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Cancer Care Quality Measures: Diagnosis and Treatment of Colorectal Cancer

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. This report on *Cancer Care Quality Measures: Diagnosis and Treatment of Colorectal Cancer* was requested and funded by the National Cancer Institute (NCI), the Centers for Medicare & Medicaid Services (CMS), and the Centers for Disease Control and Prevention (CDC). The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to **epc@ahrq.gov.**

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Structured Abstract

Objectives. To identify measures that are currently available to assess the quality of care provided to patients with colorectal cancer (CRC), and to assess the extent to which these measures have been developed and tested.

Data Sources. Published and unpublished measures identified through a computerized search of English-language citations in MEDLINE® (1966-January 2005), the Cochrane Database of Systematic Reviews, and the National Guideline Clearinghouse; through review of reference lists contained in seed articles, all included articles, and relevant review articles; and through searches of the grey literature (institutional or government reports, professional society documents, research papers, and other literature, in print or electronic format, not controlled by commercial publishing interests). Sources for grey literature included professional organization websites and the Internet.

Review Methods. Measures were selected by reviewers according to standardized criteria relating to each question, and were then rated according to their importance and usability, scientific acceptability, and extent of testing; each domain was rated from 1 (poor) to 5 (ideal).

Results. We identified a number of well-developed and well-tested CRC-related quality-of-care measures, both general process-of-care measures (on a broader scale) and technical measures (pertaining to specific details of a procedure). At least some process measures are available for diagnostic imaging, staging, surgical therapy, adjuvant chemotherapy, adjuvant radiation therapy, and colonoscopic surveillance. Various technical measures were identified for quality of colonoscopy (e.g., cecal intubation rate, complications) and staging (adequate lymph node retrieval and evaluation). These technical measures were guideline-based and well developed, but less well tested, and the linkage between them and patient outcomes, although intuitive, was not always explicitly provided. For some elements of the care pathway, such as operative reports and chemotherapy reports, no technical measures were found.

Conclusions. Some general process measures have a stronger evidence base than others. Those based on guidelines have the strongest evidence base; those derived from basic first principles supported by some research findings are relatively weaker, but are often sufficient for the task at hand. A consistent source of tension is the distinction between the clinically derived fine-tuning of the definition of a quality measure and the limitations of available data sources (which often do not contain sufficient information to act on such distinctions). Although some excellent technical measures were found, the overall development of technical measures seems less advanced than that of the general process measures.

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The Appendixes and Evidence Tables cited in this report are provided electronically at http://www.ahrq.gov/pub/evidence/pdf/colocanqm/colocanqm.pdf

Executive Summary

Introduction

The burden of illness from colorectal cancer (CRC), the second leading cause of cancer death in the U.S., is substantial. One way to reduce the burden of illness is to improve the quality of care for patients with CRC. Measuring quality of care can help identify specific areas in need of improvement. Sponsored by the Agency for Healthcare Research and Quality (AHRQ), the National Cancer Institute (NCI), the Centers for Medicare & Medicaid Services (CMS), and the Centers for Disease Control and Prevention (CDC), the Duke Evidence-base Practice Center undertook this evidence report to identify measures that are currently available to assess the quality of care provided to patients with CRC, and to assess the extent to which these measures have been developed and tested. With this basis, we also report on areas for future research with an explicit aim of developing a set of measures that can effectively evaluate the process of care provided to CRC patients. Information from this evidence report will be used by technical panels convened by the National Quality Forum (NQF) to consider cancer care quality measures.

Quality measures may be classified as structure, process, and outcome measures. While all three types are considered here, the primary focus is on process measures, whether or not such measures have been formally applied within the context of quality improvement.

Methods

Five key questions are addressed by this report:

Question 1: What quality-of-care measures are available and what evidence is available for these measures to assess the quality of diagnosis of colorectal cancer, including: (a) appropriate use of colon imaging, endoscopic visualization, and biopsy; and (b) availability and accuracy of pathologic staging?

Question 2: As appropriate to specific stages of colorectal cancer, what quality-of-care measures are available and what evidence is available for measures of quality of care of treatment of colorectal cancer, including: (a) polypectomy for malignant polyps, including evaluation of surgical margins; (b) surgical therapy for colon and rectal cancers; (c) appropriate use of adjuvant chemotherapy and adjuvant radiation therapy, including for patients with metastatic but potentially curable (hepatic/pulmonary-resectable) disease; and (d) appropriate use of radiation therapy for either curative or palliative therapy, specifically for rectal cancers?

Question 3: What quality-of-care measures are available and what evidence is available for measures of colonoscopic surveillance for colorectal cancer?

Question 4: What measures are available and what evidence is available for measures to assess the adequacy and completeness of documentation of pathology, operative, and chemotherapy reports?

Question 5: For Questions 1-4 above: (a) in what patient populations and for what purposes have these quality of care measures been used; and (b) does evidence support the use of any of these measures to assess differences in quality of care across patients' age, race/ethnicity, and/or socioeconomic status?

After finalizing the key questions in consultation with study sponsors, NQF, and a panel of national experts, we identified measures through a computerized search of English-language citations in MEDLINE® (1966-January 2005), the Cochrane Database of Systematic Reviews, and the National Guideline Clearinghouse. We also reviewed reference lists from all relevant articles and made special attempts to retrieve grey literature, loosely defined as institutional or government reports, professional society documents, research papers, fact sheets, and other literature, in print or electronic format, that is not controlled by commercial publishing interests. The basic MEDLINE search strategy was adapted for use in the other databases. The final search yielded 3,771 citations published since 1990.

Measures described in individual studies were selected by reviewers according to standardized criteria relating to each question, and were then rated according to their importance and usability (I), scientific acceptability (S), and extent of testing (T); each domain was scored from 1 (poor) to 5 (ideal). A final "I-S-T" rating was assigned to each quality measure across studies.

Results

Colon Imaging, Endoscopic Visualization, and Biopsy (Question 1a)

The best-developed measure identified was *percentage of patients who underwent appropriate evaluation for a positive fecal occult blood test [FOBT]* ($I_5S_4T_4$), which is linked to an outcome of interest (reduced mortality from CRC), based on an evidence-based recommendation, and fairly well tested. The leverage points are awareness of the positive FOBT and referral for colonoscopy.

Although the benefits of expeditious action are intuitive, the measure *time from presentation to diagnosis* ($I_3S_1T_1$) has not been explicitly linked to an outcome of interest, is not based on any evidence-based guidelines, and can therefore be considered to be relatively less well developed and untested. The same can be said for *proportion of colonoscopies that were completed in a timely fashion* ($I_5S_4T_-$).

Any measure that relates to *miss rates* ($I_5S_3T_3$) is unlikely to be useful to compare quality of care, since the methodological gold standard for determining a miss rate is tandem or closely timed colonoscopies, and such a gold standard procedure is not realistic within general clinical practice. Computed tomographic (CT) colonography, or "virtual colonoscopy," appears to be a better alternative, but is not yet part of mainstream evaluation considering the flux in the technology utilized.

Also important were technical process measures of colonoscopy such as *cecal intubation rate* ($I_5S_4T_4$), *intraprocedural complication rate* ($I_5S_4T_-$), and *postprocedural complication rate* ($I_5S_4T_4$). These technical measures are endorsed by guidelines and are meaningful indicators of quality. These measures tend to be fairly well developed, but poorly tested.

Complication rate of colonoscopy ($I_5S_4T_4$) is an important technical measures; however, an accurate definition of the measure is required.

Pathologic Staging (Question 1b)

Our literature search retrieved two process measures that have been used to assess the quality of staging of CRC:

- Adequate lymph node retrieval and evaluation ($I_5S_4T_5$).
- Percentage of newly diagnosed CRC cases who were staged using the American Joint Committee on Cancer (AJCC) system ($I_4S_3T_3$).

Adequate lymph node retrieval and evaluation is linked to an outcome of interest (better staging, leading to appropriate management and better survival) and based on evidence (the 1999 consensus statement of the College of American Pathologists (CAP) recommends evaluating 10-15 lymph nodes in node-negative patients). It is well suited as a quality measure in a broader context, and is well developed and tested. *Percentage of newly diagnosed CRC cases that were staged using the AJCC system* is another measure that is well developed, has face validity, is related to an outcome of interest, and represents an important leverage point for improving the quality of CRC care. However, it does not distinguish between pathology staging and clinical staging.

Polypectomy for Malignant Polyps (Question 2a)

No quality measures were found addressing polypectomy for malignant polyps

Surgical Therapy (Question 2b)

The most basic measure of the quality of surgical management is whether surgical therapy was provided as appropriate to the location and stage of the cancer. Results could potentially be broken out by stage or presented as a single summary measure, *surgical therapy appropriate to the location and stage of the cancer*, for example, appropriate primary therapy for CRC as defined by the NCI guidelines ($I_4S_4T_4$). The former approach provides more information and is preferable. Regarding the denominator of this measure, patients for whom the therapy is inappropriate should be excluded. This point is particularly problematic for patients with stage IV colon or rectal cancer, for whom the intent of the surgery is palliation rather than cure. Ideally, the measure should also distinguish between patients who were offered "appropriate" surgery and refused, and those patients who were not offered such surgery. Making these distinctions increases the data collection demands.

Surgical complication rates provide another very natural measure. Most variations on this measure focus on mortality rates (e.g., *30-day mortality* [$I_5S_4T_5$] or *in-hospital mortality* [$I_5S_3T_3$]), although a delineation of the actual complications would be helpful as well, this latter type of measure being relatively underdeveloped. Presumably, such a measure should be both stratified by stage and location, and risk adjusted to take into account other clinical characteristics of the patient.

For patients with rectal cancer, various measures have been proposed regarding the *rate of sphincter-saving surgery* ($I_5S_4T_4$). This is an outcome of importance to patients. However, quality measures should consider detailed information about the anatomical location and other characteristics of the tumor, which is not yet the case in practice.

Technical measures associated with surgery are underdeveloped.

Adjuvant Chemotherapy (Question 2c)

We considered measures for stage III colon cancer, stages II and III rectal cancer, and stage IV colorectal cancer. Roughly speaking, these measures were defined as the *proportion of patients with stage III colon cancer receiving adjuvant chemotherapy* ($I_5S_4T_5$), the *proportion of patients with stages II or III rectal cancer receiving chemoradiotherapy* ($I_5S_3T_2$), and the *proportion of patients with stage IV colon cancer or stage IV rectal cancer receiving palliative chemotherapy* ($I_5S_3T_2$).

Of these measures, perhaps the best-developed and best-tested measure applies to patients with stage III colon cancer. It is derived from an evidence-based recommendation, is an important leverage point, and is well tested.

Also evidence-based and well validated is the measure applying to patients with stages II or III rectal cancer. Several different versions of the measure have been created, but the ideal version of the measure is the one that most closely matches the most recent recommendations from guidelines, which specify that chemoradiotherapy is the preferred method of management for essentially all such patients.

The measure regarding palliative chemotherapy for stage IV colon cancer or stage IV rectal cancer is reasonable in principle, but suffers from the difficulty that the decision to provide this therapy should very much be made on a case-by-case basis, thus implying that prospective data collection is probably necessary.

For all the above measures, patient preference needs to be taken into account. However, this data element is particularly difficult to collect.

The measure on the *proportion of patients referred to an oncologist* ($I_5S_3T_2$) pertains to an important leverage point in practice, although it is possible that this is neither a necessary nor a sufficient condition for the provision of high-quality care.

Radiation Therapy (Question 2d)

We identified an important process measure: the *percentage of patients with stage II or III rectal cancer receiving adjuvant chemoradiotherapy* ($I_5S_3T_2$). A well-developed and tested measure, it needs to account for reasons for non-receipt of therapy (e.g., insurance coverage or patient preference).

We also identified two potential quality measures for radiation therapy related to the technical quality of its administration, with reference to two different guidelines: *adherence to radiotherapy management treatment guidelines for patients with adenocarcinoma of the rectum or sigmoid colon* ($I_5S_4T_4$) and *rate of use of modern radiation therapy techniques and adherence to recommendations of NCI-sponsored randomized controlled trials in rectal cancer patients* ($I_3S_3T_2$). However, neither of the two technical measures is appropriate for current use because they are based on outdated guidelines. These measures could be modified to make them relevant to current evidence and practice standards.

Colonoscopic Surveillance (Question 3)

Measures describing the performance of postoperative surveillance colonoscopies were fairly well developed and well motivated: their ratings ranged from $I_5S_4T_5$ for the measure *percentage of patients with CRC receiving postoperative (surveillance) colonoscopy* to $I_4S_3T_2$ for *percentage of patients with local or regional CRC who had colonoscopy or flexible sigmoidoscopy with barium enema*. The most problematic point was the lack of consensus regarding the optimal scheduling of this procedure. The numerator should include colonoscopies only, and not other tests such as barium enema or flexible sigmoidoscopy. The measure could also benefit by explicitly specifying whether patients without clearing colonoscopy should be included. "Clearing colonoscopy" (1) refers to a sufficiently comprehensive examination of the colon to exclude other significant neoplasia, such as adenomatous polyps or synchronous cancers; and (2) signifies that all polyps were removed. Technical criteria should be considered as well; for example, whether the colonoscopy was complete according to the standard of documented cecal intubation.

A measure describing the rate of perioperative colonoscopy ($I_5S_4T_4$) was similarly well motivated, but suffered from a lack of precision in distinguishing clearing colonoscopies from similar procedures pre- and postsurgery. Including this additional detail would be substantively helpful, although potentially increasing the data collection requirements, as not all databases (particularly administrative databases) will contain sufficient information to make this distinction.

Pathology, Operative, and Chemotherapy Reports (Question 4)

The quality measure *proportion of CRC cases in which pathologic staging preceded chemotherapy and radiation treatment* ($I_5S_4T_-$) is well developed, free from confounders, and is an important leverage point, but needs testing.

The quality measure *pathology report in concordance with CAP guidelines* ($I_5S_4T_-$) is well developed, free from confounders, and is an important leverage point, but needs testing. Not all items included in the CAP guidelines are related to outcomes of interest, and it may be useful to select those that address a leverage point, for example, local extent of tumor, regional lymph node metastases, or residual tumor at resected margin. This aspect is considered by the measure *adequacy of pathology reports on CRC* ($I_5S_4T_-$), which limits measurement to scientifically validated elements of the CAP guidelines, and is therefore a potentially ideal measure; however it needs field-testing.

The other measures (each being an item of the Association of Directors of Anatomic and Surgical Pathology [ADASP] guideline) take more of a micro-level perspective, addressing individual elements of the pathology report. These are well developed and address some important leverage points for improving quality of colon and rectum cancer pathology reporting standards. The most important ones are: *local extent of tumor*, *regional lymph node metastases*, and *residual tumor at surgical resection margin* (all $I_5S_5T_4$).

Technical measures relating to operative and chemotherapy reports were underdeveloped.

Patient Populations and Purposes; Age, Race/Ethnicity, and Socioeconomic Status (Questions 5a and 5b)

A number of studies have measured differences in process measures related to quality of care based on age, racial/ethnic, or socioeconomic differences; however, few studies have evaluated potential confounders that may explain the differences observed. More refined measures that evaluate a variety of covariates involved in clinical decisionmaking may be necessary to understand and explain these apparent quality-of-care differences.

Conclusions

Although we also considered measures of structure and outcome, the primary focus of this report was on measures of CRC-related processes of care. Here, the main distinction is between those measures that are general (dealing with processes of care on a broader scale) versus technical (pertaining to specific details of a procedure).

The formula for creating a general process measure is to take the sequence of steps describing the optimal pattern of care for patients with CRC, identify each of these steps as both a leverage point and a potential quality measure, and then define such a measure. For example, one of the earliest steps in the process involves the proper diagnosis of patients with a suspicion of CRC. A well-developed and well-tested measure associated with this step is *percentage of patients who underwent appropriate evaluation for a positive FOBT* ($I_5S_4T_4$). As with all ratio-based measures, it is critical to carefully define both the numerator and denominator of the measure. Here, the numerator can be based on a guideline and involves colonoscopy with complete visualization of the colon, although the literature did discuss various nuances, such as the precise definition of what complete visualization entails, how soon the colonoscopy should be performed after the positive FOBT, and so forth. The numerators of some general process measures will have a stronger evidence base than others, with those that are based on guidelines (especially those guidelines that are consistent across professional societies, when multiple such guidelines have been proffered) having the strongest evidence base, and those that are based on basic first principles supported by some research findings being relatively weaker, but often quite sufficient for the task at hand.

Regarding the denominator, “patients with positive FOBT” comprise only a subset of those patients of ultimate interest, namely, “all patients with sufficiently high clinical suspicion of CRC to require followup testing.” These patients would include those with positive tests according to other modalities (e.g., barium enema, flexible sigmoidoscopy), and also those who come to the provider’s attention because of symptoms such as bleeding. Often, a clinically precise statement of the denominator involved deleting various patients; for example, those that would be ineligible because of comorbid conditions or other clinical issues, patients that refuse a form of therapy such as chemotherapy, and so forth.

A consistent source of tension is the distinction between the clinically derived fine-tuning of the definition of the denominator of a quality measure and the limitations of available data sources (which often do not contain sufficient information to act on such distinctions). Our approach here has been to encourage the elicitation of denominators that are as precise as possible, even if the available data sources might not meet all their requirements. In practice, it is crucially important to assess both the strengths and weaknesses of available data sources.

Formal validation efforts are encouraged, but are not always strictly necessary. The assessment of data sources should include the differential impact of data quality on patient subgroups. For example, older patients tend to have more comorbidity and might thus be less likely to tolerate adjuvant chemoradiation therapy; an analysis that does not take this tendency into account could incorrectly lead to the conclusion that an age-related bias exists in the provision of such therapy. A similar caveat applies to analyses comparing patients by race and ethnicity, hospitals according to type, and so forth. Another example of bias is the inability of data sources to account for patient preferences.

Overall, the coverage of general process measures (i.e., across the various leverage points in the sequence of care) is extensive. At least some process measures are available for the steps involving diagnostic imaging, staging, surgical therapy, adjuvant chemotherapy, adjuvant radiation therapy, and colonoscopic surveillance. Additional general process measures might be developed for polyp assessment and removal, although it must be recognized that the proper clinical course of action when presented with a malignant polyp is not always clear. While the above formula could be followed to generate even more general process measures within the above categories, perhaps the task of greater importance is to continue to refine those measures that already exist. The continued expansion of the evidence base, and the continued updating guidelines, should assist this process. Moreover, the basic structure of general process measures facilitates such updating. For example, if future research suggests that the optimal interval for colonoscopic surveillance should be changed, then the structure of the existing quality measures related to surveillance need not be changed; all that would require change is the replacement of one recommended interval with another.

In contrast to general process measures, as might be anticipated, technical measures tended to be used in a formal quality improvement context. Although some excellent technical measures were found, the overall development of technical measures seems somewhat less advanced than that of the general process measures. In particular, for some elements of the care pathway, such as operative reports and chemotherapy reports, no technical measures were found. Various technical measures for quality of colonoscopy were found (e.g., cecal intubation rate). These were guideline-based, well developed, but less well tested, and the linkage between the technical measures and patient outcomes, although intuitive, was not always explicitly provided. To the extent that *complication rate of colonoscopy* ($I_5S_4T_4$) can be considered a technical measure, this area of inquiry is relatively well developed, but needs further testing. *Adequate lymph node retrieval and evaluation* ($I_5S_4T_5$) is an excellent technical measure related to disease staging, although residual areas requiring clarification remain (e.g., optimal number of lymph nodes to examine, consideration that the optimal number of lymph node depends to some extent on patient and tumor characteristics). Technical measures associated with surgery are underdeveloped. Chemoradiation therapy has a number of potential and well-justified technical measures; here, the challenge is to identify and focus on those measures having the most impact on patient outcomes. Technical measures for pathology reporting are well developed, reflecting among other things the areas of emphasis among the relevant professional societies. As noted above, no such technical process measures were identified for operative reports or chemotherapy reports, although it can quite reasonably presumed that with sufficient attention from professional societies and other stakeholders such measures could be developed.

Future Research

Perhaps the most important areas for future development of technical measures are: (a) developing such measures in those areas for which they are lacking; and (b) in areas where such measures exist, identifying and focusing on those measures that have the greatest impact on outcome. Clarifying and otherwise fine-tuning the measures is a process that should be ongoing, both for technical and general measures.

EVIDENCE REPORT

Chapter 1. Introduction

General Background

The National Cancer Policy Board (NCBP) of the Institute of Medicine (IOM) has concluded that "for many Americans with cancer, there is a wide gulf between what could be construed as the ideal and the reality of their experience with cancer care."[1] Concerns about the nation's system of cancer care prompted the NCPB to undertake a comprehensive review of the evidence on the effectiveness of cancer services and delivery systems in the U.S., the adequacy of quality assurance mechanisms, and barriers that impede access to cancer care. As a part of these efforts, the IOM released three reports entitled *Ensuring Quality Cancer Care*, *Enhancing Data Systems to Improve the Quality of Cancer Care*, and *Improving Palliative Care for Cancer*, which summarized the state of knowledge in quality cancer care and identified efforts to improve it.[1-3] A key recommendation was for further development and monitoring of measures of the quality of cancer-related health care. The focus of this evidence report is measures of the quality of care provided to patients with colorectal cancer (CRC).

The present report was sponsored by the Agency for Healthcare Research and Quality (AHRQ), the National Cancer Institute (NCI), the Centers for Medicare & Medicaid Services (CMS), and the Centers for Disease Control and Prevention (CDC). Information from the report will be used by technical panels convened by the National Quality Forum (NQF). One mission of the NQF is to encourage the development and application of validated measures of the quality of care for patients with various medical conditions. This report will provide part of the evidence base from which the NQF will make recommendations about quality measures for patients with CRC. For this report, the NQF, in conjunction with representatives of AHRQ, NCI, CMS, and CDC, provided a set of research questions of interest, a list of review criteria that have been successfully applied to quality measures in other fields, and general expertise in quality measurement, which was made available to us on an as-needed basis.

The focus of this evidence report combines two basic ideas: (a) care provided to patients with CRC; and (b) quality measures. The remainder of this Chapter provides non-technical descriptions of each. That is, it describes in basic terms what care should be expected for patients with CRC and provides an operational definition of a quality measure. More detailed discussion of these issues is provided in subsequent sections of this report.

Care of Patients With Colorectal Cancer

Burden of Disease

The burden of illness from CRC is substantial. In 2003, it is estimated that there were 145,290 new cases and 56,290 deaths attributable to CRC in the U.S. CRC is the second leading cause of cancer death in the U.S.[4]

Conceptual Model

Our conceptual model of the process of care for colon and rectal cancer patients in the U.S. is depicted in Figures 1 and 2. The next sections discuss the various elements of care represented within these figures.

