both documentation and data collection *(32)*. The movement toward widespread use of electronic medical records may minimize some of the documentation burden by improving access to a patient's medical records and increasing use of standardized templates for both orders and progress notes.

There are several limitations to this study. The first is the level of evidence found in the literature. For most indicators, strong evidence of their validity was not available from randomized controlled trials. However, this situation is common to many aspects of health care, and it was the very reason that the expert panel methodology was developed—specifically, to identify the processes that are most likely to be valid measures of quality when the highest level of evidence is not available. As the literature and investigations evaluate more processes of care in colorectal cancer surgery, additional process measures will be added and/or the current process measures will be redefined and revised. This methodology is an iterative process, in which the current work is merely the first version of the identification of these process indicators for patients undergoing colorectal cancer surgery. A second limitation is the focus of the quality indicators on perioperative care for patients undergoing colorectal cancer surgery. None of the quality indicators addresses screening for colorectal cancer, and issues of receipt of adjuvant therapy and postoperative surveillance are addressed on only the most basic level. Further work is needed to develop more specific quality measures that will ensure that the appropriate patients receive adjuvant chemotherapy or radiation therapy and that all colorectal cancer patients resected for cure receive timely and adequate surveillance to detect recurrence.

In summary, we have used a validated technique to develop process-based quality indicators for patients undergoing colorectal cancer surgery. These indicators identify potentially meaningful and important steps for providing high-quality cancer care among

health care systems, hospitals, and providers offering surgical care to patients with colorectal cancer.

References

(1) Centers for Medicare & Medicaid Services. Available at: http://www.cms.hhs.gov. [Last accessed: May 15, 2005.]

(2) Joint Commission on Accreditation of Healthcare Organizations. Available at: http://www.jointcommission.org. [Last accessed: May 15, 2005.]

(3) National Quality Forum. Available at: http://www.qualityforum.org. [Last accessed: May 15, 2005.]

(4) Health and Human Services—Hospital Compare. Available at: http://www.hospitalcompare.hhs.gov. [Last accessed: May 21, 2005.]

(5) Jemal A, Murray T, Ward E, Samuels A, Tiwari RC, Ghafoor A, et al. Cancer statistics, 2005. CA Cancer J Clin 2005;55:10–30.

(6) Hewitt M, Simone JV. Ensuring quality cancer care. Washington (DC): National Academy Press; 1999.

(7) ASCO/NCCN Quality Measures: Breast and Colorectal Cancers. Available at: http://www.asco.org/portal/site/ASCO. [Last accessed: August 23, 2006.]

(8) NCCN Physician Guidelines. Available at: http://www.nccn.org/professionals/physician_gls/default.asp. [Last accessed: August 16, 2005.]

(9) Otchy D, Hyman NH, Simmang C, Anthony T, Buie WD, Cataldo P, et al. Practice parameters for colon cancer. Dis Colon Rectum 2004;47:1269–84.

(10) Tjandra JJ, Kilkenny JW, Buie WD, Hyman N, Simmang C, Anthony T, et al. Practice parameters for the management of rectal cancer (revised). Dis Colon Rectum 2005;48:411–23.

(11) Nelson H, Petrelli N, Carlin A, Couture J, Fleshman J, Guillem J, et al. Guidelines 2000 for colon and rectal cancer surgery. J Natl Cancer Inst 2001;93:583–96.

(12) O'Malley AS, Clancy C, Thompson J, Korabathina R, Meyer GS. Clinical practice guidelines and performance indicators as related—but often misunderstood—tools. Jt Comm J Qual Saf 2004;30:163–71.

(13) Wenger NS, Shekelle PG. Assessing care of vulnerable elders: ACOVE project overview. Ann Intern Med 2001;135:642–6.

(14) Brook RH. "The RAND/UCLA Appropriateness Method," Clinical practice guideline development: methodology perspectives. Rockville (MD): Public Health Service, AHCR; 1994.

(15) Merrick NJ, Fink A, Park RE, Brook RH, Kosecoff J, Chassin MR, et al. Derivation of clinical indications for carotid endarterectomy by an expert panel. Am J Public Health 1987;77:187–90.

(16) Shekelle PG. Are appropriateness criteria ready for use in clinical practice? N Engl J Med 2001;344:677–8.

(17) Shekelle P. The appropriateness method. Med Decis Making 2004;24:228–31.

(18) Brook RH, Chassin MR, Fink A, Solomon DH, Kosecoff J, Park RE. A method for the detailed assessment of the appropriateness of medical technologies. Int J Technol Assess Health Care 1987;2:53–63.

(19) Kravitz RL, Laouri M, Kahan JP, Guzy P, Sherman T, Hilborne L, et al. Validity of criteria used for detecting underuse of coronary revascularization. JAMA 1995;274:632–8.

(20) Hemingway H, Crook AM, Feder G, Banerjee S, Dawson JR, Magee P, et al. Underuse of coronary revascularization procedures in patients considered appropriate candidates for revascularization. N Engl J Med 2001;344:645–54.

(21) Shekelle PG, MacLean CH, Morton SC, Wenger NS. Assessing care of vulnerable elders: methods for developing quality indicators. Ann Intern Med 2001;135:647–52.

(22) Park RE, Fink A, Brook RH, Chassin MR, Kahn KL, Merrick NJ, et al. Physician ratings of appropriate indications for six medical and surgical procedures. Am J Public Health 1986;76:766–72.

(23) Spencer BA, Steinberg M, Malin J, Adams J, Litwin MS. Quality-of-care indicators for early-stage prostate cancer. J Clin Oncol 2003;21:1928–36.

(24) Jones J, Hunter D. Consensus methods for medical and health services research. BMJ 1995;311:376–80.

(25) Hodgson DC, Brierley JD, Cernat G, Bondy S, Slaughter PM, Pinfold SP, et al. The consistency of panelists' appropriateness ratings: do experts produce clinically logical scores for rectal cancer treatment? Health Policy 2005;71:57–65.

(26) de Bosset V, Froehlich F, Rey JP, Thorens J, Schneider C, Wietlisbach V, et al. Do explicit appropriateness criteria enhance the diagnostic yield of colonoscopy? Endoscopy 2002;34:360–8.

(27) McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, et al. The quality of health care delivered to adults in the United States. N Engl J Med 2003;348:2635–45.

(28) Higashi T, Shekelle PG, Adams JL, Kamberg CJ, Roth CP, Solomon DH, et al. Quality of care is associated with survival in vulnerable older patients. Ann Intern Med 2005;143:274–81.

(29) McGory ML, Shekelle PG, Rubenstein LZ, Fink A, Ko CY. Developing quality indicators for elderly patients undergoing abdominal operations. J Am Coll Surg 2005;201:870–83.

(30) Clinical Outcomes of Surgical Therapy Study Group. A comparison of laparoscopically assisted and open colectomy for colon cancer. N Engl J Med 2004;350:2050–9.

(31) Khuri SF, Daley J, Henderson W, Hur K, Demakis J, Aust JB, et al. The Department of Veterans Affairs' NSQIP: the first national, validated, outcome-based, risk-adjusted, and peer-controlled program for the measurement and enhancement of the quality of surgical care. National VA Surgical Quality Improvement Program. Ann Surg 1998;228:491–507.

(32) Dimick JB, Chen SL, Taheri PA, Henderson WG, Khuri SF, Campbell DA Jr. Hospital costs associated with surgical complications: a report from the private-sector National Surgical Quality Improvement Program. J Am Coll Surg 2004;199:531–7.

Notes

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