Figure 1. Diagnosis and management of colon cancer

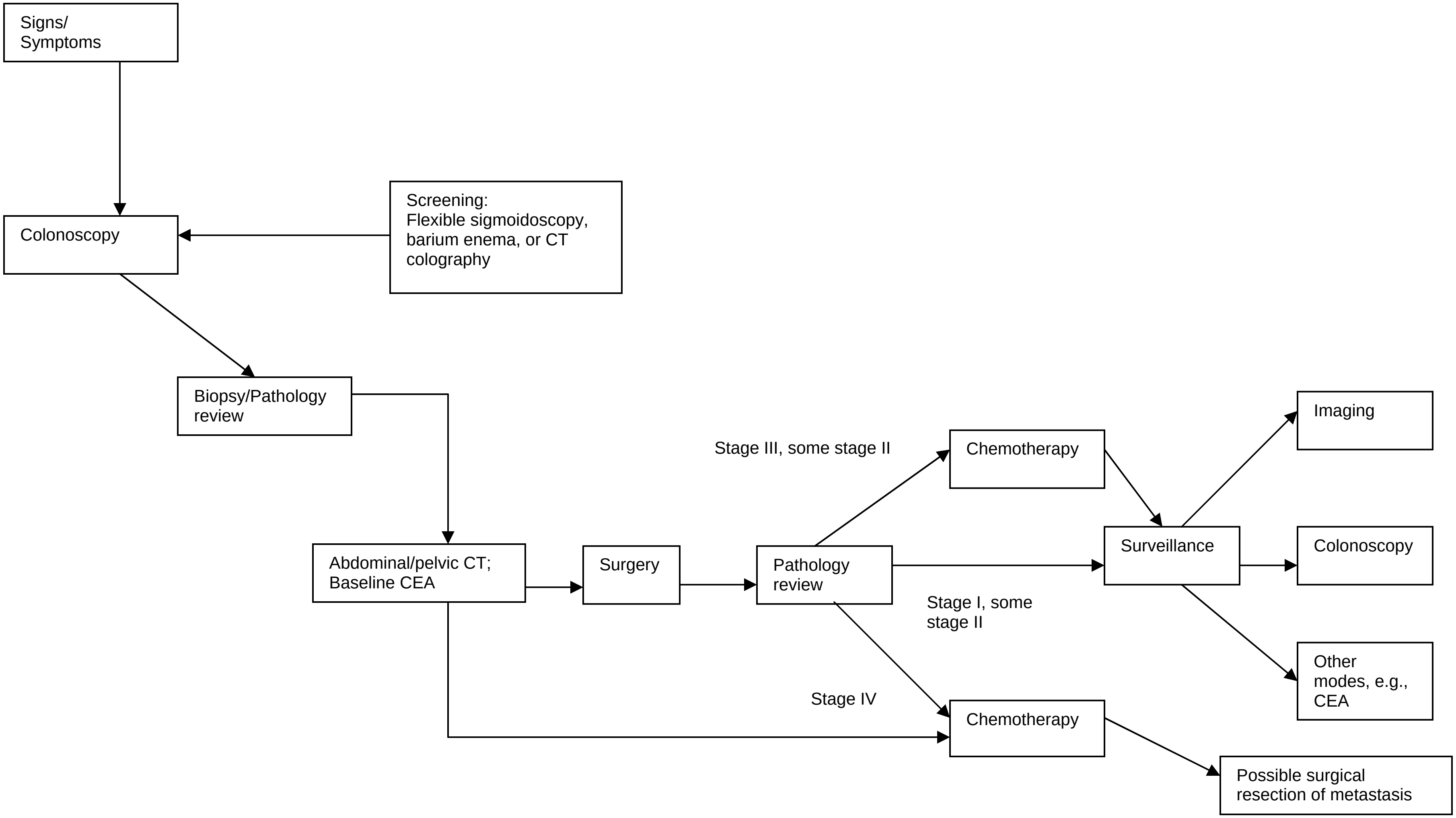
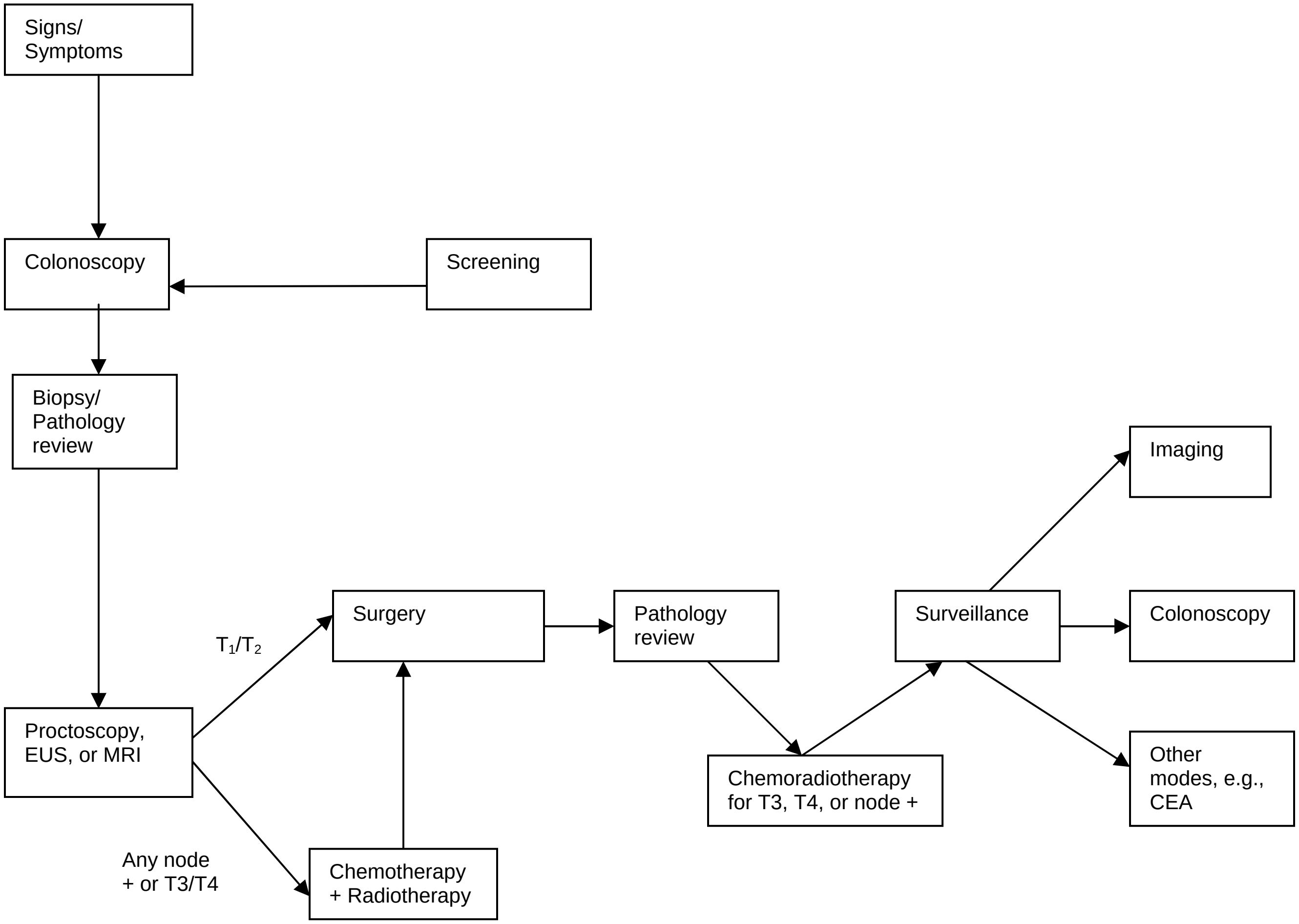


Figure 2. Diagnosis and management of rectal cancer



Diagnosis of CRC

The preferred method of CRC detection is through screening of asymptomatic patients. The clinical rationale for screening is that CRC is a cancer that is usually slow growing, and if the cancer is caught at an early stage (ideally, at the polyp stage), then it is more likely to be cured. However, in spite of demonstrated benefit and published clinical guidelines, CRC screening tests are underutilized.[5] In part due to this underutilization, some patients will be diagnosed with CRC because of symptoms.

Quality measures related to CRC screening have been evaluated elsewhere. At the request of the NQF, we restricted our analysis to: (a) the additional pattern of tests used to diagnose CRC in patients for whom either a screening test result or the presence of symptoms suggests an increased risk of CRC; and (b) screening for recurrence of disease following surgery for CRC, this latter application being termed "surveillance." The preferred test in both applications is a colonoscopy.

Colonoscopy is the most sensitive test for detection of colorectal neoplasia and the only method that allows both examination of the entire large bowel and the opportunity to biopsy or even remove suspected lesions.[6] Various screening tests such as double contrast barium enema, flexible sigmoidoscopy, and fecal occult blood test may have preceded the colonoscopy. However, these modalities are no longer recommended as followup tests.[6] Computed tomographic (CT) colonography ("virtual colonoscopy") is an emerging technology with the potential to screen for CRC, but it is not currently endorsed for screening or diagnostic evaluation.[6-10]

Staging

Surgical resection remains the most effective therapy for colorectal carcinoma. Clinical staging involves evaluating the primary tumor and the presence of nodal and distant metastases; clinical staging begins with evaluation of signs and symptoms, radiographic, and laboratory tests, and includes findings from direct visualization via endoscopy or surgery. For rectal cancer, clinical staging also includes endoscopic ultrasound or Phased Array MRI preoperatively to determine the depth of penetration and the possibility of regional nodal disease, which cannot be accurately assessed by pelvic CT scanning.

Pathologic staging is performed after surgical resection of the primary tumor, and accurate staging is critical for appropriate patient management and also for comparability of data across research studies.[11]

The prognosis of patients with colon cancer is clearly related to the degree of penetration of the tumor through the bowel wall, the presence or absence of nodal involvement, and the presence or absence of distant metastases. These three characteristics form the basis for all staging systems developed for this disease. Bowel obstruction and bowel perforation are additional indicators of poor prognosis.[12]

Although the microscopic appearance of adenocarcinoma of the colon and rectum tends to be straightforward, a detailed pathology review is essential for diagnosis, characterization, and staging. Pathologic stage combines the clinical staging information with surgical findings, incorporating data from the pathologic examination of resected primary and regional lymph nodes.[13] The pathology report is a critical step in the process of pathologic staging. Information on pathology reports should be sufficient to stage the patient using the Tumor, Node, Metastasis

Staging System (TNM).[14] Other key factors include the grade of the tumor and the surgical margin status.

The assessment of nodal metastases at the time of surgical treatment is particularly crucial for patients with apparently localized carcinoma of the colon and rectum, since the presence of nodal metastases is currently the most important factor in determining whether an individual is a candidate for adjuvant therapy.[15] Moreover, stage of disease is the single most important factor in predicting survival.[16-18] The small size of many mesenteric nodes, including some with micrometastatic carcinoma, increases the risk of missing metastases. Recent studies have demonstrated that 10 to 15 lymph nodes are needed for reliable staging.[19-21]

Management: Surgery

Standard treatment for patients with stages I-III colon cancer has been open surgical resection of the primary tumor and regional lymph nodes for localized disease. Polypectomy for malignant polyps is adequate for polyps that have not invaded the submucosa, because these tumors do not metastasize. For polyps that reveal submucosal, lymphovascular, or neural invasion, a bowel resection should be performed. Although surgery is usually reserved for patients with non-metastatic disease, palliative surgery or diverting colostomy is sometimes performed in patients with metastatic disease and bowel obstruction. Some patients who have developed metastases in the liver are also candidates for surgery. Improved surgical techniques and advances in preoperative imaging have allowed for better patient selection for resection.

Localized rectal cancer is treated by surgical resection of the primary tumor and regional lymph nodes. Although previously patients underwent surgery and then postoperative chemoradiotherapy, currently patients with clinical stage T1,2 disease proceed to surgical resection, while most patients with clinical stage T3 or T4 or N+ tumors now receive preoperative chemotherapy and radiotherapy. Most rectal cancers that are located 5 cm or more from the anal verge can be removed while preserving the anal sphincter. For small rectal cancers with favorable pathologic features, local full-thickness excisions may be adequate. The resective technique of total mesorectal excision has led to reduction in local recurrences and improvement in overall survival.[22]

Management: Chemotherapy

Because their cancers have spread beyond the colon and rectum, patients with stage III colon cancer without medical or psychosocial contraindications to treatment are recommended to have systemic adjuvant chemotherapy following surgical resection.[15] Patients with stage II and III rectal cancer also benefit from chemotherapy.[15,23] Palliative multiagent chemotherapy also increases survival for those with stage IV disease, although it is not curative.[24,25]

The steps in the process of receiving appropriate adjuvant chemotherapy are that patients with CRC must be staged appropriately, be referred to an oncologist, receive an adequate performance status evaluation, and be ascertained to be free of major postoperative complications. Chemotherapy must then be offered and administered at an appropriate dosage for an appropriate length of time.[26] Finally, adequate reporting must be provided, this requirement applying equally to surgical therapy, chemotherapy, and radiation therapy.

Management: Radiation Therapy

Because the pattern of recurrence following surgical excision is more often local in patients with rectal cancer than in those with colon cancer, the potential impact of radiation therapy is greater in patients with rectal cancer than in patients with colon cancer.[27] Both preoperative and postoperative radiation therapy decrease local failure.[28-31] Patients with stage II or III rectal cancer are at high risk for local and systemic relapse and are thus the best candidates for adjuvant therapy including chemotherapy and/or radiation therapy. However, it is important to follow precise procedures for radiation therapy in order to achieve optimum results.

The role of adjuvant radiation therapy for patients with colon cancer (above the peritoneal reflection) is not well defined and has no current standard role in the management of patients with colon cancer following curative resection.[32]

Surveillance

Surveillance refers to the ongoing followup of CRC patients after treatment. Colonoscopic surveillance after curative resection of CRC is recommended, but the optimal timing of the surveillance coloscopies after a perioperative “clearing” colonoscopy is yet to be determined. If a preoperative colonoscopy is not possible (e.g., because of an obstructing lesion), it should be performed 6 months after surgery.

Non-endoscopic or combined modality surveillance, such as following tumor markers (carcinoembryonic antigen [CEA]) or abdominal imaging (CT), is controversial. More generally, while there is an overall survival benefit for intensifying the followup of patients after curative surgery for CRC, the optimal combination of clinic visits, laboratory tests and procedures is not currently known.[33-35]

Quality Measures for Patients With Colorectal Cancer

At its most fundamental level, a “quality measure” is something that can be used to measure the quality of care provided to patients. The scope of this definition can be illustrated by example. Consider the following sequence of steps:

Type of measure	*Step*
Structural	Sufficient numbers of physicians given formal endoscopy training
	↓
General process	Greater proportion of colonoscopies
	↓
Intermediate or proximal outcome (technical process)	Reduced rate of colonoscopy complications
	↓
Distal outcome	Better 5-year patient survival because of early diagnosis of cancer

In this formulation, structural measures relate to the structural characteristics of providers and hospitals.[36] Process measures describe the components of the encounter between a physician or another health professional and a patient.[36,37] Within the category of process measures, technical measures pertain to specific details of a particular test or procedure, whereas general process measures are defined on a broader scale. Outcome measures reflect the net effect of healthcare delivery; that is, they describe what actually happens to the patient.[36,37]

When assessing quality of care, each of the above elements is of potential interest. For example, "volume-outcome" studies describe the relationship between structural characteristics and distal outcomes, recognizing that the more steps that intervene between structure and outcome the less definitive will be the inference. While our scope of work includes both structural characteristics and distal outcomes, our primary interest is in the process measures comprising the middle portion of the above pathway.

To define a process measure, the initial requirement is a statement of what constitutes high-quality clinical care; for example, "adequate bowel preparation" might be operationally defined as "no fecal material obscured a lesion 5 mm in diameter." This statement might be derived from a clinical guideline that is circulated by a professional society. (Our scope of work does not include assessing the quality of evidence used in generating guidelines, but is limited to recording which quality measures are based on guidelines and which are not). Alternatively, this statement might be based on clinical first principles supported to a greater or lesser degree by formal research findings. All else being equal, guideline-based measures are preferred, one reason being that the guideline provides a standard of care that the user of the quality measure might plausibly anticipate should be followed.

Once this statement of what constitutes high-quality clinical care is generated, the next step is to define the quality measure using a denominator denoting the number of eligible patients and a numerator denoting the number of eligible patients who satisfied the criteria for high-quality clinical care. For example, for the quality measure *rate of colonoscopy complications*, the denominator is the number of patients undergoing colonoscopy and the numerator is the number of patients undergoing colonoscopy who have at least one complication.

Process measures have been used in both the formal quality improvement context and in more general research settings, the primary difference being that in a quality improvement context various details about the measure tend to be more explicitly specified. For example, some of these details could include the goals of the quality improvement program, the users and uses of the measure, a list of potential data sources along with their advantages and disadvantages, thresholds for action (e.g., take action if the rate of colonoscopy complications exceeds two percent), and so forth. We have defined our scope of work to include both measures that have been used in a formal quality improvement context and measures that have been used in other contexts, the rationale being that many of these latter measures are excellent and could readily be adapted to quality improvement applications. As noted in the next chapter, our methods are general enough to apply not only to process measures that have been used in a quality improvement context, but also to other process measures, structural measures, and outcome measures as well.

Chapter 2. Methods

Topic Assessment and Refinement

Five key questions are addressed by this report. The Duke research team clarified and refined the overall research objectives and key questions by first consulting with the study sponsors, and then convening a panel of national experts to serve as advisors to the project. These experts were selected to represent relevant specialties including colorectal surgery, medical and radiation oncology, internal medicine, clinical pathology, and gastroenterology, as well as representatives of the National Cancer Institute (NCI) and the National Quality Forum (NQF). The eight members of the technical expert panel were:

John Z. Ayanian, M.D., M.P.P., Harvard Medical School
Steven Boyd Clauser, Ph.D., National Cancer Institute
Rodger Jeffrey Winn, M.D., National Quality Forum
Richard M. Goldberg, M.D., University of North Carolina at Chapel Hill
Marcia R. Gottfried, M.D., Duke University Medical Center
Michael P. Pignone, M.D., University of North Carolina at Chapel Hill
Dawn T. Provenzale, M.D., Duke University Medical Center
Kirk A. Ludwig, M.D., Duke University Medical Center

Six key questions were originally proposed by the report's sponsors:

Question 1: What quality-of-care measures are available and what evidence is available for these measures to assess the quality of diagnosis of colon cancer, including: (a) appropriate use of colon imaging, endoscopic visualization, and biopsy; and (b) availability and accuracy of pathologic staging?

Question 2: As appropriate to specific stages of colorectal cancer, what quality-of-care measures are available and what evidence is available for measures of quality of care of treatment of colorectal cancer, including: (a) polypectomy for malignant polyps, including evaluation of surgical margins; (b) surgical therapy specifically for rectal cancers; (c) appropriate use of adjuvant chemotherapy; and (d) appropriate use of radiation therapy for either curative or palliative therapy, specifically for rectal cancers?

Question 3: What quality-of-care measures are available and what evidence is available for measures of colonoscopic surveillance for colorectal cancer?

Question 4: What measures are available and what evidence is available for measures to assess the adequacy and completeness of documentation of pathology, operative, and chemotherapy reports?

Question 5: For questions 1-4 above: (a) in what patient populations and for what purposes have these quality-of-care measures been used; and (b) does evidence support the use of any of these measures to assess differences in quality of care across patients' age, race/ethnicity, and/or socioeconomic status?

Question 6: For questions 1-4 above, what gaps in our knowledge of measurement of quality of care are evident from the currently available evidence, either for the population of colon cancer patients as a whole, or for specific subpopulations?

As a result of conference calls with the technical experts and the report's sponsors, and in response to comments on the peer review draft, the Duke research team modified these questions. Question 6 was eliminated as a separate question, and information on gaps in our knowledge was incorporated into the responses to Questions 1-4 in Chapter 3 and into Chapter 4. The refined key questions were as follows (changes from the initial versions are italicized):

Question 1: What quality-of-care measures are available and what evidence is available for these measures to assess the quality of diagnosis of *colorectal* cancer, including: (a) appropriate use of colon imaging, endoscopic visualization, and biopsy; and (b) availability and accuracy of pathologic staging?

Question 2: As appropriate to specific stages of colorectal cancer, what quality-of-care measures are available and what evidence is available for measures of quality of care of treatment of colorectal cancer, including: (a) polypectomy for malignant polyps, including evaluation of surgical margins; (b) surgical therapy for *colon and* rectal cancers; (c) appropriate use of adjuvant chemotherapy *and adjuvant radiation therapy, including for patients with metastatic but potentially curable (hepatic/pulmonary-resectable) disease*; and (d) appropriate use of radiation therapy for either curative or palliative therapy, specifically for rectal cancers?

Question 3: What quality-of-care measures are available and what evidence is available for measures of colonoscopic surveillance for colorectal cancer?

Question 4: What measures are available and what evidence is available for measures to assess the adequacy and completeness of documentation of pathology, operative, and chemotherapy reports?

Question 5: For questions 1-4 above: (a) in what patient populations and for what purposes have these quality-of-care measures been used; and (b) does evidence support the use of any of these measures to assess differences in quality of care across patients' age, race/ethnicity, and/or socioeconomic status?

Analytic Framework

Based on the original proposal and discussions with our technical expert panel, we developed the analytical framework represented by Figures 1 and 2 (in Chapter 1). Briefly, these figures describe the various steps in the diagnosis of colorectal cancer (CRC), the treatment of CRC, and the post-treatment surveillance for recurrence of CRC. Each step describes a potential leverage point for improving the quality of care and thus represents the opportunity for defining a process measure. The ultimate goal is to improve patient outcomes, in particular both survival and quality of life.

As noted in the introduction, the quality of CRC-related care has been assessed at both the level of process and of outcome. Outcome measures most directly reflect what is ultimately of interest, but the connection with process of care might be weak (e.g., a good process of care might nevertheless result in poor outcomes), especially if (a) there are a number of links between the process of care and outcome; and/or (b) the outcome might be caused by many factors other than the process of care. With this in mind, we have separated the presentation of outcome measures from those pertaining to process. In particular, in the literature we observed outcome measures of two types: survival and quality of life. Survival measures (e.g., percentage of patients surviving 5 years) are discussed within the main body of the text (e.g., under Question 5, we describe differences in survival by age). Quality-of-life measures, which were relatively uncommon in the literature, are discussed in Appendix A.[*]

While recognizing the ultimate importance of outcomes, the main focus of the text is on measures of process. These process measures have been applied in a number of different contexts. When applied within the context of clinical epidemiology, a process measure might simply be defined as, for example, "the number of patients with stage III colon cancer receiving adjuvant chemotherapy." On the other hand, when applied within a quality improvement context, process measures generally require not just this basic descriptive component, but also additional information such as a list of data elements that are necessary to construct and/or report the measure, detailed specifications regarding the population on whom the measure is constructed, the source of the data, how the data elements are to be collected, the timing of data collection and reporting, the analytic models used to construct the measure, and the format in which the results will be presented. Measures may also include thresholds, standards, or other benchmarks of performance.

In summary, the application of a process measure in a quality improvement setting includes not just the measure itself, but also various critical details as illustrated above. Such details need not necessarily be specified when applying the same process measure in a more general research setting. Nevertheless, some process measures that have been applied outside the setting of quality improvement might be excellent candidates for the quality improvement setting, (conditional on the specification of the various additional details as noted above); accordingly, we interpreted our task as finding both the former (actual quality improvement process measures) and the latter (potential quality improvement process measures).

One of the implications of the above was the need to extend the criteria for assessing quality measures. In particular, the assessment criteria provided by the NQF are most naturally intended for the circumstance where a ratio-based process measure is applied within a quality improvement application. For such measures we applied the NQF assessment criteria as provided. For other measures, we developed criteria intended to be consistent with the principles underlying the NQF's assessment criteria, as applied to this somewhat different circumstance. Additional details are provided in the section on "Quality Assessment Criteria," below.

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

Literature Search and Review

Sources

The primary sources of literature were MEDLINE® (1966-January 2005) and the Cochrane Database of Systematic Reviews. Searches of these databases were supplemented by reviews of reference lists contained in seed articles, all included articles, relevant review articles, and meta-analyses. We made special attempts to retrieve grey literature, loosely defined as institutional or government reports, professional society documents, research papers, fact sheets, and other literature, in print or electronic format, that is not controlled by commercial publishing interests. Sources for grey literature included professional organization websites and the Internet.

Search Strategies

The basic search strategy used the National Library of Medicine's Medical Subject Headings (MeSH) key word nomenclature developed for MEDLINE® and was adapted for use in the other databases. The searches were limited to the English language. The text of the major search strategy is given in Appendix B*, as well as a history of search terms considered.

The final search, conducted in January 2005, yielded 5450 citations. When limited to publication date since 1990 and English language, this totaled 3,771 citations. These records were maintained in a ProCite (Thompson ISI ResearchSoft, Berkeley, CA) database.

Abstract and Full-Text Screening

Paired content experts from the Duke research team independently reviewed a set of abstracts and classified each as "include" or "exclude." An abstract was retained at this stage if at least one of the paired reviewers recommended that it be included, and abstractors were instructed to apply the inclusion criteria liberally. Inter-rater reliability for include/exclude decisions was tested by having five pairs of readers review a subset of abstracts (n = 765). Agreement ranged from a kappa of 0.23 to 0.46. Samples of abstracts for which abstractors disagreed were reviewed, and it was noted that most disagreements occurred for marginal articles and reflected the abstractors' attempts to be as inclusive as possible during this preliminary screening stage. A total of 874 abstracts were included for the further "full-text review" stage.

At the full-text review stage, the paired researchers independently reviewed a set of the articles, and indicated a decision to "include" or "exclude" the article for the data abstraction stage. Detailed inclusion and exclusion screening criteria were developed for this purpose (see "Full-text Screening Criteria," below). When a pair of reviewers arrived at a different opinion about whether to include an article, they were asked to reconcile the difference. Detailed inclusion and exclusion screening criteria were developed and are listed below.

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* Appendixes cited in this report are provided electronically at
http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

Full-Text Screening Criteria

The full-text screening criteria were as follows:

Include if:

- The study population pertains to adults undergoing diagnostic evaluation for, or in treatment for, colon or rectal cancer, and at least **one** of the following apply:
    - Asymptomatic patients who have been screened AND have a positive finding suspicious for colon or rectal cancer (e.g., polyps).
    - Patients being diagnosed through the use of colon imaging, endoscopic visualization, or biopsy (Question 1a).
    - Diagnosed patients undergoing pathology staging (Question 1b).
    - Patients undergoing polypectomy for malignant colonic polyps (Question 2a).
    - Patients treated with surgical therapy for either rectal cancer or colon cancer (Question 2b).
    - Patients with metastatic, but potentially curable (hepatic/pulmonary-resectable) disease, when a majority of the study population has CRC (Question 2c).
    - Patients treated with adjuvant chemotherapy or radiation therapy (Questions 2c and 2d).
    - Patients treated with palliative chemotherapy or radiotherapy (Questions 2c and 2d).
    - Patients undergoing colonoscopic surveillance (no other form of surveillance) for CRC (Question 3).

AND

- The study refers to at least **one** of the following:
    - An explicit quality measure (process, structure, or outcome).
    - A measure that assesses the adequacy and completeness of documentation of pathology, operative, or chemotherapy reports (operative procedures will include reports for colonoscopy and radiation therapy) (Question 4).
    - The testing of a quality measure's validity or reliability.
    - A data source (e.g., registry) used for measuring quality, but may not specify the quality measure itself.

Exclude if one or more of the following apply:

- The study uses non-U.S. data.

- The study was published prior to 1990.

- The report is in a non-English language.

- The study population involves any of the following:
    - The screening of asymptomatic patients.
    - Patients with familial polyposis syndrome.
    - Patients undergoing polypectomy for hereditary polyposis.
    - Patients with hereditary non-polyposis colorectal cancer.

- Patients with multiple metastases, BUT the majority of the patients ARE NOT CRC patients.

Summaries of the results of the abstract screening and full-text review are provided in Tables 1 and 2. A list of excluded articles by reason for exclusion is found in Appendix C[*].

Table 1. Results of abstract screening and full-text review

Articles identified	3,771
Abstracts reviewed	3,771
Included	948
Excluded	2,823
Full-text articles reviewed	947*
Included	74
Excluded	873

*We were unable to obtain in full-text form 1 article included at the abstract screening stage.

Table 2. Included full-text articles by research question

Question 1a:	15
Question 1b:	7
Question 2a:	0
Question 2b:	33
Question 2c:	31
Question 2d:	22
Question 3:	8
Question 4:	3
Question 5:	30
Total number of included articles	74*

*Total of table does not equal total number of included articles because some articles were included for more than one question.

Data Abstraction and Development of Evidence Tables

The Duke research team developed and piloted evidence table formats for abstracting the quality measures and related data to answer each of the six research questions (see Appendix D[*]). A pair of researchers was assigned to each research question based on clinical expertise and was instructed to abstract the quality measures and related data from the eligible articles. One of the paired researchers abstracted the quality measures and related data into the evidence tables,

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

and the second researcher over-read the article and accompanying evidence table to check for accuracy and completeness. The completed evidence tables are provided in Appendix E.

Quality Assessment Criteria

At the data abstraction stage, the abstractor was asked to evaluate each article for factors affecting external and internal validity. External validity was primarily addressed by the items on the data abstraction form pertaining to the study population.

As an assessment of internal validity, our original charge recommended that we assess the quality measures retrieved during our literature search using a set of criteria that had previously been applied by the NQF with success. These criteria are listed below.

Importance: A measure is considered important if one or more audiences find the information produced from a measure useful for some purpose. Measures can be important because:

a. There is considerable variation in the quality of care provided.
b. Quality is substandard.
c. They relate to one of the established national goals.
d. They represent a significant leverage point for achieving the goal.
e. The information produced is usable by a stakeholder in the system.

It is not necessary for all conditions to apply. However, criteria a or b must be present and be associated with c, d, or e for the measure to be considered important.

Usability: An intended audience must be able to understand the results of the measure and find them useful for decisionmaking. For a measure to be useful:

a. It must contain information that is compelling within the decisionmaking framework of the user.
b. It must assess differences that are subjected to statistical testing, e.g., between groups, over time.
c. Differences must be practically meaningful.
d. Analysis should be done appropriately.
e. It must present results that are effective and consistent with intended use.

Scientific Acceptability: A measure is scientifically acceptable if it produces consistent and credible results when implemented. There are five criteria on which to evaluate each quality measure (in a given study) to determine if it is scientifically acceptable:

Precise specifications – a specification of a measure should include its format, and a standard reference source for defining key terms (clinical conditions, procedures, etc.) that is consistent with current requirements.

Reliability – a measure is reliable when it produces the same result a high proportion of the time when assessed on the same population using the same data source.

Validity – the validity of a measure is the extent to which it accurately represents the concept being evaluated. A measure is considered valid if (1) the scores that are produced from the measure distinguish between good and bad quality, and (2) the construction of the measure adequately represents the concept of interest.

Adaptability – a measure is adaptable if it is appropriate for use in a variety of contexts and settings. Three dimensions of adaptability important to quality measurement are: (1) the ability to take into account patient preferences, (2) the flexibility to account for different clinical scenarios and (3) the applicability of the measure in different settings.

Adequacy of risk-adjustment – when there is a clear clinical rationale, a quality measure should be adjusted for risk differences when making comparisons among health plans or physicians. It is less important to risk-adjust a quality measure when using the measure to track progress toward a health goal, for example, or when measuring changes over time within a single health care setting.

Each of the above elements was scored on a 1-5 scale, with 1 denoting “poor” and 5 denoting “ideal.” The evidence tables report assessments for measures as reported in individual studies.

In order to encourage reliability between abstractors, we held a “calibration” meeting where each investigator scored the same five quality measures (picked randomly, one for each task order question), discussed the scores and the differences in individual scoring, and re-scored them. The abstractors agreed on the scores 83 percent of the time. Subsequent to this calibration meeting, at least three investigators scored every measure, and a mean score was determined and finally allocated to each criterion.

Note that at this stage there could be several scores attached to the same quality measure, and that a single study could produce more than one measure. The evidence tables include scores for every study assessing a given measure in that study.

Another purpose of the calibration meeting was to identify and resolve any questions that the abstractors might have about how to fill in the abstraction form. During this meeting it was noted that, while the above scoring system tended to perform excellently for those “actual” quality measures that were used in quality improvement applications, it performed less well for those “potential” quality measures that were reported from other research studies. For these latter measures, abstractors were instructed to fill out the abstraction form as originally designed and (a) for those elements that were not applicable, either code the measure as “poor” or “not applicable”, as indicated; and (b) when feasible, to envision an application where the measure is used in a quality improvement context, and then to score the measure according to that application. For example, for applications in which the quality measure in question was not risk-adjusted, the abstractor might nevertheless be able to express an informed opinion about whether such risk-adjustment was possible. As another example, the review criteria for usability assume that a decisionmaker and decisionmaking context has already been specified (as would be the case in a quality improvement application); in this case as well, the abstractor might nevertheless be able to envision a typical user and proceed.

Recognizing that the ultimate use of the quality measures included in our evidence report was to inform the sponsors regarding the extent to which they were ready to be applied in the field, at this final stage we rated each quality measure across studies using three criteria: importance and usability, scientific acceptability, and extent of testing. For assigning these rates, we considered all studies that had utilized the particular measure. Details of the method we used to assign these ratings are provided in Appendix F[*]. Each measure was given an "I-S-T" rating, where:

> **"I" describes the extent to which a measure is important and usable.** This rating was determined by examining all the studies that utilized the measure and considering the best application.
>
> **"S" describes the extent to which the measure is scientifically acceptable**, that is, the extent to which the measure is precisely defined, valid, reliable, adaptable, and risk-adjusted. This rating was also determined by examining all the studies that utilized the measure and considering the best application. For example, if a measure was successfully risk-adjusted in one study but not in another, we rated the measure as one in which risk-adjustment had successfully been applied.
>
> **"T" describes the extent to which the measure is tested.** This rating was determined by examining all the studies that utilized the measure and considered two aspects of the measure: (a) the number of studies that utilized the measure, and (b) the extent to which these studies were scientifically acceptable (i.e., the "S" rating).

Each of the above criteria was rated on a scale of 1-5, with 1 denoting "poor" and 5 denoting "ideal." For example, if a quality measure has been assigned a rating of $I_5S_3T_1$, the measure has high importance and moderate scientific acceptability, but has not been tested.

This final scoring and rate assignment were done exclusively by the writer of each section (the writer was an investigator trained in that content area of the report). Although we had provided objective criteria for rating the quality measures, in order to encourage maximum flexibility (especially for "potential" quality measures), the writer was instructed to adapt the basic scoring and rating rules to the quality measure using their subjective judgment. Most of our recommendations follow directly from this assignment of ratings.

For some measures that we retrieved from professional society websites or from personal communications (i.e., not from peer-reviewed literature) we did not attempt to retrieve any information regarding their testing. Therefore those measures may not have a "T" rating, although it is possible that they have undergone testing.

At the end of each section in Chapter 3, a table with the structure illustrated below (Table 3) summarizes the I-S-T ratings assigned to the quality measures considered. The text in the "Recommendations" column of each table synthesizes the information in the corresponding "Future Research" section of the text. One use of this report will be to assist the NQF technical panel in identifying gaps in measurement that could be the basis for a future research agenda. Such research might include pilot testing or assessment of the measure's appropriateness for populations other than that for which it was designed; evaluation of the appropriateness of the measure for use in routine clinical practice, quality improvement, or accountability; or data collection about the care of specific populations.

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

Table 3. Sample quality measure ratings table

Quality measure	**Quality measure rating (range 1-5, where 1 = poor and 5 = ideal)**			**Recommendations for the measure**
	Important and usable (I)	**Scientifically acceptable (S)**	**Well tested (T)**	

Note: Investigators used their judgment to determine the quality measure rating for each measure across all studies that utilized the measure. See Appendix F[*] for details.

To comment, inclusion of potential in addition to actual quality measures necessitated the above relatively modest modifications of the quality assessment process. However, since many of the potential quality measures that we identified were excellent (and since our initial consultation with NQF suggested that our charge in identifying quality measures should be defined broadly rather than narrowly), we nevertheless felt that the benefits of including these potential measures outweighed their limitations. For any particular measure, the distinction between actual and potential quality measures should be clear from the context, so those readers who wish to limit their focus to measures that have been developed and tested in quality improvement applications should be able to do so.

Additional Analyses

There were no additional analyses beyond those described here.

Peer Review Process

We employed internal and external quality-monitoring checks through every phase of the study to reduce bias, enhance consistency, and verify accuracy. Examples of internal monitoring procedures include: three progressively stricter screening opportunities for each article (abstract screening, full-text article review, data abstraction review); involvement of three individuals (two clinicians and copy editor) in each data abstraction; agreement of at least two clinicians on all included studies.

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

Our principal external quality-monitoring device was the peer review process. Nominations for peer reviewers were solicited from several sources, including our technical expert panel and interested federal agencies. The list of nominees was forwarded to AHRQ for vetting and approval.

Chapter 3. Results

Question 1a: Colon Imaging, Endoscopic Visualization, and Biopsy

Question 1a was: What quality-of-care measures are available and what evidence is available for these measures to assess the quality of diagnosis of colorectal cancer, including appropriate use of colon imaging, endoscopic visualization, and biopsy?

Background

The preferred method of colorectal cancer (CRC) detection is through screening of asymptomatic patients. However, in spite of demonstrated benefit and published clinical guidelines, CRC screening tests are underutilized.[5] In part due to underutilized screening, some patients will be diagnosed with CRC because of symptoms. The American Society for Gastrointestinal Endoscopy (ASGE) strongly endorses colonoscopy in the diagnosis of CRC and further states that "multiple biopsy specimens should be obtained from all suspicious lesions, and polypoid lesions should be removed."[38] In addition, patients who have a positive CRC screening test by any modality other than colonoscopy (i.e., fecal occult blood test [FOBT], flexible sigmoidoscopy, or double contrast barium enema [DCBE]) require a full colonoscopy for further evaluation.[6] DCBE was previously considered acceptable for the followup of a positive FOBT, but the latest guidelines emphasize that colonoscopy is the preferred followup test based on the sensitivity of colonoscopy.[6] Virtual colonoscopy is another promising and emerging imaging technique that has some advantages over traditional colonoscopy.[6-10]

Studies of colonoscopy miss rates for adenomas underscore that even this "gold standard" is not perfect.[39] In 2002 a Multi-Society Task Force published its recommendations for assessment of quality in the technical performance of colonoscopy.[40] Quality targets included: use of recommended screening and surveillance (e.g., postcancer resection) guidelines, cecal intubation rates of ≥ 90 percent overall and ≥ 95 percent of screening cases, documentation of cecal intubation by landmarks, mean colonic examination time (generally on withdrawal of colonoscope) of at least 6 to 10 minutes, incidence of perforation < 1/1,000 (all) and < 1/2,000 (screening exams), and incidence of postpolypectomy bleeding (< 1/100). Recommendations for the colonoscopy procedure report included documentation of procedure time; quality of bowel preparation; cecal landmarks; and polyps identified, removed (technique), and recovered.

Results

Our literature search revealed several quality measures for outcomes of interest related to this question:

- Percentage of patients with positive FOBT who underwent an appropriate evaluation.[41-45]
- Time from patient presentation with symptoms to cancer diagnosis.[46]

- Proportion of colonoscopies that were completed in a timely fashion.[47]
- Percentage of patients with colon or rectal cancer undergoing colonoscopy as part of their evaluation.[48]
- Colonoscopic miss rate for significant colonic neoplasia.[49,50]
- Complication rate of colonoscopy.[51]
- Serious postendoscopic procedure complication rates.[47,52]
- Rate of unplanned reversal of sedation medication.[47]
- Intraprocedure colonoscopy complication rate.[53]
- Colonoscopy completion rate.[54]
- Cecal intubation rate.[47,52]
- Adenoma removal rate for patients over 50 years old.[47]
- Percentage of patients with adequate bowel preparation prior to colonoscopy.[47,52,55]
- Proportion of colonoscopies performed by physicians with specialized training.[47]
- Proportion of patients who adequately understood the colonoscopy procedure.[53]

General Process Measures. The first, and most widely used, measure we consider is the *percentage of patients who underwent appropriate evaluation for a positive FOBT.* This is a general process measure that depends critically on the specification of what constitutes an "appropriate" evaluation. The measure is based on evidence-based guidelines that have evolved over time as additional data on what constitutes an appropriate evaluation have become available. The older American Cancer Society (ACS) guidelines[56] recommended the combination of barium enema and flexible sigmoidoscopy if a colonoscopy was not performed. The 1997 guidelines[57] allowed for either colonoscopy or barium enema for followup of a positive FOBT. The updated 2003 guidelines[6] emphasized that colonoscopy was the preferred method of followup for a positive FOBT because of newer data supporting the increased sensitivity of colonoscopy to detect adenomatous polyps. Therefore, depending on the guideline cited, age of the data, and the timing of the study publication, "adequate evaluation" could be defensibly defined with some variation. Ideally, "appropriate evaluation" should also include consideration of the maximum acceptable time lag between the positive FOBT and a more definitive diagnostic workup, although the above guidelines do not explicitly specify such a time lag.

In applying this measure, Shields et al.[41] used data from 1986-1988 and defined "adequate evaluation" as colonoscopy or DCBE with flexible sigmoidoscopy per the cited 1980 ACS guidelines.[58] The measure was applied in a community-based mass screening program, and the source included patient self-report up to 3 years after the evaluation. Such an extensive delay might call the reliability of self-report data into question.

Levin et al.[42] used data from 1993 and defined "adequate evaluation" as colonoscopy or DCBE per the 1992 ACS guidelines.[56] The data sources were patient and physician self-report, the accuracy of which were not tested. Although formal validation was not performed, it was found that consultation of a gastroenterologist significantly increased the chance of adequate evaluation, thus supporting the discriminant validity of the measure.

Baig et al.[43] defined "appropriate evaluation" to include colonoscopy or DCBE (without flexible sigmoidoscopy), which is consistent with the 1997 guidelines,[57] although these guidelines were not explicitly cited. The followup period was restricted to 60 days, which may limit the usability and adaptability of this measure in systems where 2-month followup may not be possible (e.g., the Veterans Administration [VA] system). The data sources were provider survey and health maintenance organization (HMO) claims data.

Myers et al.[44] defined "adequate evaluation" as colonoscopy or DCBE with flexible sigmoidoscopy within 180 days, which may be a more realistic followup period. This study was in the setting of an intervention to improve followup rates for positive FOBT. Data sources were physician surveys and HMO administration claims data.

Mandel et al.[45] is another variation on this same measure and defined "appropriate evaluation" as followup colonoscopy or DCBE with flexible sigmoidoscopy. What is most noteworthy about this version of the measure is the study population: an 18-year followup from one of the original clinical trials that demonstrated the efficacy of FOBT. These data may be difficult to generalize, since patients that are enrolled in a clinical trial could be expected to have higher rates of appropriate followup than general practice.

Two measures focus on timeliness. One is the *time from patient presentation with symptoms to physician diagnosis*. Marble et al.[46] applied this measure to tumor registry data from a single medical center. Details of how time to diagnosis was determined are lacking. Moreover, there was no explicit demonstration that delays in diagnosis are related to survival (or any other outcome of interest). This measure is not well developed.

A related measure, proposed by Minnesota Gastroenterology PA as part of their internal quality improvement initiative,[47] is the *proportion of colonoscopies that were completed in a timely fashion*, where timeliness is operationally defined as "acceptable to patient and referring physician according to internal practice standards." Ideally, this internal practice standard should reflect the indication for the procedure. While potentially important, this measure is not clearly linked to outcomes of interest or validated.

Another general process measure was applied by Beart et al.:[48] *percentage of patients with colon or rectal cancer undergoing colonoscopy as part of their evaluation.* The major flaw in this measure is the failure to distinguish between those colonoscopies used for the purpose of diagnosis and those used for preoperative clearance. This measure is not considered further.

Yet another general process measure is the *colonoscopy miss rate* (i.e., the miss rate for detection of significant colonic neoplasia). Haseman et al.[50] defined this measure as "percentage of colon cancers not detected by colonoscopy in symptomatic patients." He performed a retrospective review of colon cancer cases that were not detected during a colonoscopy performed up to 3 years prior to cancer diagnosis. The numerator and denominator were well defined; however, the assumption that lesions should have been detected up to 3 years prior is not validated. Further limitations to the study were that the hospitals had volunteered to participate and that this was a retrospective review.

Shehadeh et al.[49] estimated the miss rate for “big” (≥ 10 mm) polyps by retrospectively reviewing the endoscopy database and pathology records of patients with an initial colonoscopy including polypectomy and at least one subsequent colonoscopy at a single, academically affiliated VA medical center. “Big” polyps seen on the subsequent colonoscopy were considered “missed” by the first colonoscopy. While the rate of missed advanced adenomatous polyps is a potentially important quality indicator, the method of measuring this value is more appropriately obtained with a prospective design and consideration of tandem colonic examinations.

Technical Process Measures. Some of the most fundamental technical measures concern procedural complication rates. Various specific measures have been proposed. Ure et al.[51] use the measure *complication rate of colonoscopy*. The numerator included the following complications: bowel perforation, intraprocedural complications (hypoxia [O_2 saturation < 90 percent], hypotension, bradycardia, hemorrhage), postpolypectomy bleeding, cardiopulmonary arrest, and death. The presence or absence of any complications was noted and the rates of individual complications were separately described, as was the total number of complications. Some of the complications (i.e., the numerator) were more precisely described than others. Overall this measure could be better developed and needs to be risk-adjusted. Furthermore, the importance of the individual complications is not uniform. For example, in terms of patient outcomes, perforation, postpolypectomy bleeding and death have established importance, whereas complications such as intraprocedural hypoxia treated with supplemental oxygen may not be clinically important.

Minnesota Gastroenterology PA[47] defined the complication rate measure as *serious postendoscopy complication rate*, where the serious complications considered included death within 30 days, perforation, bleeding with transfusion, cardiopulmonary arrest, and unplanned surgery. Focusing on these severe and well-described complications adds to the development, importance, and face validity of this measure. Similarly, a large VA study[52] was conducted in order to study major complication rates following screening colonoscopy. The complications were defined accurately and evaluated rigorously for up to 30 days after the procedure.

Potentially less serious, but clinically important, complications of sedation are captured by a second complication measure, proposed by the same group, the *rate of unplanned reversal of sedation medication*.[47]

The National Quality Measures Clearinghouse (NQMC) publishes a similar measure, *intraprocedure colonoscopy complication rate* (proposed by the Accreditation Association for Ambulatory Health Care [AAHC] Institute for Quality Improvement), which includes arrhythmia, bleeding requiring treatment, extended recovery, hospital transfer, hypotension, hypoxia, perforations, and respiratory arrest.[53] The specific definitions of these complications are lacking, although guidelines by the Accreditation Association for Ambulatory Health Care (AAAHC) Institute for Quality Improvement are cited.[59]

Another technical measure is the *colonoscopy completion rate,* i.e., whether the colonoscopy was adequately completed. The Colon Cancer Workgroup[54] applied the definition “colonoscopy to the ileocecal valve performed prior to surgical resection of CRC.” This measure is well developed and is based on National Comprehensive Cancer Network (NCCN) guidelines.[24] Cases of obstructing or perforated carcinoma should be excluded from the denominator of this measure. Ure et al.[51] similarly defined colonoscopy completion rate as “visualization of the cecum or ileocolic anastomosis.” The rationale is similar to the above.

Cecal intubation rates and *adenoma removal rates* for patients over 50 years old were quality measures proposed by Minnesota Gastroenterology PA.[47] Both are well defined, linked to outcomes of interest, and based on guidelines.[40] Cecal intubation was defined as examination of the entire colon to the cecum or to a surgical anastomosis (when applicable). Adenoma removal rates were assessed in patients over 50 years of age. The rationale for this latter measure appears to be that if the adenoma detection rate is less than "population norms," then polyps are probably being missed. "Population norms" were well defined.

Another technical measure pertains to the *quality of bowel preparation preceding the colonoscopy*. Harewood et al.[55] examined the relationship between adequate bowel preparation and the detection of colonic polyps or cancer. The data source was a national gastrointestinal endoscopic database (Clinical Outcomes Research Initiative [CORI]), and the findings supported significantly greater detection of colonic neoplasia (although not necessarily cancer) in patients with adequate bowel preparation compared to without adequate preparation. This measure is important, but a more appropriate quality measure for health care might be the *documentation* of the bowel preparation quality at the time of the procedure, as this may affect the interval of the next examination and the level of certainty that neoplasia or malignancy has been ruled out. Weaknesses of the study itself included the lack of validation of the CORI data, lack of standardized definitions for the quality of bowel preparation, and inconsistent histology data for colonic lesions.

Minnesota Gastroenterology PA[47] also utilizes a measure of the "proportion of colonoscopies with adequate preparation." This version of the measure is more specific: "no fecal material obscured a lesion 5 mm or more in diameter and a high quality examination takes place."

All measures proposed by Minnesota Gastroenterology PA have been implemented within their system and will require further testing for broader application.

Other Measures. Minnesota Gastroenterology PA[47] propose a structural measure of the *proportion of colonoscopies performed by physicians with specialized training (gastroenterology, colorectal surgery, general surgery, pediatric surgery)*. This follows ASGE guidelines.[60] The measure is well defined, but needs validation and testing.

The NQMC[53] publishes the measure *proportion of patients who respond "yes" to whether they have an adequate understanding of their procedure as asked in a post procedure telephone interview* (proposed by the AAHC Institute for Quality Improvement). This is guideline-based,[59] but not validated (e.g., patients may want to give socially acceptable answers in a telephone interview), and measures only *perception* of understanding and not true understanding.

A final quality measure is an indirect one: *incidence of metastatic diagnosis among health plan members aged 50 or older*.[61] Reduction of metastatic disease is supported by NCCN guidelines[24] as a measure of the long-term effectiveness of cancer screening programs, one component of which is quality of diagnosis. Because the primary determinant of this outcome is likely to be the proportion of eligible patients undergoing screening, this measure is considered to be outside the scope of interest here.

Conclusions

We retrieved several general, technical, and structural measures that have been utilized in the United States for assessing the quality of care related to diagnosis of CRC. Ratings for these measures are given in Table 4; further details are provided in Evidence Tables 1 and 2 in

Appendix E[*]. Perhaps the most important, well-developed, and widely tested[41-44] measure identified was *percentage of patients who underwent appropriate evaluation for a positive FOBT* ($I_5S_4T_4$), which is linked to an outcome of interest (reduced mortality from CRC) and is based on an evidence-based recommendation. The leverage points are awareness of the positive FOBT and referral for colonoscopy.

Although the benefits of expeditious action are intuitive, *time from presentation to diagnosis* has not been explicitly linked to an outcome of interest, is not based on any evidence-based guidelines, and can therefore be considered to be relatively less well developed and untested ($I_3S_1T_1$). The same can be said for the technical measure *proportion of colonoscopies that were completed in a timely fashion* ($I_5S_4T_-$).

Any measure that relates to *miss rates* ($I_5S_3T_3$) is open to debate because no matter how the miss rate is estimated it is unlikely to be useful to compare quality of care, since the methodological gold standard for determining a miss rate is tandem or closely timed colonoscopies, and such a gold standard procedure is not realistic within general clinical practice. In other words, it is not realistically possible, in practice, to determine whether a case has in fact been "missed."

Also important is the technical process measure of colonoscopy: *cecal intubation rate* ($I_5S_4T_4$). This technical measure is endorsed by guidelines, but is inconsistently linked to outcomes of interest; it tends to be fairly well developed, but poorly tested. While *cecal intubation rate* is an important measure, a precise definition of intubation is required for appropriate evaluation. Toward this end, *colonoscopy completion rate* ($I_5S_4T_-$), specified in the studies we examined as visualization "to the ileocecal valve" or "of the entire cecum or ileocolic anastomosis," may be a better measure.

Intraprocedural complication rate ($I_5S_4T_-$), *postprocedural complication rate* ($I_5S_4T_4$), and *complication rate of colonoscopy* ($I_5S_4T_4$) are other important technical measures; however, an accurate definition of the complication rate is required. Complications should be divided into those of a severe nature with links to outcomes of interest (e.g., bleeding requiring transfusion or hospitalization) and those of a more minor nature (e.g., intraprocedural transient hypoxia with oxygen saturation < 90 percent reversed with oxygen supplementation via nasal canula and resolution during the recovery period). For purposes of data collection (particularly since colonoscopy is primarily an outpatient procedure) it may also be useful to divide complications into intraprocedural complications, immediately postprocedural complications (e.g., within 2 hours), and 30-day postprocedural complications. This final category would require not only examination of medical records, but potentially patient survey in order to determine whether the patient was treated at another facility.

Patient understanding of the colonoscopy procedure was fairly well developed, but its relationship to outcomes has not been definitively demonstrated ($I_5S_4T_-$).

The Multi-Society Task Force guidelines[40] suggest an additional potentially useful quality measure, *colonoscopic withdrawal time* (which has been linked to polyp detection rates), but we found no data on development or validation of this potential measure.

The recommendations made herein are based on a review of currently available data. Obviously, future data or clinical realities (e.g., costs, changes in societal goals) or the development of new technologies may alter the recommendations in the future. Nonetheless, for the major recommendations, we do not expect their basic core importance to change.

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

Table 4. Quality measure ratings – Question 1a

Quality measure	Quality measure rating (range 1-5, where 1 = poor and 5 = ideal)			Recommendations for the measure
	Important and usable (I)	Scientifically acceptable (S)	Well tested (T)	
General measures				
Percentage of patients with positive FOBT who underwent an appropriate evaluation[41-45]	5	4	4	Further testing required with reliable data sources.
Time from patient presentation with symptoms to cancer diagnosis[46]	3	1	1	Additional testing required with larger data set. Measure should be clearly linked to the outcome of interest.
Proportion of colonoscopies that were completed in a timely fashion[47]	5	4	-	Additional testing required with larger data set. Measure should be clearly linked to the outcome of interest.
Percentage of patients with colon or rectal cancer undergoing colonoscopy as part of their evaluation[48]	4	3	2	Measure should be clearly linked to the outcome of interest, such as change in patient management, more accurate staging.
Colonoscopy miss rate for significant colonic neoplasia[49,50]	5	3	3	No matter how the miss rate is estimated, this is likely not a usable measure because tandem or closely timed colonoscopies are not performed in general clinical practice.
Technical measures				
Complication rate of colonoscopy[51]	5	4	4	Complications to be identified need to be those that are clinically relevant, and precisely defined. The period during which they are identified needs to be accurately specified.
Serious postendoscopic procedure complication rate[47,52]	5	4	4	Studies have been performed for screening colonoscopies only.
Rate of unplanned reversal of sedation medication[47]	5	4	-	Testing required.
Intraprocedure colonoscopy complication rate[53]	5	4	-	Testing required.

Table 4. Quality measure ratings – Question 1a – continued

Quality measure	**Quality measure rating (range 1-5, where 1 = poor and 5 = ideal)**			**Recommendations for the measure**
	Important and usable (I)	**Scientifically acceptable (S)**	**Well tested (T)**	
Colonoscopy completion rate[54]	5	4	-	Must explicitly exclude from the numerator and denominator patients who are unable to undergo complete colonoscopy prior to surgery (because of obstruction, need for emergent operation, etc.).
Cecal intubation rate[47,52]	5	4	4	Testing required. "Cecal intubation" should be appropriately defined including method of cecal identification by landmarks (appendical orifice and ileocecal valve).
Adenoma removal rate for patients over 50 years old[47]	5	4	-	Testing required, including validation of the "benchmark" adenoma rate for different patient populations and establishment of both clinically and statistically relevant deviations from these benchmarks.
Percentage of patients with adequate bowel preparation prior to colonoscopy[47,52,55]	5	4	4	Additional testing of the measure required. Needs to be linked to a provider- or facility-level process for, e.g., adequate instruction for bowel preparation. Otherwise, this is a measure of patient adherence and not a measure of the quality of care.
Proportion of colonoscopies performed by physicians with specialized training[47]	5	4	-	Needs to be developed and further tested on a representative group of physicians. Also, the definition of specialized training needs to be evaluated, specifically is there a threshold number of procedures required?
Percentage of patients with an adequate understanding of the colonoscopy procedure[53]	5	4	-	Testing required. The link to an outcome of interest needs to be established (e.g., patient satisfaction, patient compliance with next scheduled procedure).

Note: Investigators used their judgment to determine the quality measure rating for each measure across all studies that utilized the measure. See Appendix F* for details.

Future Research

Since several potentially useful quality measures for diagnosis of CRC were retrieved, future work should focus on correcting any deficiencies of these measures. For the measure *percentage of patients who underwent appropriate evaluation for a positive FOBT,* the numerator should include only those patients who underwent colonoscopy, as this reflects the most recent guidelines.[6] The denominator should include all patients who underwent FOBT by the appropriate technique (stool collection at home, any applicable dietary or medication restriction [depends on the specific FOBT used], results evaluated by a certified laboratory) and had a positive test (defined as any positive window). The following patients should be excluded from the numerator and denominator: those with positive occult blood test based on a digital rectal exam only; individuals for whom screening is inappropriate either because of life-limiting comorbidity, because they are younger than screening guidelines recommend or because they are not yet due for screening (e.g., had a colonoscopy within the past 5 to 10 years); and individuals who were offered colonoscopy, but refused. The first and second exclusions are based on the premise that one cannot measure the quality of screening followup if the screening itself was incorrectly performed or inappropriately applied. The third exclusion reflects that patient preference, if based on an informed decision, should not penalize the provider or system being evaluated.

One additional point to resolve in the definition of “adequate evaluation” is the maximum acceptable time lag between the positive FOBT and the subsequent colonoscopy. At present, this specification cannot rely on recourse to a guideline, but might instead be derived from basic first principles and the structural characteristics of the health systems being studied.

Finally, it should be noted that this quality measure needs to undergo additional testing. The link between followup of positive FOBT and CRC-specific survival is well supported. The reliability and accuracy of various data sources, however, require additional investigation. Data sources could include chart review, administrative claims data, patient survey, and provider survey.

Other technical process measures of colonoscopy also have potential for improvement to become useful quality measures. These measures should address the accuracy and safety of the procedure. *Complication rates* require precise descriptions including the specific complication (e.g., bleeding), the definition (e.g., bleeding that results in hospitalization or transfusion), and the time frame (e.g., within 30 days of the procedure). It would be best to separately collect the data for individual complications within prespecified time frames (e.g., intraprocedural, within 2 hours of the procedure, within 30 days) even if the complications might be reasonably reported in combination. Potential data sources are procedural flow sheets, chart review, and patient survey. These sources require testing for reliability and accuracy. *Cecal intubation rate* requires a precise definition and should include those patients postcecal resection by the inclusion of “to the surgical anastomosis.” The numerator should include all patients who meet this definition. The denominator should include all colonoscopies regardless of test indication. Patients with obstructing lesions should be excluded from the numerator and denominator. Patients with other

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* Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

reasons for failed complete colonoscopy, such as poorly tolerated examination, poor bowel preparation, or intraprocedural complications, should still be included in the denominator. Success and accuracy of this quality measure depends on accurate documentation of cecal landmarks or surgical anastomoses in the colonoscopy report. The first step is to have documentation of the extent of the colonoscopy as a required part of the colonoscopy report template. The next and more difficult step is validation of the report itself and of collective endoscopic databases, such as CORI. Corroboration by another health provider or inclusion of a still picture or video documentation are possible methods to compare the report to another source of information. Results may be biased if those performing the colonoscopy know that they are being observed.

Question 1b: Pathologic Staging

Question 1b was: What quality-of-care measures are available and what evidence is available for these measures to assess the quality of diagnosis of colorectal cancer, including the availability and accuracy of pathologic staging?

Background

Although the microscopic appearance of adenocarcinoma of the colon and rectum tends to be straightforward, a detailed pathology review is essential for diagnosis, characterization, and staging. Stage is the most accurate predictor of survival for patients with CRC, and accurate staging is critical for appropriate patient management and meaningful clinical research.[62] Pathologic stage combines the clinical staging information with surgical findings, incorporating data from the pathologic examination of resected primary and regional lymph nodes.[13]

Historically, numerous different staging systems for CRC have been used, but a single internationally recognized system is required to ensure a common language for cancer that is understood by clinicians in all specialties. The Tumor, Node, Metastasis (TNM) Staging System of the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC) fulfills this mandate and has the added advantages of being data-driven, updated on a regular basis, multidisciplinary in design, and applicable to all current techniques of stage evaluation.[14] Uniquely, the TNM Staging System is governed by rules of application, both general and site-specific.[63]

The single most important determinant of prognosis in patients with apparently localized carcinoma of the colon and rectum is the presence or absence of nodal metastases at the time of surgical treatment. Patients with stage I or II cancer of the colon or rectum have an anticipated 5-year survival rate in excess of 75 percent. In contrast, individuals with N1 disease have a 5-year survival rate of only 45 to 60 percent.[64] The presence of nodal metastases is currently the most important factor in determining whether an individual is a candidate for adjuvant therapy[15] and is arguably the single most important factor in predicting survival.[16-18]

Nodal staging accuracy for colorectal carcinoma is currently under scrutiny. Several factors contribute to variation in nodal staging accuracy, including the amount of mesentery resected, fixative, diligence of search for nodes, and number of histologic levels examined. The small size of many mesenteric nodes, including some with micrometastatic carcinoma, increases the risk of missing metastases. Recent studies demonstrated that 10 to 15 lymph nodes are needed for reliable staging. Although the exact number of lymph nodes required for adequate lymph node evaluation in patients has been debated, the 1999 consensus statement by the College of American Pathologists (CAP) recommended evaluating 12 to 15 nodes in node-negative patients.[19]

There is evidence to indicate that the quantity of lymph node harvest has a direct effect on staging.[20,21,65] The principles of surgical resection of colon and rectal cancer dictate *en bloc* removal of the cancer and sufficient proximal and distal bowel to encompass potential submucosal lymphatic tumor spread and include the regional mesenteric draining lymphatics. Standard resections of the colon and rectum are founded on anatomic structures that provide not only for adequate radial and longitudinal margins but for adequate regional lymph node clearance as well. Despite these well-recognized guidelines, there may be substantial variability in the type of resection performed for CRC, which could lead to variability in the number of nodes removed. Additionally, the number of nodes in a surgical specimen may vary from one patient to another and may perhaps depend on the extent and diligence of the pathologic examination,[66] since many pathologists are unfamiliar with these rules or unsure how to interpret them in specific situations.[67]

Results

Our literature search retrieved two process measures that have been utilized to assess the quality of staging of CRC:

- Adequate lymph node retrieval and evaluation.[13,54,61,68,69]

- Percentage of newly diagnosed CRC cases who were staged using the AJCC system.[70,71]

Applications have ranged from clinical epidemiology to quality improvement.

Baxter et al.[68] applied the measure *adequate lymph node retrieval and evaluation*. Adequate sampling was defined as an examination of at least 12 lymph nodes, based on the UICC and the AJCC definitions. Population-based data from the National Cancer Institute's (NCI's) Surveillance, Epidemiology, and End Results (SEER) program was used for this purpose. Exclusion criteria were clearly mentioned (in situ or metastatic disease, patients with prior malignancies, non-adenocarcinomas, patients with appendiceal malignancies who underwent radical surgery and did not receive neoadjuvant radiation). The study evaluated the mean and the median number of lymph nodes examined. More traditional ratio-based measures of the proportion of patients who had no lymph nodes examined and the proportion of patients who had at least 12 nodes examined were also calculated. Trends over time were evaluated and tested for any association with patient age, race/ethnicity, sex, or geographic location; year of diagnosis; or tumor stage, grade, and anatomic site. The study was limited by its use of population-based data with partial information on patient factors, tumor factors, and specimen adequacy. The measure does not account for the fact that lymph node evaluation depends on the surgical quality, which could lead to variability in the number of nodes removed. Additionally, the number of nodes in a surgical specimen may vary from one patient to another.

An Institute of Medicine (IOM) report[13] proposed a similar measure to assess the quality of cancer care in Georgia. In this case, appropriate histological assessment of CRC was defined as an assessment of 12 or more lymph nodes; this measure is thus essentially equivalent to one of the variations of the measure described by Baxter et al.,[68] above.

Two other measures used an essentially identical structure, but prescribed retrieval of different numbers of lymph nodes for their thresholds. The National Committee for Quality Assurance (NCQA)[61] proposed 14 lymph nodes, based on NCCN guidelines.[24] The Colon Cancer Workgroup,[54] on the other hand, proposed eight lymph nodes and based this decision on the SEER median of eight.

Galvis et al.[69] utilized a similar measure to compare the pathology specimen gross examination performance of pathology residents and pathologists' assistants. Investigators retrospectively reviewed surgical pathology reports for 176 colorectal specimens (submitted from 1997-1999) from one anatomic pathology laboratory serving a teaching center. For all specimens, the total number of lymph nodes retrieved, the number of positive nodes retrieved, and the length of colorectal specimens were recorded. The measure is not explicitly validated; however it is known that the number of lymph nodes sampled is an important predictor of CRC outcomes.[20,21] The measure was applied at a single center and needs further testing.

It should be noted that this measure (*adequate lymph node retrieval and evaluation*) requires documentation of the examination on operation notes and pathology gross specimen examination reports. The choice of the number of lymph nodes could be an institutional decision. A trigger that was utilized by the Colon Cancer Workgroup[54] may be insightful: this institution evaluates any situation where a hospital or a surgeon-pathologist combination regularly obtains fewer than eight lymph nodes. The group also recognizes that rectal cancer resection specimens may have fewer lymph nodes.

Steele[71] analyzed the National Cancer Data Base (NCDB) to examine the trends in stage at diagnosis. Although not explicitly defined as a quality measure, the *percentage of newly diagnosed CRC cases that were staged using the AJCC system* was reported and used as a marker of appropriate cancer diagnosis and treatment over the time period studied. The study evaluated trends over time, census region, and hospital type. This measure can be generalized, but is limited by its inability to differentiate between those cases that were staged using pathology criteria versus those that utilized clinical criteria for staging.

Chiaverini et al.[70] utilized essentially the same measure to assess the progress in the control of CRC from 1987-2000 in Rhode Island using data from the Rhode Island Cancer Registry.

Conclusions

We retrieved two major quality measures that have been utilized in the United States for assessing the quality of pathology staging of patients with CRC. Ratings for these measures are given below in Table 5; further details are provided in Evidence Tables 3 and 4 in Appendix E[*].

Adequate lymph node retrieval and evaluation is linked to an outcome of interest (better staging, leading to appropriate management and better survival) and based on evidence.[20,21,65,72-77] It is also well developed and tested ($I_5S_4T_5$) and could be utilized for internal quality assessment of personnel.

It may be important to note that the number of lymph nodes examined reflects not only the quality of pathology care, but also reflects an interaction between tumor factors (right-sided

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

colon resections may often contain a larger mesentry and more lymph nodes) and the quality of the surgical procedure (removal of an adequate number of lymph nodes, an adequate length of specimen, and surgical clearance).[78]

Percentage of newly diagnosed CRC cases that were staged using the AJCC system is another measure that is well developed, has face validity, is related to an outcome of interest, and represents an important leverage point for improving the quality of CRC care.[71] However, it does not distinguish between pathology and clinical staging ($I_4S_3T_3$).

The recommendations made herein are based on a review of currently available data. Obviously, future data or clinical realities (e.g., costs, changes in societal goals) or the development of new technologies may alter the recommendations in the future. Nonetheless, for the major recommendations, we do not expect their basic core importance to change.

Table 5. Quality measure ratings – Question 1b

Quality measure	**Quality measure ratings (range 1-5, where 1 = poor and 5 = ideal)**			**Recommendations for the measure**
	Important and usable (I)	**Scientifically acceptable (S)**	**Well tested (T)**	
Technical measure				
Adequate lymph node retrieval and evaluation[13,54,61,68,69]	5	4	5	Lymph node evaluation also depends on the quality of surgery and tumor-related factors (these factors are true for all pathology measures). Could be utilized for internal quality assessment of personnel.
General measure				
Percentage of newly diagnosed CRC cases who were staged using the AJCC system[70,71]	4	3	3	Needs further testing. In order to evaluate quality of pathology staging a distinction must be made between clinical and pathology staging.

Note: Investigators used their judgment to determine the quality measure rating for each measure across all studies that utilized the measure. See Appendix F[*] for details.

Future Research

For newly diagnosed CRC cases to be staged according to the AJCC (or another) system is a necessary, but not sufficient, condition for accurate pathologic staging. Recognizing this, future research should focus on clarifying precisely what constitutes an adequate lymph node evaluation. In particular, first principles suggest that not all patients should have exactly the same number of lymph nodes evaluated, and expanding the evidence base on this subject would

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

be of help. Also, in order to better establish the points of leverage, components of these measures that are attributable to the surgeon should be separated from those that are attributable to the pathologist.

Question 2a: Polypectomy for Malignant Polyps

Question 2, in its entirety, was: As appropriate to specific stages of colorectal cancer, what quality-of-care measures are available and what evidence is available for measures of quality of care of treatment of colorectal cancer, including: (a) polypectomy for malignant polyps, including evaluation of surgical margins; (b) surgical therapy for colon and rectal cancers; (c) appropriate use of adjuvant chemotherapy and adjuvant radiation therapy, including for patients with metastatic but potentially curable (hepatic/pulmonary-resectable) disease; and (d) appropriate use of radiation therapy for either curative or palliative therapy, specifically for rectal cancers? We will discuss each of the subquestions (a, b, c, and d) in separate sections, beginning with Question 2a.

Question 2a was: As appropriate to specific stages of colorectal cancer, what quality-of-care measures are available and what evidence is available for measures of quality of care of treatment of colorectal cancer, including polypectomy for malignant polyps, including evaluation of surgical margins?

Background

Adenomas of the gastrointestinal tract may undergo malignant transformation in the adenoma-carcinoma sequence and are regarded as precursors of most colorectal carcinomas. Colonoscopy is considered a safe and effective method of screening for colorectal adenomas, and endoscopic polypectomy has been demonstrated to prevent progression to adenocarcinoma. The term “malignant polyp” refers to a macroscopically benign-appearing adenoma in which invasive carcinoma is detected histologically in the resected specimen. With tumor infiltration through the lamina propria and possible invasion of venous and lymphatic vessels, malignant polyps have the potential for lymph node metastases, and endoscopic polypectomy may not be curative. The decision on subsequent management of malignant polyps may be difficult because of controversial studies in the literature. Several studies show adequacy of endoscopic polypectomy alone for selected cases, but some authors advocate colectomy for any invasive carcinoma arising in an adenoma. Many endoscopists tend to favor subsequent surgery as the strategy of choice for all these patients.[79] Some elements of this decision include level of invasion (probably the most important factor), the type of polyp, the presence of lymphatic or blood vessel invasion, poor differentiation of the tumor, and positive margins of resection in the polypectomy section.

Even though subsequent management decisions are difficult and must be individualized to the circumstances of individual patients, one point of general agreement is that a crucial piece of information is provided by the pathology report, the successful generation of which requires the surgeon to collect the specimen according to sound clinical principles and the pathologist to provide a comprehensive report. In some cases, the result of this report will suggest a clear plan of action: for example, for a level 0 invasion of a pedunculated adenoma a polypectomy should suffice, while a level 4 invasion of a sessile adenoma into subserosal connective tissue or microscopic cancer at the resection margin[80] suggests surgery. However, there are many intermediate cases between these two extremes for which guidelines are either not present or not helpful.

Results

No quality measures on this topic were found.

Conclusions

In the absence of any current quality measures, our recommendations are derived from basic first principles and are provided immediately below, under “Future Research.”

Future Research

The clinical decision for the treatment of a malignant polyp (e.g., endoscopic polypectomy alone, endoscopic polypectomy followed by segmental colectomy, colonic resection alone, primary colotomy and polypectomy) is not straightforward, and the evidence base is relatively modest (e.g., including the lack of guidelines). Accordingly, potential measures of the form *percentage of patients with malignant polyps receiving a certain form of treatment* do not seem to be a fruitful approach at present, although as the evidence base improves this kind of measure might be specified for those subgroups of patients for which the clinical decision is clear. On the other hand, a measure such as *percentage of patients with malignant polyps receiving a sufficiently comprehensive evaluation (however defined), and treatment selected from a menu of appropriate alternatives (this menu perhaps specified using expert consensus)* might be helpful.

Recognizing the importance of the collection and analysis of the pathologic specimen, various technical measures could be generated. The portion of Question 4 that pertains to pathology reports illustrates how such reports might be formatted.

In summary, for future research we recommend extending the pathology reports described in Question 4 to the analysis of polyps, developing more general measures addressing the overall adequacy of the evaluation of possibly malignant polyps, and developing measures that specify whether a patient received one out of a set of clinically reasonable treatments. Notably, the CAP has a checklist available for polypectomy specimens.

Question 2b: Surgical Therapy

Question 2b was: As appropriate to specific stages of colorectal cancer, what quality-of-care measures are available and what evidence is available for measures of quality of care of treatment of colorectal cancer, including surgical therapy for colon and rectal cancers?

Background

In responding to this question, we extended the patient population to include patients with colon cancer, as well as patients with rectal cancer.

Surgery is part of the standard management of patients with colon and rectal cancer stages I, II, and III, and for selected patients with stage IV disease. In addition, chemotherapy is the standard adjuvant therapy for stage III colon cancer, and chemoradiotherapy is the standard adjuvant therapy for stage II and III rectal cancer.[81] However, for stage IV colon and rectal cancer, chemotherapy alone may be appropriate,[81] with surgery and/or radiation reserved for palliation of symptoms due to bulky primary tumors.

Although adjuvant therapies have improved local recurrence rates and survival, it remains clear that proper surgical resection is critical in determining the overall outcome of a patient with CRC. In regards to colon cancer, it is important to remove the tumor with adequate margins and provide the pathologist proper mesenteric tissue to allow for proper lymph node sampling. Precise surgical technique is even more critical for rectal cancer.

One of the most significant advances in the treatment of rectal cancer has been the concept of performing rectal cancer resection according to the principle of total mesorectal excision (TME). Previously, blunt dissection irrespective of the anatomic planes of the rectum was widely utilized and taught as the proper mechanism to excise rectal tumors. However, 15 to 50 percent local recurrence rates were reported using these blunt techniques. In 1982, Heald et al.[82] recognized that most local recurrences after rectal cancer resection were a result of inadequate and imprecise surgical excision of the rectal lymphovascular pedicle that may contain micrometastases. Moreover, they recognized that by using meticulous, sharp dissection under direct vision and not violating the anatomical planes of the visceral and parietal pelvic fascia down to the level of the levator ani muscles, the rectum and its mesentery could be removed as an intact unit. The quality of the excision can be examined by careful macroscopic as well as microscopic assessment of the resection specimen.[83] These techniques dramatically reduced the incidence of positive lateral margins and led to astonishingly low local failure rates while still performing a sphincter-preserving operation. Recently, several studies have concluded that using combined modalities and TME, local recurrence remains under 10 percent, with cancer-specific survival of over 70 percent[22] compared with conventional blunt surgical techniques, where local failure rates range from 15 to 45 percent.[84,85] In these studies, precise anatomic dissection also prevented injury to the sympathetic and parasympathetic nerves in the pelvis, which reduced the previously high incidence of bladder and sexual dysfunction following rectal cancer surgery. TME has rapidly been adopted throughout the world.

The appropriate approach to surgery for rectal cancer depends to a large extent on tumor characteristics as measured with such tools as endoscopic ultrasound (EUS), computed tomography (CT) scans, magnetic resonance imaging (MRI), and history and physical examination. NCI guidelines currently recommend rigid proctoscopy, EUS, or MRI and an abdomino-pelvic CT to stage the cancer preoperatively. By implication, measures that focus on sphincter preservation rates should take the characteristics of the tumor into consideration.

Regardless of the location of the tumor, one of the critical tasks of the surgeon is to generate a high-quality specimen for the pathologist to analyze. Classically, this has been perceived as removing the major vasculature to the section of colon being removed or a total mesorectal excision for rectal cancers. This technique assures adequate lymph node harvesting for the pathologist, although the precise number of nodes cannot be described by the surgeon. These measures are difficult to ascertain and are again a function of the surgeon’s technical abilities. These should be considered valid measures of the quality of surgery since they determine the subsequent pathology staging of the tumor and management decisions based on the stage.

Survival of CRC increases with the number of lymph nodes recovered, regardless of their positivity.[65]

An important point to note in any outcome measure related to surgery is the need to examine all management processes beyond surgical resection (as appropriate to stage and location of tumor): was adjuvant therapy offered subsequent to surgery?; did the patient refuse it?; was radiotherapy offered?; was surveillance performed?

Results

We identified a number of measures that have been utilized to assess the quality of surgery in colon and rectal cancer. These are either general measures that assess whether surgery was performed, or technical measures that assess the quality of the surgical technique employed. Each measure takes the form of a numerator describing the number of eligible patients receiving some form of surgery for colon cancer, rectal cancer, or for both types of cancers, divided by a denominator describing the number of eligible patients.

Regarding the denominator, there is considerable variation: some measures focus on colon cancer only, some focus on rectal cancer only, and some focus on both. The best approach to quality measures is to focus on a single location and stage (e.g., stages I and II colon cancer, or stage III colon cancer) or to present the data disaggregated by location and stage.

Newcomb et al.[86] and Demissie et al.[87] have studied rates of refusal in patients and have determined that a significant percentage of patients refuse to undergo surgery (from 9 to 33 percent, with refusal rates being higher among African-Americans) and chemotherapy (from 16 to 33 percent, with refusal rates being higher among the elderly). With these observations in mind, all measures should incorporate patient preference within them, or else adopt a measure that assesses “intent-to-treat rates” instead of rates of “treatment received.”

Measures That do not Account for Stage. Several general process measures have been utilized to assess the surgery-related quality of care in all available colon and rectal cancer patients, without accounting for stage and/or location. For example, such a strategy would be necessitated when available administrative databases do not contain this information. A common and very serious problem with all these measures is that *not* performing surgery may be appropriate for some stages of colon and rectal cancer (e.g., stage IV colon and rectal cancer). Accordingly, these measures are simply listed here and are not considered further.

The aforementioned measures include:

- Rate of surgery for CRC.[88,89]
- Percentage of patients with CRC who received surgery.[86,90,91]
- Number of CRC patients who received surgery as part of primary treatment.[92]

Measures That Assess Appropriate Receipt (or Non-Receipt) of Surgery for Colon or Rectal Cancer for Patients Having Cancers of Various Location and Stage. Demissie et al.[87] analyzed the SEER database (which contains specific information regarding physician recommendations regarding surgical treatment, the actual receipt of the treatment, and reasons for not receiving treatment) to determine *non-receipt of surgery*. The numerator and denominator were well defined. Results were presented by stage of tumor and histologic type. The study considered the intention of the surgeon to treat as an important factor in categorizing patients as "having received standard surgical treatment;" a sensitivity analysis was performed using the actual treatment received to observe if the results were significantly different.

Cooper et al.[93] utilized Medicare provider analysis and review files from 1984 to 1987 to study whether race was associated with differences in curative *surgical resection rates*. The numerator and denominator were moderately well defined. The results were presented by race, by differentiating black and white patients in the population studied. Differences in race-related patient preferences may have accounted for the observed difference in receipt of surgical resection among black and white patients.

Merrill et al.[91] also analyzed the *rate of surgical resection* by using two tumor registries, part of the SEER databases, Medicare inpatient claims data, two HMO databases, and 1990 U.S. census data. An appropriate definition was used to specify the numerator and denominator, for all stages of tumor 0-IV. The aim of the study was to compare treatment utilization in HMO and fee-for-service (FFS) settings for Medicare colorectal cancer cases.

Steele[71] used the NCDB to assess trends in colon and rectal cancer diagnosis and management in order to provide benchmarks for clinicians and policymakers. An appropriate rate was used, and the numerator and denominator were specified: *percentage of stage 0-III colon cancer patients who underwent surgery, and stage III patients who received chemotherapy in addition to surgery*. AJCC staging was used, and the measure was based on AJCC guidelines. The NCDB may overstate performance because of its voluntary nature.

Roetzheim et al.[94] studied the impact of health insurance and race on colorectal cancer surgery using the measure *percentage of patients with CRC who underwent cancer-directed surgery*. Cancer-directed surgery rates were identified from the Florida Cancer Database System, supplemented with information from discharge abstracts using *Current Procedural Terminology* (CPT) codes. The measure was precisely defined, and confounders examined were age, sex, marital status, household income, and educational level; site of cancer; stage at diagnosis (information was not detailed); residence; and comorbid scores. The study evaluated colon and rectal cancer patients separately and concluded that treatments received by patients varied considerably according to insurance payer: those with HMO insurance were more likely to receive definitive surgical treatment, and this difference increased with advancing cancer stage. Among non-Medicare patients, those having Medicaid and the uninsured were less likely to receive surgical treatment than private FFS patients. There were no differences between races in receipt of definitive surgical treatment.

Temple et al.[95] assessed two measures for stage IV rectal cancer: *cancer-directed surgery rates* and *metastatectomy rates*. The general approach regarding the measure was well structured, numerators and denominators were defined, and the SEER-Medicare registry was used as the data source. The main difficulty with this measure is that the evidence for a health benefit from removing the primary cancer in patients with stage IV cancer is uncertain and likely to be highly patient-dependent. In many cases, such patients may derive greater benefit from more aggressive systemic chemotherapy than from surgical intervention.

O'Connell et al.[96] compared *cancer-directed surgery rates* by age using data from the 1991-1999 SEER database. The measure was precisely specified, AJCC staging was used for defining the tumor stage, and results were appropriately broken out by stage. Patient preference was not accounted for. There was no validation of the receipt of surgery beyond the usual policies of the SEER registry, which are quite stringent: accuracy is ensured by checking the accuracy of sample cases by re-abstracting data from medical records every year. The completeness has been recorded as 98 percent.[97] The study is limited by the age and geographic constraints of the linked SEER-Medicare files.

O'Connell et al.[98] later assessed cancer-directed surgery rates in order to compare rectal cancer patient outcomes in younger and older patients using the SEER registry.

Hyman et al.[99] also measured the *curative resection rate* by utilizing a voluntary registry created by the Vermont chapter of ACS with the Vermont Program for Quality Health Care. The study did not specifically aim to compare quality of care among participating surgeons, but rather to compare quality of care with national benchmarks.

A better defined measure was *percentage of patients with colon or rectal cancer who had curative resection.*[100] Curative surgery in this 10-year retrospective study using a tumor registry was defined as surgery performed in the absence of documented spread. The well-defined measure was utilized to compare surgery rates and outcomes in black and white patients with CRC with some risk-adjustment. There were no significant differences in treatments received between black and white patients; but significantly worse survival was noted among black patients in spite of similar rates of chemotherapy and radiation treatments received by patients of the two races.

Tropman et al.[101] assessed the *rates of appropriate primary therapy (wide surgical resection and anastomosis) for CRC as defined by the NCI guidelines*. The denominator included patients with stages I-III colon cancer, all of whom should receive surgery in the absence of contraindications or refusal. Medical records and physician office records were used to collect data. The only addition that may be suggested is the documentation of patient preference for or against surgical treatment.

Govindrajan et al.[102] studied the impact of race on *rate of surgery in stage II and III colon cancer patients* in a small group of CRC patients over the period 1984-1994 in a single institution through a retrospective analysis of a hospital tumor registry. The numerator and the denominator were appropriately defined, and results were presented by location of the tumor and stage of the disease. The degree to which these results can be generalized is unknown, as is the quality of the data obtained from this registry.

Sphincter-Saving Surgery for Rectal Cancer. Schrag et al.[103] used the SEER-Medicare database to study *ostomy rates* after adjusting for various patient characteristics. The measure is well defined, risk-adjusted, and relevant. However, details regarding the tumor (e.g., size of tumor, distance from the anal verge) were not considered.

Hodgson et al.[104] utilized a similar measure, the *rate of colostomy for patients with rectal and rectosigmoid cancers*. The adequately defined measure was studied by examining the California Cancer Registry. The validity and risk-adjustment for this study was fair.

Morris et al.[105] used the SEER database to examine the *rate of sphincter-preserving operations*. However, this study did not allow the authors to examine the anatomical location of the tumor, which would influence the type of operation performed. The measure used precise specifications for including patients, and the data sources were fairly reliable. Risk-adjustment was not adequately performed.

A similar measure was used by Simons et al.,[106] who analyzed a regional cancer surveillance program registry (the quality of the registry is unknown) to study the *sphincter-saving procedure rate* for patients with different stages of rectal cancer. (The main predictor of interest was hospital volume, and the data set was matched by stage.) The numerator and the denominator were well defined.

In a recent study, Purves et al.[107] compared *rates of sphincter-saving procedures and abdomino-pelvic resections* among surgeons with varying caseload volumes. They utilized the 1997 Nationwide Inpatient Sample (NIS) and the Hospital Cost and Utilization Project (HCUP) databases; the measure was well defined, but the data sources had no information regarding tumor staging.

The NCQA[61] proposed the quality measure *percentage of rectal cancer cases that received a sphincter preservation procedure at time of surgery*. It was based on the NCCN guideline,[25] was well defined, and suggested that the data sources could be cancer registries and claims data.

Schrag et al.[108] followed 2,815 patients to assess the *abdominal perineal resection (APR) rates*. The denominator was all patients identified from the SEER-Medicare linked registry for 1992-1996, aged 65 years and older, with stage I-IV rectal cancer undergoing surgery and receiving FFS care. APR rates were compared by providers with different case volumes. A deficiency of this measure is that while APR is not the ideal procedure for most patients, it is clearly indicated for some. As currently constructed, the measure does not differentiate between those patients for whom APR is indicated.

Measures That Assess the Quality of Surgery for Colon and/or Rectal Cancer. Controlling for tumor stage, Read et al.[109] evaluated the impact of surgeon specialty on the extent to which patients experienced local tumor recurrence, or *local control rate*. Patients undergoing curative treatment for primary rectal adenocarcinoma with neoadjuvant radiotherapy followed by proctectomy were followed for 5 years using medical records, cancer registry, or physician/patient data. The measure was well specified and adjusted for tumor size and location.

One of the measures most often utilized to measure the technical quality of CRC surgery is whether the surgical specimen provided was sufficient to accurately stage the cancer. Such measures[13,54,61] are discussed under Question 1b (pathologic staging). This section will focus on measures that assess the complications and outcomes of surgery.

Measures That Assess the Complication Rates of Colon and/or Rectal Cancer Surgery. Patients greater than 80 years old with colon or rectal cancer during 1961-1987 from a single institution were studied by Coburn et al.,[110] who calculated the *postsurgical complication rate* (i.e., any complication), including anastomotic leak rates. Inpatient, outpatient, and office records were utilized as data sources. The measures were not clearly specified (e.g., the period within which postsurgical complications or leak rate would be assessed was not defined), and the ability to generalize to other data sources is uncertain.

Measures That Assess Intermediate Outcomes of Surgery for Colon and/or Rectal Cancer. *Thirty-day mortality* and *in-hospital mortality* are two intermediate outcomes that can assess the quality of surgery. However, important considerations for these measures are the comorbidity score and the stage of cancer. Unless these two factors are accounted for, these measures are unlikely to be valid. Another important consideration is the nature of the lesions: whether the lesions operated upon were obstructed or perforated is important to consider because these factors are associated with a higher risk of postoperative mortality.

Rabeneck et al.[111] assessed *30-day operative mortality rates* using the national VA patient treatment file. The measure is well-defined and compares mortality in elderly versus younger patients following surgical resection for colorectal cancer.

Coburn et al.[110] also assesses *30-day mortality* for patients who received operative treatment for colon and rectal cancer between 1961-1987. This measure is well defined using inpatient, outpatient, and office records as data sources. The study adjusted for obstructed and perforated lesions, but not for comorbidities.

Cooper et al.[93] performed a similar analysis using Medicare provider analysis and review files. Comobidities and nature of lesions were not considered.

Schrag et al.[103,108,112] compared *30-day mortality rates* for low- and high-volume hospitals. In several studies, they assessed the rates for colon cancer, rectal cancer, or both cancers. They adjusted for most confounders: stage and hospital volume, comorbid illnesses, age, sex, race, socioeconomic status, and acuity of hospitalization.

Hodgson et al.[104]also examined the impact of hospital volume on *postoperative (30-day) mortality rates* of patients diagnosed with rectal cancer stages I-III using state registries.

Temple et al.[95] restricted the measure to *30-day mortality for stage IV colon cancer*. Using the SEER database and Medicare claims data, they defined the measure precisely and adjusted for comorbidities. Whittle et al.[113] also used *perioperative mortality rate* for colon cancer patients enrolled in Medicare. The measure was not adjusted for by disease stage, comorbid factors, or emergency presentation, all which can affect peri- and postoperative survival rates.

A well-defined measure was used by Agarwal et al.[114] to assess *30-day operative mortality rate*, by analyzing a tumor registry from 1975 to 1980. Five-year survival distributions, as well as analyses by stage, were done to determine what factors influence operative mortality.

Dimick et al.,[115] Harmon et al.,[116] and Ko et al.[117] assessed *in-hospital mortality rates*. All of them defined the numerator and denominator appropriately. All of them adjusted for comorbid conditions, nature of admission (urgent versus emergent), age, and sex of patients. Dimick and colleagues[115] used the NIS for colon cancer resections to compare mortality by hospital volume. Harmon et al.[116] utilized Health Services Cost Review Commission (HSCRC) data, and Ko and colleagues[117] used the NIS to examine both hospital and surgeon volume impact on mortality rates.

Conclusions

Ratings for the measures described here are given in Table 6; further details are provided in Evidence Tables 5 and 6 in Appendix E[*]. The most basic measure of the quality of surgical management is whether surgical therapy is provided as appropriate to the location and stage of the cancer. Results could potentially be broken out by stage or presented as a single summary measure, *rates of appropriate primary therapy for CRC as defined by the NCI guidelines* ($I_4S_4T_4$). Regarding the denominator of this measure, patients for whom the therapy is inappropriate should be excluded. This point is particularly problematic for patients with stage IV colon or rectal cancer, for whom the intent of the surgery is palliation rather than cure. Ideally, the measure should also distinguish between patients who were offered "appropriate" surgery and refused, and those patients who were not offered such surgery. Making these

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

distinctions increases the data collection demands (e.g., although sometimes included within registries, such information is not included in the typical administrative database).

Surgical complication rates are another very natural measure. Most variations on this measure focus on *mortality rates* (e.g., 30-day mortality [$I_5S_4T_5$], in-hospital mortality [$I_5S_3T_3$]), although a delineation of the actual complications would be helpful as well, this latter type of measure being relatively underdeveloped. Presumably, such a measure should be both stratified by stage and location, and also risk-adjusted to take into account other clinical characteristics of the patient.

For patients with rectal cancer, various measures have been proposed regarding the *rate of sphincter-saving surgery* ($I_5S_4T_4$). This is an outcome of importance to patients. However, quality measures should consider detailed information about the anatomical location and other characteristics of the tumor, which is not yet the case in practice.

Technical measures associated with surgery are underdeveloped.

The recommendations made herein are based on a review of currently available data. Obviously, future data or clinical realities (e.g., costs, changes in societal goals) or the development of new technologies may alter the recommendations in the future. Nonetheless, for the major recommendations, we do not expect their basic core importance to change. For example, no matter how surgery changes technically, it will not be able to cure all stage III patients.

Table 6. Quality measure ratings – Question 2b

Quality measure	**Quality measure rating (range 1-5, where 1 = poor and 5 = ideal)**			**Recommendations for the measure**
	Important and usable (I)	**Scientifically acceptable (S)**	**Well tested (T)**	
General measures				
Non-receipt of surgery[87]	5	4	4	Data sources should include stage and location of tumor.
Surgical resection rates[91,93]	5	4	4	Data sources should include stage and location of tumor.
Percentage of stage III colon cancer patients receiving surgery and chemotherapy[71]	4	3	2	Needs testing.
Percentage of CRC patients who underwent cancer-directed surgery[94-96,98]	4	3	3	"Cancer-directed surgery" needs to be defined with reference to a guideline.
Metastastectomy rate for rectal cancer[95]	4	3	2	Needs testing.
Curative resection rate[99,100]	5	3	4	"Curative resection" needs to be accurately defined.
Rate of appropriate primary therapy for CRC as defined by the NCI guidelines[101]	4	4	4	-

Table 6. Quality measure ratings – Question 2b – continued

Quality measure	Quality measure rating (range 1-5, where 1 = poor and 5 = ideal)			Recommendations for the measure
	Important and usable (I)	Scientifically acceptable (S)	Well tested (T)	
Percentage of colon cancer patients (stages specified as 0-III or I-II or II & III) who underwent surgery[102]	5	2	1	Needs to be precisely defined.
Ostomy rates[103,104]	5	4	5	Details need to include the precise preoperative measurement of the tumor from the anal verge, the assessment of the tumor's involvement of the anal sphincter complex, the "fixed" nature of the tumor, preoperative sphincter function of the patient, the body habitus of the patient, and finally the patient's preference for kind of surgery performed.
Percentage of rectal cancer cases receiving a sphincter preservation procedure at time of surgery[61,105-107]	5	4	4	Details need to include the precise preoperative measurement of the tumor from the anal verge, the assessment of the tumor's involvement of the anal sphincter complex, the "fixed" nature of the tumor, preoperative sphincter function of the patient, the body habitus of the patient, and finally the patient's preference for kind of surgery performed.
Abdominoperineal resection (APR) rate[108]	5	4	4	Details need to include the precise preoperative measurement of the tumor from the anal verge, the assessment of the tumor's involvement of the anal sphincter complex, the "fixed" nature of the tumor, preoperative sphincter function of the patient, the body habitus of the patient, and finally the patient's preference for kind of surgery performed.
Local control rate[109]	4	4	4	Depends to some degree on management subsequent to surgery.

Table 6. Quality measure ratings – Question 2b – continued

Quality measure	Quality measure rating (range 1-5, where 1 = poor and 5 = ideal)			Recommendations for the measure
	Important and usable (I)	Scientifically acceptable (S)	Well tested (T)	
Complication rate[110]	5	3	2	Complications include anastomatic leak rate.
30-day mortality rate[93,95,103,104,108,110-114]	5	4	5	Comorbid illnesses, tumor biology, tumor location and stage, perioperative care may all affect 30-day mortality rate.
In-hospital mortality rate[115-117]	5	3	3	Time frame under consideration needs to be precisely defined. Several factors apart from the quality of surgery could contribute to mortality.

Note: Investigators used their judgment to determine the quality measure rating for each measure across all studies that utilized the measure. See Appendix F* for details.

Future Research

Staging Workup. Considering the relevance of an appropriate staging workup and the availability of NCI guidelines defining it, quality measures that assess this workup would be appropriate.

Appropriate Primary Therapy for Stage IV CRC. Although the NCI standards have been used effectively for stage I-III colorectal cancers, there does not seem to be a consensus on the effectiveness, timing, or type of surgery that should be performed on a patient with metastatic disease. The reason for this may be multi-factorial, including physicians' historic pessimism, the heterogeneous nature of stage IV disease (e.g., ranging from a single liver metastasis to carcinomatosis), the risk of obstruction, and the use of new highly potent chemotherapy agents. At present, this heterogeneity greatly complicates the use of quality measures based on anything but data sources that describe in detail both the patient's clinical condition and preferences. The question of metastasectomy for patients with stage IV CRC remains controversial. Future research should focus on determining appropriate management modalities for stage IV CRC. Quality measures can only be developed subsequent to this research.

Improvement in Sphincter-Preserving Data. Following complete oncologic resection, sphincter-preservation remains an important aspect of rectal surgery for the patient. However, the current data comparing sphincter-preserving operations to APRs reveal very high APR rates. However, these data often lack critical details, including the precise preoperative measurement of the tumor from the anal verge, the assessment of the tumor's involvement of the anal sphincter

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* Appendixes cited in this report are provided electronically at
http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

complex, the “fixed” nature of the tumor, preoperative sphincter function of the patient, the body habitus of the patient, and finally the patient’s preference for kind of surgery performed. Ideal measures should account for all these aspects that lead to decisions regarding APR.

Anastomotic Leak Rates. Quality measures need to be developed to determine what factors influence this potentially life-threatening risk following colon or rectal excision. In regards to rectal cancer, numerous factors may affect the leak rates, including comorbid illnesses, obesity, and use of preoperative chemoradiation. Finally, surgical experience and potential volume/outcome measures could be examined for relationship to this complication rate.

Recurrence Rates Following Resection of CRC. For colon cancer, recurrence rates may be influenced by the number of lymph nodes harvested during the colectomy. With rectal cancers, the use of TME has clearly decreased the local recurrence rates; however, the margin that should be considered adequate is controversial. Twenty years ago, the surgical dictum was to obtain a 5 cm margin; however, within the last 10 years, this has been reduced to a 2 cm margin, and now even this distance is being questioned. There clearly is a need for a well-constructed trial to examine this critical surgical issue, the results of which could lead to specifying the optimal surgical margins as part of a quality measure.

Improvement in Quality of Rectal Surgery. Quality measures need to be developed to ascertain that the operation was performed according to the principles of TME and the specimen retrieved is ideal.

Complications of Rectal Cancer Surgery Due to the Use of Neoadjuvant Therapy. Although several recent studies demonstrate no apparent increase in surgical complications with the use of preoperative chemoradiation, newer and potentially more toxic approaches may further complicate this already difficult procedure. If so, this should be accounted for by quality measures. Bladder and sexual dysfunction also need to be assessed, although recent evidence indicates that these complications may be multifactorial, with radiation playing a much larger role.[118-122]

Appropriate Treatment for T1 Rectal Cancer. This is very controversial. Recommendations vary from transanal excision with or without chemoradiation to proctectomy. Unless there is adequate research leading to consensus regarding treatment, no quality measure can be developed in this area.

Question 2c: Adjuvant Chemotherapy

Question 2c was: As appropriate to specific stages of colorectal cancer, what quality-of-care measures are available and what evidence is available for measures of quality care of treatment of colorectal cancer, including appropriate use of adjuvant chemotherapy and adjuvant radiation therapy, including for patients with metastatic but potentially curable (hepatic/pulmonary-resectable) disease?

Background

In responding to this question, we extended the original patient population to include patients with metastatic but potentially curable (hepatic/pulmonary-resectable) disease. We also extended the definition of adjuvant therapy to include chemotherapy, radiation therapy, and their combination.

We identified a number of measures that have been utilized to assess the appropriate use of adjuvant chemotherapy. Each measure takes the form of a numerator describing the number of eligible patients receiving some form of adjuvant therapy (e.g., adjuvant chemotherapy, adjuvant chemotherapy plus radiation therapy) divided by a denominator describing the number of patients in whom the treatment is indicated. The 1990 National Institutes of Health (NIH) Consensus Guidelines state that patients with stage II and III rectal cancer should receive adjuvant chemotherapy plus radiation therapy, whereas patients with stage III colon cancer should receive chemotherapy alone.[15] Although most of the quality measures regarding appropriate use of adjuvant chemotherapy and radiotherapy for patients with colorectal cancer used the 1990 NIH consensus guidelines as a benchmark, it is important to note that these guidelines may no longer represent state-of-the-art treatment for all patients. For example, for carefully selected patients with T1-2N1 or T3N0 rectal cancer, some authorities have suggested that omission of adjuvant radiation therapy be evaluated in clinical trials.[123] More recent recommendations from the American Society of Clinical Oncology say that adjuvant chemotherapy might also be clinically reasonable, on a case-by-case basis, for patients with stage II colon cancer.[23] The NCCN guidelines state that both chemotherapy and radiation therapy might be considered for palliation of patients with stage IV rectal cancer,[25] and chemotherapy plus monoclonal antibodies (cetuximab and bevacizumab) as palliation for patients with stage IV colon cancer,[24] at least among those patients that can tolerate these therapies. Regarding resected stage IV colorectal cancer, the NCCN guidelines also state that patients who have completely resected liver metastases should be offered 6 months of adjuvant chemotherapy.

Regarding the denominator, there is considerable variation in stage of cancer: this includes reporting the results of stages I, II, III, and IV separately; limiting consideration to a single stage (e.g., stage III); grouping stages II and III; and grouping stages into local (stages I and II), regional (stage III), and distant (stage IV). Some measures focus on colon cancer only, some focus on rectal cancer only, and some focus on colorectal cancer without differentiating between the two. The best approaches are to focus on a single location and stage (e.g., stage III colon cancer) or to present the data disaggregated by location and stage (e.g., stage I rectal cancer, stage I colon cancer, and stage IV colon cancer). It is also reasonable to combine those circumstances where the guideline recommendation is the same (e.g., stage II rectal cancer and stage III rectal cancer). The approach to be avoided is the grouping of circumstances for which the guideline recommendation differs (e.g., the recommendation for stage III rectal cancer is chemotherapy plus radiation therapy, while the recommendation for stage III colon cancer is chemotherapy only, so the grouping of stage III CRC should be avoided).

It should be noted that there is substantial overlap in the measures considered under Questions 2c and 2d. As an organizing principle, all general measures that described chemotherapy and/or radiation therapy are included under Question 2c. The primary focus under Question 2d is technical measures pertaining to radiation therapy (regardless of whether this radiation therapy is given with chemotherapy).

Results

Measures That do not Specify Stage and/or Location. A few versions of the basic measures do not specify stage of disease. Because the clinical issues are so different among patients with different stages of disease, measures that do not explicitly include stage cannot be recommended. Examples include Dominitz et al.,[88] which used an administrative database that did not include information on stage, the National Patient Treatment File from the Department of Veterans Affairs. This was also attempted by Wudel et al.[100] in a circumstance where the sample size was too small to subdivide patients by stage. Coia et al.[124] used the Patterns of Care Study database, a nationally based sample of patients receiving radiation therapy during 1988, to inquire how many patients receiving radiation for cancer of the colon or the rectum also received surgery. Beginning with the subset of patients receiving radiation, rather than all patients with disease of a certain stage, makes the measure impossible to map back to an inception cohort of all patients with a certain stage of disease, and thus difficult to interpret. Coburn et al.[110] analyzed the effect of age on the provision of adjuvant therapy, but did not break out the analysis by stage (or provide a precise description of the database used).

Measures That Use Suboptimal Combinations of Stage and/or Location. The measure by Newcomb and Carbone[86] makes an inadequate differentiation between types of cancer, using the categories of local, regional, and distant colorectal cancers, with colon and rectal cancers grouped (i.e., the measure does not recognize that the guideline recommendations within the category "regional" differ according to location and stage). Stage was based on a state tumor registry, and adjuvant therapy was based on patient report (which is unvalidated). This version of the basic adjuvant therapy measure is not recommended.

The measure by Govindarajan et al.[102] also makes an inadequate differentiation between types of cancers. Medical records of patients with stage II or III colon or rectal cancer treated at a hospital in Arkansas between 1984 and 1997 were used to report the numbers receiving surgery, radiation, and chemotherapy. Not only were the data for stages and locations with different guideline recommendations combined, it was not possible to tell how many patients had, for example, both surgery and radiation (e.g., the number of patients with surgery, regardless of radiation status, is presented). This approach is not recommended.

Rogers et al.[90] identified patients with CRC from Tennessee Medicare and Medicaid files over the period 1984-1994. The primary intention was the elucidation of racial differences in processes and outcomes of care, including the use of chemotherapy, in stage III colorectal cancer. Moreover, there was no validation of the very low use of adjuvant therapy against medical records, suggesting that these administrative data files might not have been appropriate for this purpose. Combining stage III colon cancer and stage III rectal cancer is suboptimal, and this measure is not recommended.

NCQA[61] described the measure *percent of late stage (stage ≥ III) colon cancer patients that received one or more courses of adjuvant chemotherapy within 1 year of initial cancer surgery* and specified the window for receiving adjuvant therapy (to allow inclusion of therapy up to 1 year from surgery), the stages of colon cancer when adjuvant therapy is administered (stage III and greater), and the number of courses of chemotherapy. A potential problem with this measure is that adjuvant therapy for resected stage IV patients is not a standard recommendation because there is not universal agreement on its benefits, so application of this measure could lead to the impression that too few patients are receiving adjuvant therapy.

Measures for Stage IV Colorectal Cancer. Temple et al.[95] followed patients identified from the SEER-Medicare linked registry for 1991-1996, aged 65 years and older, with stage IV colon or rectal cancer, enrolled in a FFS health plan. Patients were cross-classified according to the use of primary-cancer-directed surgery, chemotherapy, and radiation therapy. The use of adjuvant chemotherapy, with or without radiation therapy, might be considered to be a potential quality measure, although it is not supported by a guideline that suggests that this strategy is likely to be beneficial for all patients. In particular, this is a decision that should be made on a case-by-case basis in consideration of the characteristics of the tumor, comorbidities (e.g., the poor performance status of many patients would preclude the use of chemotherapy), and patient preferences. The most reasonable application of such a measure would be in a database that includes a record of those cases where a physician considered the potential application of adjuvant therapy, but in consultation with the patient decided against it. In the absence of such information, this is not a version of the basic quality measure that can be strongly recommended.

Measures for Stage III Colon Cancer. Potosky et al.[125] followed patients in the SEER registry (1990-1991 and 1995), aged 21 and above, who had completed surgery. For approximately 81 percent of sampled cases, the offer or administration of adjuvant therapy was verified by physician contacts. The authors note that "doctor verification significantly improves the completeness of chemotherapy ascertainment because adjuvant chemotherapy is frequently given outside the hospital setting, and a note of any planned chemotherapy is typically not reported in the hospital record." The numerator was the number of patients "offered, recommended or administered adjuvant 5-Fluorouracil (5-FU) plus levamisole or leucovorin." This version of the measure reflects physician intention rather than actual receipt of therapy, since patients that are offered but refuse the therapy are nevertheless included in its numerator. Adjuvant chemotherapy use was broken out by various sociodemographic characteristics. The study does not explicitly validate the quality measure.

Hyman et al.[99] reported data from a surgeon-initiated registry in Vermont during 1999-2001. The measure is the *number of stage III colon cancers that were offered referral for adjuvant therapy*. Because this is a prospectively collected registry, this information is likely to be collected with particularly high accuracy. The degree to which this database can be generalized is uncertain.

Mahoney et al.[126] followed 69 patients identified from a New Jersey tumor registry for 1989-1996 with stage III colon cancer and focused on a chart-based examination of the reason that adjuvant chemotherapy might not be provided. Of 35 patients not receiving chemotherapy therapy, 12 were not offered such therapy, 11 refused, 7 were too old, and 5 had significant concomitant disease. Although a small study, this provides support for the notion that administrative databases will understate provider compliance with guidelines by omitting information that might document that this therapy was either offered but declined, or else might not have been clinically appropriate.

Ayanian et al.[127] followed patients identified from three regional registries within the California Cancer Registry during 1996-1997 who were 18 or older, with stage III adenocarcinoma of the colon, surviving at least 30 days postsurgery. Information about adjuvant therapy was obtained from physician surveys and office records. The numerator of the quality measure was the number of patients receiving adjuvant chemotherapy. The study does not validate the quality measure, but does include some validation of the data sources. The sensitivity of routinely collected registry on receipt of chemotherapy (i.e., using medical record review as the gold standard) was 87 percent. Various sociodemographic characteristics were considered. Results from a single state registry might not reflect national patterns of care.

Schrag et al.[103,112,128] followed patients identified from the SEER-Medicare linked registry for 1991-1996, aged 65 years and older, with stage III colon cancer, enrolled in a FFS health plan and surviving at least 3 months. The numerator was the number of these patients who received chemotherapy within 3 months of surgery. Among others, the impacts of age, race, and hospital volume were considered. There was no validation of the receipt of chemotherapy beyond the usual policies of the SEER registry, although an unpublished reference asserting that the SEER data has 90 percent sensitivity for identifying the use of chemotherapy was cited. The study is limited by the age and geographic constraints of the linked SEER-Medicare files.

Sundararajan et al.[129] followed patients identified from the SEER-Medicare linked registry for 1992-1996, aged 65 years and older, with stage III colon cancer, enrolled in a FFS health plan and surviving at least 4 months. The numerator was the number of patients receiving 5-FU within 4 months. Strengths and weaknesses of the measure are essentially identical to the discussion of Schrag et al. above.

Keating et al.[130] utilized SEER-Medicare linked data for 1993-1999 and followed patients aged 66 years and above, with stage III colon cancer, who were enrolled in FFS Medicare Parts A and B. The numerator was the number of patients who received adjuvant chemotherapy. County-specific utilization rates were calculated and compared according to market share of FFS plans versus HMOs. The study does not validate the quality measure and is limited by the age and geographic constraints of the SEER-Medicare linked files. Use of adjuvant chemotherapy is not validated against medical records (with the exception of the usual SEER Registry procedures) and might be underestimated.

Beart et al.[48] presented a similar analysis, subdivided by both location and stage, for patients treated in 1983 and 1988 in the national survey of the Commission on Cancer, a nationally based survey including up to 25 cases per hospital per year. The numerator was the number of patients receiving chemotherapy, of all stage III colon cancer patients.

Tropman et al.[101] followed patients identified from tumor registries in North and South Carolina during 1991 and 1996 and supplemented by review of medical records. The numerator was the number of patients that were treated with the consensus-based guidelines at the time of the cancer. This application was otherwise unremarkable.[131]

The Colon Cancer Workgroup[54] attempted to refine the numerator of the basic quality measure further by specifying “lymph node positive colon cancer” instead of using the terminology “stage III.” Specifically, the measure is defined by the declarative statement “adjuvant chemotherapy is administered to patients with lymph node positive colon cancer.” It is noted that older patients and those patients with many comorbidities might be poor candidates for chemotherapy. This refinement of the basic measure was not explicitly validated beyond the argument for its face validity.

The IOM, in *Assessing the Quality of Cancer Care*,[13] described the measure *adjuvant chemotherapy after surgery for stage III colon cancer*. It is well defined: “number of patients with stage III colon cancer who receive a full course of adjuvant chemotherapy after surgery, divided by the number of node-positive stage III patients who undergo surgery.” The rationale is as before, the primary distinction being the basis of the measure in the more recent 2005 guidelines from the NCCN.[24]

Measures for Stages II and III Rectal Cancer. Ayanian et al.[127] followed patients identified from three regional registries of the California Cancer Registry during 1996-1997 who were 18 or older, with stage III adenocarcinoma of the colon, surviving at least 30 days postsurgery. Information about adjuvant chemotherapy and radiation therapy was obtained from physician surveys and office records. The numerator of the measure was the number of patients receiving both adjuvant chemotherapy and radiation therapy. The study does not validate the quality measure, but validates the data sources. The sensitivity of routinely collected registry data for whether patients actually received chemotherapy was 87 percent, while the sensitivity for radiation therapy was 93 percent. Various sociodemographic characteristics were considered. Results from a single state registry might not reflect national patterns of care.

Keating et al.[130] utilized SEER-Medicare linked data for 1993-1999 and followed patients aged 66 years and above, with stage II or III rectal cancer, who were enrolled in FFS Medicare Parts A and B. The numerator was whether patients received adjuvant chemotherapy and radiation therapy. County-specific utilization rates were calculated and compared according to market share of FFS versus HMOs. The study does not validate the quality measure and is limited to the age and geographic constraints of the SEER-Medicare linked files. Neither adjuvant chemotherapy nor radiation therapy was validated against medical records (with the exception of the usual SEER Registry procedures), and might be underestimated.

Schrag et al.[132] followed patients identified from the SEER-Medicare linked registry for 1992-1996, aged 65 years and older, with stage II or stage III rectal cancer, enrolled in a FFS health plan and surviving at least 4 months. Two versions of the numerator were given: the number of these patients who received adjuvant chemotherapy (with 5-FU) and radiation therapy within 4 months of surgery, and the number of these patients that received radiation alone; the number of patients receiving adjuvant chemotherapy alone was also noted. Among others, the impacts of age and race were considered. There was no validation of the receipt of chemotherapy and radiation therapy beyond the usual policies of the SEER registry, so it is possible that these are underreported. Results are also presented separately by stage. The analysis recognizes that radiation might be given preoperatively, thus making the distinction between preoperative and postoperative use of radiation therapy. The study is limited by the age and geographic constraints of the linked SEER-Medicare files.

Hyman et al.,[99] mentioned above, reported data from a surgeon-initiated registry in Vermont during 1999-2001. The measure is the *number of stage II or stage III rectal cancers that were offered referral for adjuvant therapy*. Presumably, this would be the stage at which radiation therapy would be considered as well, although it was not precisely specified whether this adjuvant therapy included chemotherapy, radiation therapy, or both. Because this is a prospectively collected registry, this information is likely to be collected accurately. The degree to which this database can be generalized is uncertain.

Potosky et al.[125] followed patients in the SEER registry (1990-1991 and 1995), aged 21 and above, who had completed surgery. The numerator was the number of patients “offered, recommended or administered adjuvant 5-FU plus levamisole or leucovorin.” For approximately 81 percent of sampled cases, the offer or administration of adjuvant therapy was verified by physician contacts. While the data were presented separately according to whether the numerator was the number of patients receiving chemotherapy only, the number of patients receiving radiation therapy alone, or the number of patients receiving both, the authors considered the primary quality measure to be the receipt of chemotherapy (i.e., regardless of radiation). Adjuvant chemotherapy use was broken out by various sociodemographic characteristics. The study does not explicitly validate the quality measure.

Neugut et al.[133] followed patients identified from the SEER-Medicare linked registry for 1992 and 1996, with stage II or stage III rectal cancer, enrolled in a FFS health plan and surviving at least 4 months. The numerators of the potential measures were the number of patients receiving chemotherapy only, the number of patients receiving radiation therapy alone, and the number of patients receiving both. Among others, the impacts of age, sex, and race were considered. There was no validation of the receipt of chemotherapy and radiation therapy beyond the usual policies of the SEER registry, so it is possible that these are underreported. Results are also presented separately by stage. The study is limited by the age and geographic constraints of the linked SEER-Medicare files.

Reports That are Disaggregated by Stage and Location (or Stage Only). Any report that disaggregates results by location and stage has the potential to create a quality measure for each available subgroup. For example, Steele et al.[131] uses data on colon cancer cases from the NCDB during 1985, 1988, and 1990; breaks this out into stage 0, stage I, stage II, stage III, and stage IV; then classifies treatment as surgery only, surgery and chemotherapy, surgery radiation and chemotherapy, other, and none. An example of a possible quality measure is *the number of patients with stage III cancer receiving surgery and chemotherapy*. Steele[71] presents a similar analysis using both colon and rectal cancer patients (i.e., subdivided by both location and stage) from 1991, as does Steele[134] using patients from 1992. Jessup et al.[135] presents a similar analysis of this data base for the years 1986, 1987, 1988, 1990, 1991, 1992, and 1993. Participation in the NCDB is voluntary and thus has the potential to skew the results in the direction of overstating performance.

Beart et al.[48] presents a similar analysis, subdivided by both location and stage, for patients treated in 1983 and 1988, in the national survey of the Commission on Cancer, a nationally based survey including up to 25 cases per hospital per year.

Roetzheim et al.[94] presents a similar analysis, subdivided by location and stage (but not both), for patients treated in 1994, from Florida’s statewide cancer registry. Because the guidelines recommendations for stage III colon cancer differ from those of stage III rectal cancer, it would have been preferable to disaggregate the analysis by both location and stage.

Retchin and Brown[136] collected data using medical record review by nurse abstractors (for a comparison of HMO versus FFS, after first identifying potential cases from administrative files), and disaggregated the data by stage but not location and stage. Inter-rater reliability of the abstraction was assessed, as was a comparison versus a sham chart. Because the guideline recommendations for stage III colon cancer differ from those of stage III rectal cancer, it would have been preferable to disaggregate the analysis by both location and stage.

Other: Intermediate Process Measures. A quality measure developed by Oliveria and colleagues[137] is *referral to a medical oncologist for consideration of adjuvant chemotherapy*. This intermediate process measure is indirectly based on the 1990 NIH Consensus Statement on chemotherapy utilization in stage III disease.[15] Since most chemotherapy is administered by medical oncologists, “referral to a medical oncologist” is a first step in assuring compliance with this guideline. The denominator consists of members of a Massachusetts HMO newly diagnosed with CRC from 1997 to 1999. For purposes of assessing chemotherapy utilization, the analysis was performed by stage. The numerator is the subset of these patients referred to a medical oncologist within 4 months of surgery. Data were obtained from the computerized database of the HMO. The study does not specifically validate the quality measure, but reliability of the data sources was ascertained by reviewing medical records to confirm data in the computerized database. The study is limited by the use of data from a single HMO.

Conclusions

With the exception of the intermediate process measure described by Oliveria et al.,[137] all the measures we identified took the form of *number of patients receiving one or more forms of adjuvant therapy divided by the number of patients with some form of CRC*. Not all of these measures were applied in a formal quality improvement context; for example, for the purpose of documenting national patterns of care, Steele[71,131] cross-classifies the universe of CRC patients into all possible combinations of location and stage, then for each of these possible combinations reports the number of patients receiving adjuvant chemotherapy, adjuvant radiation therapy, both chemotherapy and radiation therapy, and so forth. These potential quality measures more closely approximate actual quality measures when an additional analytical step is taken; that is, to select (e.g., based on guidelines) for its numerator the most appropriate item from the list of possible adjuvant therapies. (For example, the appropriate numerator for patients with stage III colon cancer is the number of patients receiving adjuvant chemotherapy).

Our presentation is organized according to the denominator of the quality measure (e.g., measures for patients with stage III colon cancer). Measures having certain denominators will not be formally rated. In particular, when an investigator uses as the denominator every possible combination of location and stage then (so long as the numerator is also reported at a high level of detail) the reader has complete freedom to define whatever quality measure is desired. We also do not formally rate those measures that fail to specify stage and/or location, or else specify suboptimal combinations of stage and/or location (here, the former is an example of the latter). The most typical such combination of a stage and location involves the grouping of circumstances for which the guideline recommendation differs (e.g., the recommendation for stage III rectal cancer is chemotherapy plus radiation therapy, while the recommendation for stage III colon cancer is chemotherapy only, so the grouping of stage III colorectal cancer should be avoided).

With this in mind, we considered measures for stage III colon cancer, stages II and III rectal cancer, and stage IV colorectal cancer. Roughly speaking, these measures were defined as the *proportion of patients with stage III colon cancer receiving adjuvant chemotherapy* ($I_5S_4T_5$), the *proportion of patients with stages II or III rectal cancer receiving chemoradiotherapy* ($I_5S_3T_2$), and the *proportion of patients with stage IV colon cancer or stage IV rectal cancer receiving palliative chemotherapy* ($I_5S_3T_2$).

Of these measures, perhaps the best developed and best-tested measure applies to patients with stage III colon cancer. It is derived from an evidence-based recommendation.[15,138-140] Various investigators have attempted to fine-tune the measure; for example, by further defining stage III as lymph node positive, by specifying the maximum time between surgery and the receipt of adjuvant therapy, and so forth. Such enhancements seem clinically plausible and follow the principle that quality measures should be specified as precisely as possible, but they do not change the basic nature of the measure. In particular, applications that use slightly different approaches to specifying the above details should be sufficiently comparable for most practical purposes.

Perhaps more salient are other features of the measure and/or the databases from which this measure can be estimated. In particular, because chemotherapy is often administered on an outpatient basis, administrative inpatient databases tend to underestimate the number of patients that receive chemotherapy. Some investigators have supplemented the use of administrative databases by contacting the treating physician directly, although it must be acknowledged that such an approach is costly and time-consuming. At the very least, users of administrative databases should either find or generate some estimate of the likely number of patients for whom the administration of chemotherapy will be missed.

Another important distinction applies to the difference between the numbers of patients receiving adjuvant chemotherapy, the greater number of patients who are offered this therapy, and the (perhaps) still greater number of patients who should be offered this therapy. In some quality measurement applications the appropriate numerator is the number of patients for whom the recommended therapy is offered, for others it is the number of patients for whom this therapy is actually received. A significant number of patients refuse chemotherapy when offered. Moreover, failure to consider the number of patients who should be offered this therapy can potentially bias the comparison between groups; for example, one explanation for the lower rate of utilization of adjuvant chemotherapy among older patients is that poorer functional status is more likely to preclude its use. Comorbidities, particularly including the presence of post-operative complications, should also be considered. Investigators that work with administrative databases can probably do no better than to use standard techniques of risk-adjustment, while at the same time recognizing that these techniques cannot capture all the nuances of clinical decisionmaking. When data are collected prospectively, the ideal is to document each component of the decision: whether and why each patient was considered by the physician to be eligible or ineligible for adjuvant chemotherapy, whether this therapy was offered, whether this therapy was accepted, and whether this therapy was completed.

With the above background in mind, it can be noted that the quality measure *proportion of patients with stage III colon cancer receiving adjuvant chemotherapy* ($I_5S_4T_5$) is important, represents a significant leverage point in the care of patients that is strongly associated with outcomes, and has been used in various applications such as comparing quality of care provided over years of diagnosis, clinical variables of the condition, sex, age, race, marital status, median income of patients, geographic regions of the country, and across health care delivery systems.

Also evidence-based and well validated is the measure assessing the *percentage of patients with stages II and III rectal cancer receiving chemoradiotherapy* ($I_5S_3T_2$). Most considerations are similar to those for stage III colon cancer and are not repeated here. For stages II and III rectal cancer, somewhat different versions of the measure have been created. As discussed under Question 2d, the ideal version of the measure is the one that most closely matches the most recent recommendations from guidelines, which specify that chemoradiotherapy is the preferred method of management for essentially all such patients.

The measure *proportion of patients with stage IV colon cancer or stage IV rectal cancer receiving palliative chemotherapy* ($I_5S_3T_2$) is reasonable in principle, but suffers from the difficulty that the decision to provide this therapy should very much be made on a case-by-case basis, thus implying that prospective data collection is probably necessary.

The measure on the *proportion of patients referred to an oncologist* ($I_5S_3T_2$) pertains to an important leverage point in practice, although it must be admitted that this is neither a necessary nor a sufficient condition for the provision of high-quality care. Thus, the relationship between the quality measure and outcomes, while plausible, seems less direct that is the case for the other measures in this section.

Final ratings for these measures are summarized below in Table 7; further details are provided in Evidence Tables 7 and 8 in Appendix E*.

The recommendations made herein are based on a review of currently available data. Obviously, future data or clinical realities (e.g., costs, changes in societal goals) or the development of new technologies may alter the recommendations in the future. Nonetheless, for the major recommendations, we do not expect their basic core importance to change. For example, the need for adjuvant therapy for stage III colon cancer is unlikely to change.

Table 7. Quality measure ratings – Question 2c

Quality measure	**Quality measure rating (range 1-5, where 1 = poor and 5 = ideal)**			**Recommendations for the measure**
	Important and usable (I)	**Scientifically acceptable (S)**	**Well tested (T)**	
General measures				
Percentage of patients with stage III colon cancer receiving adjuvant chemotherapy[13,54,71,103,112,126,128,129,131,134,135]	5	4	5	Quality of the data needs to be ensured. The importance of patient preferences is elucidated in the studies.
Percentage of patients with stage II or III rectal cancer receiving chemoradiotherapy[132]	5	3	2	Guidelines for adjuvant therapy for colon and rectum cancers are distinct; measures need to be distinct, too. Needs to account for possible reasons for non-receipt of therapy (e.g., insurance coverage or patient preference).
Percentage of patients with stage IV colon cancer or stage IV rectal cancer receiving palliative chemotherapy[95,136]	5	3	2	Additional testing of quality measure required; risk-adjustment is especially important. Further development and testing needed.
Percentage of patients referred to medical oncologist for consideration of adjuvant chemotherapy[137]	5	3	2	Testing needed with more studies.

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

Table 7. Quality measure ratings – Question 2c – continued

Quality measure	Quality measure rating (range 1-5, where 1 = poor and 5 = ideal)			Recommendations for the measure
	Important and usable (I)	Scientifically acceptable (S)	Well tested (T)	
Percentage of patients with stage III colon and stage II and III rectal cancer receiving adjuvant chemotherapy[48,90,99,125,127,130]	5	4	4	Quality of the data needs to be addressed. Studies address the need for validation of registry data with office records. Risk-adjustment is important, and patient preference should be accounted for.
Rate of adjuvant chemotherapy for CRC[86,88,94,100-102]	5	3	3	Measures for colon and rectal cancer need to be distinct.
Percentage of patients receiving adjuvant radiotherapy who also received adjuvant chemotherapy for cancer of the sigmoid colon or rectum[124]	4	3	2	More extensive testing is required (in conjunction with measures for radiation therapy).
Adjuvant therapy rates[110]	5	3	2	More testing to be conducted from more recent data.
Use of chemotherapy in Stage II and III rectal patients[131,133,134]	5	3	3	Quality measure to be tested with more studies, with patient preference taken into account, and with risk-adjustment for comorbidities.
Percentage of late stage rectal cancer (stage ≥ III) that received one or more courses of adjuvant chemotherapy within 1 year of initial cancer surgery[61]	5	4	-	Testing needed on whether specifying "late stage (stage ≥ III)" produces similar results as specifying "stage III" because there is no agreement on use of adjuvant chemotherapy for stage IV.

Note: Investigators used their judgment to determine the quality measure rating for each measure across all studies that utilized the measure. See Appendix F[*] for details.

Future Research

Our recommendations for future research involve better definitions of the measures discussed above and development of new measures.

Regarding the quality measure *adjuvant chemotherapy administered to patients with lymph node positive colon cancer patients*, it is important to determine if the same number of cases will

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

be found for the numerator as would be found if “stage III” or “regional disease” is used to define these patients.

Regarding the quality measure *use of adjuvant chemotherapy for stage III colon cancer*, the ideal denominator would be patients with stage III colon cancer, who have had a complete surgical resection, and who have no contraindications to chemotherapy or severe comorbidities. Two possible ideal numerators arise. The first is the number of individuals offered chemotherapy, and the second is the number of individuals who received chemotherapy. More research would need to focus on determinants of actually receiving chemotherapy among patients offered chemotherapy. Also, research should center on which of the two numerators yields a better indicator of quality care. Furthermore, for the measure to be useful, adequate documentation must be available. Most databases discussed above do not take into account the fact that some patients will decline the offer of chemotherapy. More research is necessary on how to best derive data for whether chemotherapy was offered and received.

The receipt of chemotherapy is only a surrogate marker for whether patients received the correct agents, dose, and schedule. Data in breast cancer and lymphoma therapy demonstrate that inadequate dose intensity leads to inferior outcomes. While these data are not available for CRC, it is possible that similar observations would be made. Research on the ideal measure of “proper chemotherapy administration” is necessary. Further study is necessary on whether a global measure of chemotherapy adequacy (dose intensity) or individual measures (adequate dose, adequate frequency, adequate duration) is preferred.

The toxicities of chemotherapy can be substantial, and mortality is reported. Measures of the quality of chemotherapy could include the rate of toxicities, but more study on whether this is a true indication of quality is necessary.

Regarding the quality measure *referral to medical oncologist for consideration of adjuvant chemotherapy*, it is necessary to determine how this measure correlates with a measure of whether patients were offered chemotherapy. Also, this measure is entirely untested.

Although perhaps outside the current scope of interest, as a point of context it might be noted that the quality of the facility in which chemotherapy is administered is also quite important. Such issues as ensuring sterility, correct dose and concentration, correct diluent, correct vessel and tubing for holding the chemotherapy, and care in how the drug is actually administered to the patient are crucial not only for colon cancer, but for chemotherapy in general.

Question 2d: Radiation Therapy

Question 2d was: As appropriate to specific stages of colorectal cancer, what quality-of-care measures are available and what evidence is available for measures of quality of care of treatment of colorectal cancer, including appropriate use of radiation therapy for either curative or palliative therapy, specifically for rectal cancers?

Background

In patients with locally advanced rectal cancer, multiple randomized controlled trials have demonstrated that adjuvant chemoradiotherapy decreases local failure and improves overall survival.[141,142] Based on these results, the NIH issued a Consensus Statement in 1990 recommending that all patients with TNM stage II (i.e., a tumor penetrating the rectal wall, without regional lymph node involvement) or stage III (i.e., any tumor with regional lymph node involvement) rectal cancer receive postoperative adjuvant chemoradiotherapy.[15] Since 1990, a number of important developments have occurred which have led to significant changes in the management of patients with rectal cancer. Preoperative chemoradiotherapy has been compared to postoperative chemoradiotherapy, and has been found to improve local control and reduce toxicity while being equally effective with regard to survival.[143] The use of TME has reduced rates of locoregional recurrence compared with older surgical techniques. (Local recurrence may further reduced with the use of adjuvant radiotherapy in combination with TME, although the absolute benefit of radiotherapy is lower in patients undergoing TME as compared to older, less comprehensive resections.[144]) Finally, refinements in risk stratification for the heterogeneous group of patients with stage II and III rectal cancer have enabled tailoring of treatment approaches based on the estimated risks of locoregional and distant failure associated with each Tumor-Node stage combination.[123]

Given the importance of adjuvant chemoradiotherapy for rectal cancer, delivered either preoperatively or postoperatively, efforts to ensure that it is offered to patients who can tolerate it (likely the vast majority of patients who are medically fit for surgery), and that it is delivered in accordance with accepted standards are crucial components of quality medical care for rectal cancer patients. The outcomes of interest regarding adjuvant chemoradiotherapy are locoregional recurrence, overall survival, sphincter preservation, toxicity, and quality of life. The major leverage points are as follows:

1) Adequate preoperative staging.
2) Referral to medical and radiation oncology if tumor stage T3 or T4, or if nodal involvement suspected.
3) Delivery of chemotherapy and radiotherapy in accordance with accepted professional standards.

The first leverage point is addressed under Question 1b. Our literature search did not reveal any measures that addressed the second leverage point. The available measures with regard to the third leverage point are discussed below.

It should be noted that there is substantial overlap in the measures considered under Questions 2c and 2d. As an organizing principle, all general measures that described chemotherapy and/or radiation therapy are included under Question 2c. The primary focus under Question 2d is technical measures pertaining to radiation therapy (regardless of whether this radiation therapy is given with chemotherapy).

Results

We identified two types of quality measures. The first type, a process measure, addresses the question of whether patients with rectal cancer receive radiation therapy as appropriate to their stage of disease. The second type of measure, a technical measure, addresses the question of whether the technique used to deliver radiation therapy conformed to accepted standards of quality.

Measures of the first type are discussed as part of the response to Question 2c, above. In particular, we first eliminated from further discussion those measures that did not specify stage and/or location,[88,100,110,124] and also those measures that used suboptimal combinations of stage and/or location.[86,90,102] Then we noted that investigators who report the data according to the finest possible disaggregation of stage and location, and use as their numerators a cross-classification of chemotherapy versus radiation therapy, implicitly allow the users to create a guideline-based measure for each stage of disease;[48,71,94,134-136] these measures are not discussed further. In other words, those investigators who used the most extensive possible treatment of their data by stage and location could, by implication, group the data in whatever way seems appropriate; in particular, the group could map to the guidelines when discussing grouping by stage and location. This report does not consider these further and instead only considers those studies that grouped the data before presenting results. Finally, Temple et al.[95] measures the *proportion of patients with stage IV colon or rectal cancer receiving palliative chemotherapy, radiation therapy, or both*. This measure has been included, although there are no guidelines or evidence regarding the use of palliative radiotherapy.

The main focus of the potential process measures was patients with stages II or III rectal cancer. Measures by Ayanian et al.,[127] Keating et al.,[130] Schrag et al.,[132] Hyman et al.,[99] Potosky et al.,[125] O'Connell et al.,[98] Baxter et al.,[145] and Neugut et al.[133] were discussed; additional and similar applications by Morris et al.[105] and Demissie et al.[87] were identified as part of the literature review for Question 2d. This set of measures primarily differs according to whether their potential numerators were broken out according to the presence of chemotherapy or radiation therapy, or instead were broken out according to the presence of chemoradiotherapy (i.e., adjuvant chemotherapy plus radiation therapy). Implicitly, the former set of measures is agnostic about the most appropriate treatment for this class of patients and simply strives to describe utilization among the two clinically plausible approaches of chemotherapy and radiation therapy. On the other hand, the latter set of measures, which are based on the NCI and NCCN guidelines, explicitly assume that chemoradiotherapy is the approach of choice. The issues will be discussed more fully in the "Conclusions" section of this Chapter.

Since the above process measures have already been described under Question 2c, this section is limited to a description of the various technical measures that have been applied to radiation therapy for patients with rectal cancer.

The report by Kline et al.[146] serves as the basis for the potential technical quality measure *adherence to radiotherapy management treatment guidelines for patients with adenocarcinoma of the rectum or sigmoid colon*. This measure is based on consensus guidelines from the Patterns of Care Study (PCS) Treatment Planning Committee. It is well developed. The numerator and denominator are well specified. The data source was the 1989-1990 PCS survey. The study compares quality indicators across three different types of radiotherapy facilities including academic centers, hospital-based practices, and freestanding facilities. The following indicators of quality of radiation therapy were assessed: placement of clips by surgeon when tumor adhered to other pelvic structures; isodose distribution generated for dose prescription; beam energy used should be ≥ 4 MeV; use of at least three radiation therapy fields; fields should be shaped with custom blocks; wedges or compensators should be used as needed; port films should be taken; patients should be simulated with contrast in the rectum; a small bowel series should be done if the total dose will exceed 50 Gy; and prone setup should be used. The PCS Treatment Planning Committee guidelines also suggested that information from a pelvis CT should be used for radiation therapy planning. The fact that a random sampling of health care facilities in the U.S. was used suggests that the results are a valid representation of radiotherapy practice in the U.S. However, the study is limited by the fact that the PCS survey was conducted during the 1989-90 time period, and radiotherapy practices have changed considerably since then.

The report by Minsky et al.[147] formed the basis for the potential technical quality measure *rate of use of modern radiation therapy techniques and adherence to recommendations of NCI* *sponsored randomized controlled trials in rectal cancer patients*. This measure is based on recommendations by a consensus of experts (the PCS Rectal Cancer Committee) and on adherence to recommendations from randomized control trials. It is well developed. The numerator and denominator were clearly specified. The data source was the PCS national survey in radiation therapy for the years 1992-1994.[148] Many factors considered indicative of high-quality radiation therapy were measured in the survey, including the field arrangement; the prescription point; the beam energy; the patient position; treatment of all fields each day; treatment with a full bladder; use of a belly board; attempt to exclude the small bowel in patients treated postoperatively; use of small bowel contrast; placement of surgical clips; and inclusion of the scar in all treatment fields in patients treated with APR. Information on the radiotherapy dose to the whole pelvis and to the boost field, the radiation fraction size, and the total treatment time were obtained by the survey, although the authors do not make any assessment of what they view as the appropriate radiation dose, fraction size, or treatment duration. Therefore, adherence to guidelines with regard to those radiotherapy factors cannot be assessed from this report. The data source was not validated. The fact that a random sampling of health care facilities in the U.S. was used suggests that the results are a valid representation of radiotherapy practice in the U.S. However, the study is limited by the fact that the PCS survey was conducted during the 1992-1994 time period, and radiotherapy practices have changed considerably since then.

Conclusions

Perhaps the most important process measure for appropriate use of radiation therapy for rectal cancer identified by our literature search is the *percentage of patients with stage II or III rectal cancer who received adjuvant chemoradiotherapy* ($I_5S_3T_2$). In particular, this measure is linked to an outcome of interest (locoregional control and survival) and is based on an evidence-based recommendation.[15,25] It is well developed, fairly well tested, and a significant leverage point. An ideal version of this measure would explicitly consider possible contraindications to therapy (e.g., serious medical comorbidity, previous pelvic radiotherapy, inflammatory bowel disease, or connective tissue disorder), the distinction between being offered and receiving therapy, and the reasons for non-receipt of adjuvant therapy. Indeed, while this measure can be used for comparing the quality of care for patients of different demographic characteristics, treated in different health care settings, and with different insurance coverage, unless the reasons for non-receipt of therapy are analyzed, then the potential remains that the application of this measure could be biased (e.g., older patients are more likely to have contraindications to chemoradiotherapy than younger patients).

The other version of this process measure that might reasonably be considered is to break out the numerator into patients receiving chemotherapy alone, radiation therapy alone, both chemotherapy and radiation therapy, and neither chemotherapy nor radiation therapy. Although concurrent administration of chemotherapy and radiotherapy is the preferred approach to treatment, there may be circumstances when clinicians recommend one adjuvant modality but not the other. For example, it might be reasonable to offer adjuvant chemotherapy but omit adjuvant radiotherapy in a patient with a significant connective tissue disease (e.g., systemic lupus erythematosus or scleroderma), or in a patient who has received prior pelvic irradiation for prostate cancer or cervical cancer.

While it is vitally important to know whether a patient received chemoradiotherapy, it is also critical to assess the technical quality of its administration. Obtaining information on the details of chemotherapy and radiotherapy obviously presents a significantly greater challenge than determining simply whether chemotherapy or radiotherapy was used at all. The two potential quality measures for the technical administration of radiotherapy identified in this report demonstrate that this type of measure is feasible. Final ratings for these measures are described in Table 8; further details are provided in Evidence Table 9 in Appendix E[*]. In addition to demonstrating feasibility, these studies also illustrate some of the hazards of attempting to ascertain this type of data. In particular, a significant challenge is obtaining data in a timely fashion. If there is excessive delay between data collection and reporting of the results, there is a significant risk that the results will not be applicable to modern practice. Because of this time lag, neither of the two technical radiotherapy quality measures reviewed above is ready for immediate use.

The recommendations made herein are based on a review of currently available data. Obviously, future data or clinical realities (e.g., costs, changes in societal goals) or the development of new technologies may alter the recommendations in the future. Nonetheless, for the major recommendations, we do not expect their basic core importance to change. For example, the need for adjuvant therapy for stage III colon cancer is unlikely to change.

Table 8. Quality measure ratings – Question 2d

Quality measure	**Quality measure rating (range 1-5, where 1 = poor and 5 = ideal)**			**Recommendations for the measure**
	Important and usable (I)	**Scientifically acceptable (S)**	**Well tested (T)**	
General measures				
Percentage of patients with stage II or III rectal cancer receiving chemoradiotherapy[132]	5	3	2	Guidelines for adjuvant therapy for colon and rectum cancers are distinct; measures need to be distinct, too. Needs to account for possible reasons for non-receipt of therapy (e.g., insurance coverage or patient preference).
Percentage of patients with stage II and III rectal cancer receiving radiation therapy[48,91,98,105,132,133]	5	4	4	Quality of the data needs to be addressed. Studies address the need for validation of registry data with office records. Risk-adjustment is important, and patient preference should be accounted for.
Non-receipt of standard radiation therapy[87]	5	4	4	-

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

Table 8. Quality measure ratings – Question 2d – continued

Quality measure	Quality measure rating (range 1-5, where 1 = poor and 5 = ideal)			Recommendations for the measure
	Important and usable (I)	Scientifically acceptable (S)	Well tested (T)	
Rate of adjuvant radiation therapy for patients with stage II or III rectal cancer[71,130,131,134,145]	5	3	3	-
Percentage of patients with stage IV colon or rectal cancer receiving palliative chemotherapy, radiation therapy, or both[95]	4	3	2	-
Technical measures				
Adherence of radiotherapy management treatment guidelines for patients with adenocarcinoma of the rectum or sigmoid colon[146]	5	4	4	Needs to be updated by a panel of radiotherapy experts to reflect current standards of practice. No data exist linking any of these measures to outcomes such as reduced locoregional recurrence rates, improved disease-free or overall survival, or reduced complication rates.
Rate of use of modern radiation therapy techniques and adherence to recommendations of NCI-sponsored randomized controlled trials in rectal cancer patients[147]	3	3	2	Needs to be updated by a panel of radiotherapy experts to reflect current standards of practice. No data exist linking any of these measures to outcomes such as reduced locoregional recurrence rates, improved disease-free or overall survival, or reduced complication rates.

Note: Investigators used their judgment to determine the quality measure rating for each measure across all studies that utilized the measure. See Appendix F[*] for details.

Future Research

The limitations of the process measures for the stage-appropriate administration of radiation therapy for colorectal cancer and the avenues for future research on these process measures are discussed above in the "Future Research" section of Question 2c. Herein we provide suggestions for future research on technical measures of the quality of radiation therapy for patients with colorectal cancer.

One major drawback to both of the technical radiotherapy measures described above (adherence to radiotherapy management treatment guidelines for patients with adenocarcinoma

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

of the rectum or sigmoid colon and rate of use of modern RT techniques and adherence to recommendations of NCI-sponsored randomized controlled trials in rectal cancer patients) is obsolescence due to the time lag between the collection of the data and the reporting of the results.

The feasibility and cost-effectiveness of real-time technical measures of the quality of radiation therapy for CRC need to be investigated. With modern telecommunications, the delay between collection of data on radiotherapy treatment parameters and reporting could potentially be greatly reduced and meaningful, timely quality measures obtained. A panel of radiotherapy experts could determine the components of high quality radiotherapy in modern day practice and a survey could potentially be conducted via telephone or the internet so that the data could be rapidly obtained and used to ensure uniform quality across radiotherapy facilities.

The principle of radiotherapy quality assurance in “real time” has been demonstrated by several ongoing radiotherapy trials administered by the Radiation Therapy Oncology Group (RTOG). The RTOG has established mechanisms for (1) credentialing of facilities participating in RTOG trials, and (2) rapid review and approval of radiotherapy plans for specific patients enrolled on these trials. The costs of reviewing every colorectal cancer patient’s radiotherapy treatment plan would likely be prohibitively large. However, facilities might be encouraged/required to undergo random sampling of cases as part of a quality assurance mechanism.

The major shortcoming of both of the technical measures of the quality of radiation therapy for CRC that are reviewed in this report is that neither have been linked to outcomes such as reduced locoregional recurrence rates, improved disease-free or overall survival, or reduced complication rates. An implicit assumption has been made that the technical quality of radiation therapy is linked to at least some of these outcomes, but there is very little if any data demonstrating that such a link exists. Establishing links between specific technical measures of the quality of radiotherapy and these outcomes should be a priority of future research on this type of quality measure.

Finally, in creating measures of the technical quality of radiation therapy, one significant issue for future research is whether the quality of radiation therapy should be reported with regard to specific technical parameters or whether it can be summarized by one global measure. In other words, should the results of a quality measure’s individual items should be combined into a total score (in effect, creating a single measure), or should they be assessed as individual items (in effect, creating a large number of measures)? If one argues that any deficiency in the provision of radiation therapy can potentially lead to a worsening of patient outcomes, and furthermore that the points of leverage are each individual element of radiation therapy practice, then developers of quality measures should perform at least some (although not necessarily all) analyses at the level of the individual element. On the other hand, if one argues that there will inevitably be some heterogeneity in radiotherapy practices, even among high quality radiation therapy centers, then developers should employ a global measure of the quality of radiation therapy. Research is needed to determine which of these types of measures is more important, usable, and scientifically acceptable.

Question 3: Colonoscopic Surveillance

Question 3 was: What quality-of-care measures are available and what evidence is available for measures of colonoscopic surveillance for colorectal cancer?

Background

Surveillance refers to the ongoing followup of those at increased risk for disease after treatment. Surveillance leads to decreased incidence of CRC and improved survival;[33,149,150] however, heterogeneity of followup strategies has precluded assessment of the optimal combination of clinic visits, laboratory tests, and procedures.[33] The effectiveness of non-endoscopic or combined modality surveillance, such as following tumor markers (carcinoembryonic antigen [CEA]) or abdominal CT imaging, is controversial.

Several professional societies have endorsed guidelines for colonoscopic surveillance after curative resection of CRC (Table 9). These guidelines are similar, but differ on the timing of the first colonoscopy after a perioperative "clearing" colonoscopy. "Clearing the colon" (1) refers to a sufficiently comprehensive examination of the colon to exclude other significant neoplasia, such as adenomatous polyps or synchronous cancers, and (2) signifies that all polyps were removed.

All of the most recent guidelines specifically endorse colonoscopy for bowel surveillance. Several older articles described measures that included sigmoidoscopy with or without barium enema as part of a more generic "bowel surveillance." Since these other two modalities are no longer endorsed for surveillance, we have excluded articles where the colonoscopy rate was not reported separately.

Table 9. Guidelines for colonoscopic surveillance after curative resection of CRC

Guideline	Clearing colonoscopy	1st surveillance colonoscopy, time postresection	2nd surveillance colonoscopy, if first was normal
American Gastroenterological Association (AGA)[6]	At diagnosis or within 6 months of resection	3 years	5 years
ACS[151]	Not discussed	1 year	3 years
American Society of Colon and Rectal Surgeons (ASCRS)[152]	At diagnosis or within 6 months of resection	3 years	3 years
American Society of Clinical Oncology (ASCO)[153]	Pre- or perioperative colonoscopy	3 to 5 years	3 to 5 years
ASGE[154]	At or around the time of resection	3 years	3 to 6 years
NCCN[24]	At diagnosis or within 3 to 6 months of resection	1 year	2 to 3 years

Sigmoidoscopy and barium enema are not currently recommended for surveillance in CRC patients and are beyond the scope of the present question. Several of the studies we considered combined colonoscopy with other bowel imaging in the numerator,[155-157] which made these measures less useable and important. In cases where receipt of colonoscopy could not be separated from other bowel imaging modalities, we excluded the study.[155,156]

Results

Postoperative (Surveillance) Colonoscopy. Several studies, using slightly different definitions, examined the measure *percentage of patients receiving postoperative surveillance colonoscopy*. Cooper and colleagues published two studies evaluating the same measure in the same study population.[158,159] These studies defined the quality measure the "percentage of patients with non-metastatic CRC who had colonoscopy up to 3 years after diagnosis." This process (general) measure was based on earlier versions of current guidelines,[57,160,161] which recommended postoperative surveillance, but the timing of the surveillance (relative to the cancer resection) was not specifically included in the guideline. The numerator and denominator for the measure were ill defined. The two stages of CRC were "local" and "regional." The data source was a merged SEER and Medicare administrative database. Neither the measure nor the data source was validated in this study, although the measure has face validity, being guideline-based. The results are limited due to the inclusion of patients aged 65 and older, restriction to the nine SEER regions, and the lack of clinical details from an administrative database to determine if these were truly "surveillance" colonoscopies or diagnostic procedures to evaluate symptoms. The data are relatively dated (diagnosis in 1991 with followup through 1994), and although subjects had to have survived at least 6 months for inclusion, other attempts to risk-adjust this measure (e.g., it is inappropriate to perform surveillance colonoscopy in patients with poor anticipated survival) were not attempted.

Lafata et al.[162] used administrative data and tumor registry data and defined the measure as the "percentage of patients with CRC who received a followup colonoscopy." "Followup" meant 2 months to 8 years postresection with curative intent. The measure is fairly well developed. The timing of the colonoscopy was not included in the measure. Cited guidelines included ASCRS 1992,[161] ASCO 1999,[163] NCCN 1996,[164] and AGA 1997.[57] The setting was a large multispecialty group and affiliated HMO in Michigan. The restricted geographic location and exclusive HMO setting are limitations.

Keating et al.[130] used the SEER-Medicare database to measure the "percentage of patients who underwent colonoscopy." They specifically examined whether or not the colonoscopy was performed 7 to 18 months after diagnosis. A comorbidity score was measured and used in an adjusted analysis that was primarily aimed at examining the relationship between managed care market share and the quality measure, but the measure did not explicitly exclude any patients with high comorbidity burden who may not have been surveillance candidates.

Retchin and Brown[136] used HMO clinical data and Medicare claims data to examine the "proportion of patients with CRC who had undergone surgery who had had a colonoscopy by 6 months postresection." This definition of the measure was based on a physician advisory panel and not on published guidelines. It is possible that some of these colonoscopies were in fact "clearing colonoscopies" and not the first surveillance examination. This measure was well described, but not well developed or well tested.

An IOM report[13] described a similar measure with the suggested use of the Medicare-SEER merged database or databases derived from medical records. In this case, the measure was refined as *number of stage I to stage III CRC cases with a colonoscopy within 1 year of surgery*, which was based on the NCCN guideline. This was a better developed measure because of the explicit inclusion of surveillance colonoscopy timing congruent with at least one published guideline. The usability of the specific timing, however, is unclear since conflicting guidelines exist. This measure, as described in this report,[13] was not risk-adjusted although it was noted that “local practice patterns and patient-related factors affect the use of endoscopic procedures.”

Rulyak et al.[157] used HMO claims data, HMO pathology databases, and SEER data from Seattle to measure the *percentage of patients with local or regional CRC who had colonoscopy or flexible sigmoidoscopy with barium enema*. They examined two time points: 18 months and 5 years after diagnosis. The weaknesses were the inclusion of a small number of cases of non-colonoscopic surveillance and the use of a 5-year time point (which is not related to any published guidelines). In this regard, the 18-month time frame is reasonable and arguably close to the 1-year recommendation of some guidelines (NCCN, ACS). The measure was not explicitly risk-adjusted, but patients who did not live at least 6 months after diagnosis were excluded.

NCQA[61] proposed the measure *percentage of colon cancer cases who receive followup colonoscopy within 36 months of surgical treatment*. This version of the quality measure is well developed in that it includes only colonoscopy and specifies a guideline-endorsed surveillance interval. Its weakness is a lack of adjustment for patients too sick to benefit from surveillance either because of advanced cancer (i.e., in the absence of specifying disease stage or curative intent, patients with palliative operations could have been included in the denominator), or from comorbid illnesses.

NCQA[61] also proposed another measure: *percentage of rectal cancer cases that received endoscopic examination within 12 months per NCCN guidelines*. The caveats listed above apply to the importance, validity, and usability of this measure as well.

Perioperative (Clearing) Colonoscopy. Keating et al.[130] used the SEER-Medicare database to measure the *percentage of patients who underwent colonoscopy pre- or postoperatively* (defined as in the period of 45 days prior to diagnosis through 30 days after surgery). While the measure is referred to as “complete colonoscopy,” this can be difficult to determine from procedure codes alone, as any endoscopy past the splenic flexure may be coded as a “colonoscopy” even if it was not “complete” by the criteria of documented cecal intubation. Furthermore the guidelines (see Table 9, above) allow for up to 6 months postresection to perform the “clearing” colonoscopy in cases where preoperative complete colonoscopy was not possible due to obstruction by the tumor.

Conclusions

Ratings for the quality measures discussed in this section are given below in Table 10; further details are provided in Evidence Tables 10 and 11 in Appendix E[*].

The measures describing the performance of postoperative surveillance colonoscopies were fairly well developed and well motivated: their ratings ranged from $I_5S_4T_5$ for the measure *percentage of patients with CRC receiving postoperative (surveillance) colonoscopy* to $I_4S_3T_2$ for *percentage of patients with local or regional CRC who had colonoscopy or flexible sigmoidoscopy with barium enema*. The most problematic point was the lack of consensus regarding the optimal scheduling of this procedure. (Even in the absence of such consensus, an ideal measure would be based on at least one guideline and roughly concordant with the others.)

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[*] Appendixes cited in this report are provided electronically at
http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

The numerator should include colonoscopies only, and not other tests such as barium enema or flexible sigmoidoscopy. The measure could also benefit by explicitly specifying whether patients without clearing colonoscopy should be included. Technical criteria should be considered as well; for example, whether the colonoscopy was complete according to the standard of documented cecal intubation.

The measure describing the performance of perioperative colonoscopy was similarly well motivated, but suffered from a lack of precision in distinguishing clearing colonoscopies from similar procedures pre- and postsurgery ($I_5S_4T_4$). Including this additional detail would be substantively helpful, although potentially increasing the data collection requirements as not all databases (particularly administrative databases) will contain sufficient information to make this distinction.

An additional methodological issue involves the linkage between clearing and surveillance colonoscopies. One approach is to measure the rates of clearing colonoscopy and surveillance colonoscopy, separately evaluating both the performance and timing of a complete perioperative colonoscopy and complete surveillance colonoscopy. A second approach is to define the colonoscopic surveillance measure to include only those patients who underwent a clearing colonoscopy. The limitation of the latter approach is that a patient who failed to undergo perioperative clearing colonoscopy, but then had a first postoperative colonoscopy at 2 years, would be excluded from any measure of colonoscopic surveillance quality of care. As a result, an opportunity to improve CRC care will be missed. A limitation of only evaluating presurgical colonoscopy (rather than perioperative colonoscopy) is that some patients will be unable to have a complete colonoscopy at that time due to obstruction or need for emergent surgery (e.g., perforation).

Various technical measures examining critical details of the colonoscopy are examined under Question 1a.

The recommendations made herein are based on a review of currently available data. Obviously, future data or clinical realities (e.g., costs, changes in societal goals) or the development of new technologies may alter the recommendations in the future. Nonetheless, for the major recommendations, we do not expect their basic core importance to change.

Table 10. Quality measure ratings – Question 3

Quality measure	Quality measure rating (range 1-5, where 1 = poor and 5 = ideal)			Recommendations for the measure
	Important and usable (I)	**Scientifically acceptable (S)**	**Well tested (T)**	
General measures				
Percentage of patients with CRC receiving postoperative (surveillance) colonoscopy[130,136,158,159,162]	5	4	5	Needs a guideline-concordant time frame (e.g., 1 year or 3 years postresection). Testing needed, particularly of the data source (was staging accurate?; was documentation of colonoscopy accurate?).
Number of stage I to stage III CRC cases with a colonoscopy within 1 year of surgery[13]	5	4	-	Need to specify that a clearing colonoscopy was performed. Testing needed, particularly of the data source (was staging accurate?; was documentation of colonoscopy accurate?).
Percentage of patients with local or regional CRC who had colonoscopy or flexible sigmoidoscopy with barium enema[157]	4	3	2	Needs to include colonoscopy only.
Percentage of colon cancer cases who receive followup colonoscopy within 36 months of surgical treatment[61]	5	4	-	Testing needed, particularly of the data source (was staging accurate?; was documentation of colonoscopy accurate?).
Percentage of rectal cancer cases that received a post surgical endoscopic examination within 12 months postsurgery[61]	5	4	-	Need to clarify if this is clearing or surveillance colonoscopy, and if the latter, need to specify that clearing colonoscopy was performed. Timing should be guideline-concordant, i.e., at 1 year not within 1 year.
Percentage of patients who underwent colonoscopy pre- or postoperatively[130]	5	4	4	Need to distinguish clearing colonoscopies from similar procedures pre- and postsurgery. Further testing needed, particularly of the data source (was staging accurate?; was documentation of colonoscopy accurate?).

Note: Investigators used their judgment to determine the quality measure rating for each measure across all studies that utilized the measure. See Appendix F[*] for details.

Future Research

Several potential quality measures related to postoperative colonoscopy were retrieved. They relate to two important clinical issues that should be the focus of future research: (1) performance of postoperative surveillance colonoscopy, and (2) the performance of perioperative clearing colonoscopy. The actual surveillance colonoscopy should be defined as the first followup colonoscopy after both resection of the cancer and after “clearing of the colon” for other significant neoplasia (adenomatous polyps or synchronous cancers). Therefore, the clearing colonoscopy is a leverage point for the surveillance colonoscopy and is arguably worth measuring separately. It should be noted at this point that patients with unresectable metastases should be excluded from the denominator for measures regarding surveillance, since they do not benefit from it.

While several professional societies endorse guidelines for colonoscopic surveillance after curative resection of CRC (Table 9), the evidence upon which these guidelines are based is somewhat indirect. The mortality benefit of colonoscopic surveillance has not been tested in randomized controlled trials. The general logic is that individuals with a personal history of cancer are at increased risk for colon or rectal cancer and therefore should have at least as much and likely more followup as those individuals at average risk for CRC. The first step to improve the quality measure is to strengthen the link of the quality measure to outcomes of interest. The ideal outcome would be survival, but intermediate outcomes such as changes in patient management, or detection of metachronous or recurrent cancers at a treatable stage, may also be of interest. Without outcomes data it is not surprising that the guidelines differ on the timing of the first surveillance colonoscopy. The lack of consensus regarding the timing is one of the limiting factors for developing an appropriate measure. Outcomes data would encourage consistency across the guidelines, but even without the data consensus could be achieved. Once a standard interval for surveillance colonoscopy is established, the quality measure should reflect this interval (e.g., *percentage of patients who receive the first surveillance colonoscopy at 3 years*).

Any measure of colonoscopic surveillance should exclude all patients with greater than stage III disease at diagnosis, patients who died before the first surveillance colonoscopy was due, and patients who did not undergo resection of the cancer (with curative intent). It is reasonable to assume that patients in sufficient health to undergo and survive the cancer resection would be in sufficient health to undergo at least the first surveillance colonoscopy. This is particularly true if the ACS and NCCN recommendations of a 1-year interval are followed. On the other hand, it is conceivable that within a 3-year time frame the health status of an individual could change considerably and therefore need to reevaluated for the appropriateness (and safety) of followup colonoscopy.

The clearing colonoscopy, while not itself postoperative surveillance, also requires evaluation to make the measure of the colonoscopic surveillance precise and guideline-concordant. The clearing colonoscopy, which is an important opportunity to improve CRC care, should be defined as “complete” (to cecal landmarks or surgical anastomosis), with “adequate

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

bowel preparation" ("no fecal material obscured a lesion 5 mm or more in diameter and a high quality examination takes place"), and with all polyps removed. The denominator is "the number of patients diagnosed with colon or rectal cancer." The numerator is "the number of patients who undergo the clearing colonoscopy either prior to surgical resection or within 6 months of resection."

Finally, the data sources need evaluation for reliability and accuracy. While administrative or claims data can provide cancer diagnosis and documentation of procedures (surgical resection, colonoscopy) they will need supplementation with other data for accurate staging (e.g. registry data, chart review) and for details of the colonoscopy itself. The latter will most likely require examination of colonoscopy reports as preparation quality, extent of procedure, and documentation of polyps or masses seen and removed are not documented in other data sources. A standard colonoscopy report template, entered into an electronic database, would facilitate use of the quality measurement. In addition, chart review may be necessary to determine changes in the health status of the patient if the first surveillance interval follows the 3-year rather than the 1-year recommendation.

Question 4: Pathology, Operative, and Chemotherapy Reports

Question 4 was: What measures are available and what evidence is available for measures to assess the adequacy and completeness of documentation of pathology, operative, and chemotherapy reports?

Background

Our literature search did not reveal any measures that related to the documentation of surgical and chemotherapy reports. Accordingly, this section will focus on pathology reports.

The pathology report is the product of several steps, which include surgical dissection and histologic block selection, communication between surgeon and pathologist, pathologic dissection with macroscopic and microscopic analysis, and finally dictation and transcription of the completed report. It is important for making decisions regarding adequacy of surgical resection, need for adjuvant therapy, and surveillance. Therefore, a poor quality pathology report can adversely affect clinical outcomes.[165] Additional value of pathology reports includes their ability to provide information for clinical audits, for assessing accuracy of new diagnostic and preoperative staging techniques, and for comparing patient groups in clinical trials.

In recent years, the Association of Directors of Anatomic and Surgical Pathology (ADASP) and CAP have both undertaken to publish guidelines for the reporting of common cancers.[166,167] While the formats of the two guidelines are somewhat different, their contents are essentially the same.

The American College of Surgery Commission on Cancer (ACS-COC) accredits cancer centers in the United States. Recently, the ACS-COC decided to require elements deemed as essential by the CAP to be described in all pathology reports in their accredited cancer centers as of January 2004. However, they do not require that the specific CAP protocols or synoptic reports be utilized. ADASP has also updated all of its protocols and checklists to comply with the ACS-COC requirements. The different elements in the revised ADASP Diagnostic

Checklists have been divided into the categories *Required* and *Optional*. The term *Required* in this context signifies only compliance with the ACS-COC guidelines. ADASP realizes that specimens and practices vary, and it will not be possible to report these elements in every case.

CAP has developed and updated guidelines for reporting cancers of the colon and rectum and offers protocols to assist pathologists in providing clinically useful and relevant information in the reporting of the results of their examination of surgical specimens.[168] CAP regards the reporting elements in the Surgical Pathology Cancer Case Summary portion of its protocols as essential elements of the pathology report. However, the manner in which these elements are reported is at the discretion of each pathologist – taking into account clinician preferences, institutional policies, and individual practice. CAP also recognizes that the ACS-COC mandated the use of the checklist elements of the protocols as part of the Cancer Program Standards for Approved Cancer Programs. However, not all these elements stipulated in the CAP checklist are required for accreditation (for approved cancer programs) purposes, since not all of them are validated for use in patient management (e.g., venous invasion).

Results

The IOM report *Assessing the Quality of Cancer Care*[13] proposed the quality measure *proportion of CRC cases in which pathologic staging preceded chemotherapy and radiation treatment*. The numerator is the number of new CRC cases with a medical chart documentation of pathologic stage before chemotherapy or radiation is initiated; the denominator is the number of new CRC cases with chemotherapy or radiation treatment. The measure recommends that medical records be used as the data source.

The Colon Cancer Workgroup[54] recommended the measure *pathology report in concordance with CAP guidelines*. They further define the measure as pathology reporting that includes lymph nodes resected, number of nodes positive, tumor characteristics (grade, depth of invasion), and mucosal and radial margins. They stipulate the data required for application of the measure (pathology and surgical reports); it is based on the CAP and NCCN guidelines, clinically relevant, is amenable to change by providers and the system, and is free from confounders. The measure was utilized for assessing and improving quality of care in a single health system. The measure is well developed, and is linked to an outcome of interest. No information was available regarding testing.

The IOM[13] recommended the measure *adequacy of pathology reports on CRC* to assess the quality of cancer care in Georgia. Adequacy is defined as those reports that meet the CAP data elements as required by the ACS-COC. The measure is important, usable, precisely defined, valid, recommends fairly reliable data sources, and the conditions for use of the measure are stated. Risk-adjustment need not be applied in this context.

Wei et al.[165] evaluated variations in colon carcinoma reporting by laboratory type and hospital volume, as related to the ADASP recommendations, in order to identify areas for improvement. Data were collected from pathology reports from patients participating in a population-based cancer study (North Carolina Cancer Study [NCCS] from 1997 to 2000). The denominator consisted of patients who had surgically resected T2-4 pathologically confirmed invasive adenocarcinoma and for whom surgical pathology reports were available and who resided in the 33-county area used for NCCS. Patients with T0s and T1 were excluded because several items of the pathology report were not applicable to localized malignancies. The following items were included in the evaluation: percentage of reports that mentioned (a) how specimen was received; (b) how it was identified; (c) part of intestine included; (d) the tumor site; (e) proximity of tumor to the nearest margin; (f) macroscopic subtype; (g) tumor dimensions; (h) macroscopic depth of penetration; (i) appearance of serosa adjacent to the tumor; (j) appearance of residual bowel; (k) histological features including histologic type and grade; (l) depth of infiltration; (m) lymph node metastases; and (n) involvement of margins. Overall percentage of each reported characteristic was noted. Pathology laboratories were categorized as contract, teaching hospital, or community hospital laboratories in one analysis, and categorized by hospital case volume in another. The study did not assess the accuracy of the reported findings, and did not assess the impact of pathology reports on patient outcome. Each of these items can be considered to be a separate quality measure. A global score was not calculated.

We did not identify any manuscripts dealing with the adequacy of chemotherapy reports. Although currently the most important measure is whether chemotherapy is administered to stage III colon cancer patients, there may be future interest in determining whether an adequate dose intensity was given. Giving an adequate amount of chemotherapy is important for the outcome of patients with breast cancer, and if similar data are reported for colon cancer in the future, then it will be important to be able to measure whether adequate chemotherapy has been given. In this case, the documentation contained in chemotherapy reports will need to be of high quality (e.g., reporting the agents given and their dosage).

Conclusions

Pathology reports play a very important role in providing clinically useful and relevant information from the examination of surgically resected specimens.

Ratings for the quality measures discussed in this section are given below in Table 11; further details are provided in Evidence Tables 12 and 13 in Appendix E[*]. The quality measure *proportion of CRC cases in which pathologic staging preceded chemotherapy and radiation treatment*,[13] is well developed, free from confounders, and is an important leverage point, but needs testing ($I_5S_4T_-$).

The quality measure *pathology report in concordance with CAP guidelines*[54] is well developed, free from confounders, and is an important leverage point, but needs testing ($I_5S_4T_-$). Not all items included in the CAP guidelines are related to outcomes of interest, and it may be useful to select those that address a leverage point. This aspect is considered by the measure *adequacy of pathology reports on CRC,* which limits measurement to scientifically validated elements of the CAP guidelines, and is therefore a potentially ideal measure; however, it needs field-testing ($I_5S_4T_-$).[13]

The other measures (each being an item of the ADASP guideline) take more of a micro-level perspective, addressing individual elements of the pathology report. These are well developed, and address some important leverage points for improving quality of colon and rectum cancer pathology reporting standards.[165] The most important ones are: *local extent of tumor*, *regional lymph node metastases*, and *residual tumor at surgical resection margin*. If those elements are selected, the process measures will address a leverage point, and be related to an outcome of interest ($I_5S_5T_4$).

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

The advantage of using individual items as measures is that they allow a comparison between laboratories that utilize different guidelines (e.g., ADASP guidelines instead of CAP recommendations), or permit a comparison of only those items that have a proven link to survival and therefore are leverage points, or allow one to perform a comparison over time, as the continued availability of evidence may alter the relevance of some elements of the checklists/guidelines.

When utilizing any of these measures to assess and/or compare quality of pathology reporting the following considerations are relevant: (a) the measures evaluate the presence or absence of certain items in a report, not the accuracy of those items; and (b) some omissions in a pathology report may not represent poor quality of care: some microscopic reporting (e.g. depth of penetration) may obviate the need for reporting on macroscopic features (e.g. appearance of tumor); and (c) the measures may not distinguish between quality of the surgical procedure and quality of pathology services.

The recommendations made herein are based on a review of currently available data. Obviously, future data or clinical realities (e.g., costs, changes in societal goals) or the development of new technologies may alter the recommendations in the future. Nonetheless, for the major recommendations, we do not expect their basic core importance to change.

Table 11. Quality measure ratings – Question 4

Quality measure	**Quality measurerating (range 1-5, where 1 = poor and 5 = ideal)**			**Recommendations for the measure**
	Important and usable (I)	**Scientifically acceptable (S)**	**Well tested (T)**	
General measures				
Proportion of CRC cases in which pathologic staging preceded chemotherapy and radiation treatment[13]	5	4	-	Needs testing.
Pathology report in concordance with CAP guidelines[13]	5	4	-	Validity needs to be tested. Reliability will depend on the quality of data available in laboratories. Not all items in the CAP guidelines are related to outcomes of interest.
Adequacy of pathology reports on CRC[13]	5	4	-	The inclusion of validated elements makes this measure particularly useful. Needs testing.
Technical measures				
Percentage of reports mentioning how specimen was received[165]	5	5	4	Reliability will depend on the quality of data available in laboratories.
Percentage of reports mentioning how specimen was identified[165]	5	5	4	Validity needs to be tested. Reliability will depend on the quality of data available in laboratories.

Table 11. Quality measure ratings – Question 4 – continued

Quality measure	Quality measurerating (range 1-5, where 1 = poor and 5 = ideal)			Recommendations for the measure
	Important and usable (I)	Scientifically acceptable (S)	Well tested (T)	
Percentage of reports mentioning part of intestine included[165]	5	5	4	Validity needs to be tested. Reliability will depend on the quality of data available in laboratories.
Percentage of reports mentioning the tumor site[165]	5	5	4	Validity needs to be tested.
Percentage of reports mentioning proximity of tumor to the nearest margin[165]	5	5	4	Validity needs to be tested. Reliability will depend on the quality of data available in laboratories.
Percentage of reports mentioning macroscopic subtype[165]	5	5	4	Validity needs to be tested. Reliability will depend on the quality of data available in laboratories.
Percentage of reports mentioning tumor dimensions[165]	5	5	4	Validity needs to be tested.
Percentage of reports mentioning macroscopic depth of penetration[165]	5	5	4	Validity needs to be tested. Reliability will depend on the quality of data available in laboratories.
Percentage of reports mentioning appearance of serosa adjacent to the tumor[165]	5	5	4	Validity needs to be tested. Reliability will depend on the quality of data available in laboratories.
Percentage of reports mentioning appearance of residual bowel[165]	5	5	4	Validity needs to be tested. Reliability will depend on the quality of data available in laboratories.
Percentage of reports mentioning histological features including histologic type and grade[165]	5	5	4	Reliability will depend on the quality of data available in laboratories.
Percentage of reports mentioning depth of infiltration[165]	5	5	4	Reliability will depend on the quality of data available in laboratories.
Percentage of reports mentioning lymph node metastases[165]	5	5	4	Reliability will depend on the quality of data available in laboratories.
Percentage of reports mentioning involvement of margins[165]	5	5	4	Reliability will depend on the quality of data available in laboratories.

Note: Investigators used their judgment to determine the quality measure rating for each measure across all studies that utilized the measure. See Appendix F[*] for details.

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

Future Research

The basic and sound premise behind the currently available measures of the quality of pathology reports is that standardization of reports is a crucial step toward the goal of ensuring their quality. Additional and related areas for development include the development of summary scoring systems (i.e., for those measures that include multiple items), assessing the relative importance of various items, and extending the evidence base that links elements of the pathology report to patient outcomes.

This same premise can be applied with equal force to operative and chemotherapy reports, and generating analogous measures should be a high priority for future research. With special reference to rectal cancers, TME of rectal tumors has clearly demonstrated a reduction in local recurrence and an improvement in long-term survival. However, it is difficult to discern if in fact a TME has been performed, since operative notes tend to be extemporaneous. Perhaps the inclusion of specific anatomic landmarks in the operative note, as well as the pathologist comment on the gross integrity of the rectal facial planes, would help confirm the fact that a TME of the rectum was performed. Then surgical results of rectal cancer procedures could be directly compared without the confounding factor of surgical technique.

Standardized chemotherapy notes could also be developed to include information on patient preferences regarding chemotherapy. In addition, since “receipt” of chemotherapy is only a surrogate marker for whether patients receive the correct agents, dose, and schedule, reports should include the latter sort of information. In order for chemotherapy reports to be of use, more research will be needed on whether information that would be contained in such reports (agents used, dose used, over what period of time) will need to be established for colon cancer. Subsequently, a more global measure, such as chemotherapy dose intensity, will need to be evaluated for whether it is related to outcome.

As illustrated in the development of quality measures for pathology reports, the role of the professional society can be key.

Question 5a: Patient Populations and Purposes

Question 5a was: For questions 1-4 above, in what patient populations and for what purposes have these quality of care measures been used?

The variety of patient populations for which the various quality of care measures have been used is described in detail primarily in the evidence tables (see Appendix E[*]), secondarily in this Chapter under Questions 1-4, and also in Tables 12-15 under Question 5b. This section is intended as a summary and synthesis of these presentations.

In brief, patients have been studied at every stage of the sequence from diagnosis to treatment to posttreatment surveillance. Patient populations (data sources) include population-based registries (in particular, the SEER registries, but also the NCDB, statewide registries, and others); administrative files of primarily FFS patients (in particular, Medicare databases); administrative files of HMOs; direct patient interview (either alone or in conjunction with another data source such as a registry); hospital records; individual facility records; and (less commonly) randomized trials.

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

Comments about individual data sources are included in the responses to Questions 1-4. As a rule, technical measures require access to one or more elements that will not be available in administrative or similar kinds of databases and require a special effort to collect. Such technical measures are usually applied in the context of formal quality improvement (or quality measurement), and their inputs are obtained either from medical record audit or the establishment of data collection protocols that include the appropriate elements. The latter approach is preferable, as the accompanying systemization both encourages the collection of accurate data and serves as a prompt toward improving the technical quality of care.

For example, consider the pathology reporting system that focuses on the 14 submeasures of (a) how the specimen was received; (b) how it was identified; (c) the part of the intestine included; (d) the tumor site; (e) proximity of tumor to the nearest margin; (f) macroscopic subtype; (g) tumor dimensions; (h) macroscopic depth of penetration; (i) appearance of serosa adjacent to the tumor; (j) appearance of residual bowel; (k) histological features including histologic type and grade; (l) depth of infiltration; (m) lymph node metastases; and (n) involvement of margins. At present, these measures all focus on the percentage of reports for which these various elements are mentioned. However, if at an individual facility the system of reporting was changed to include, for example, a spreadsheet including each of the 14 elements for each patient, then such a system would serve as a prompt for the pathologist and surgeon to cooperatively work to ensure that all these elements were in fact collected as desired.

As noted elsewhere, in contrast to technical process measures, general process and outcome measures have been used not only in the quality improvement setting but also in more general research settings as well. Many general process and outcome measures can be obtained from extant databases (e.g., 5-year survival can be obtained by linking with the National Death Index, while the presence of serious complications can be obtained from administrative claims, as can the presence of adjuvant chemotherapy), although the link between the quality measure and the data source must be examined on a case-by-case basis in order to assure that the information in question is collected with sufficient reliability.

Question 5b: Age, Race/Ethnicity, and Socioeconomic Status

Question 5b was: For questions 1-4 above, does evidence support the use of any of these measures to assess differences in quality of care across patients' age, race/ethnicity, and/or socioeconomic status?

Background

We identified several types of reports that were relevant to the question of the usefulness of quality measures to assess differences in the quality of care across various patient-level characteristics. A relatively small number of studies were specifically intended to assess the impact of patient, provider, or health system characteristics on measures of either process or outcome. There were a far greater number of studies that evaluated and reported, to a limited extent, data on the association of such patient, provider, or system characteristics with process or outcome measures.

This section of the report is intended to provide a comprehensive list and description of those studies that were designed to measure and examine the impact of patient characteristics on processes and outcomes. The report identifies a representative, but not necessarily complete, list of studies for which evaluation of patient level characteristics was not a stated goal. Reasons for making this distinction include: (1) studies designed to assess patient factors will be more reliable in their measurement and analysis; (2) studies for which patient characteristics were not the major focus of the analysis are more difficult to identify (and, thus, were more subject to biased ascertainment); and (3) possible reporting bias (studies that mention age, race, or socioeconomic status associations in passing are more likely to do so if a statistically significant result is found).

Results

Tables 12-15 summarize the use of various CRC quality-of-care measures by various patient characteristics including age, sex, race/ethnicity, and socioeconomic status. The investigators reported 29 instances in which age was related to either outcomes (n = 6) or process measures (n = 23; Table 12). Many studies described lower rates of use of chemotherapy or radiation therapy for older compared with younger patients using age cutoffs ranging from 65 to 85; however, few studies controlled for relevant covariates (e.g., performance status or comorbid illnesses) that might explain this difference.

Similarly, in five cases (Table 13) sex was related to either outcomes (n = 1) or process measures (n = 4). Four of the five studies described lower rates of use of adjuvant chemotherapy or radiation therapy for women compared with men; however, none controlled for relevant covariates (e.g., performance status or comorbid illnesses) that might explain this difference.

Race was related to process measures, most commonly receipt of certain types of treatment in 30 instances (Table 14). With the exception of several measures in the VA system, which did not show racial differences,[88] each study found that whites were more likely than blacks to receive certain types of treatment including surgery, chemotherapy, and radiotherapy.

Finally, in 16 instances (Table 15) socioeconomic status was related to process measures, most commonly receipt of certain types of treatment. Socioeconomic status was most commonly measured as income or health insurance status. More than half of the studies found that patients of higher socioeconomic status were more likely than patients of lower socioeconomic status to receive certain types of treatment; however, several studies showed no statistically significant differences in quality measures across socioeconomic status.

Table 12. Quality measures used to assess differences in quality of care by patients' age

Question	Quality measure	Study	Results – age
1a	Colonoscopy complication rate	Ure et al.[51]	Compared to patients 50-70 yr (1%), patients ≥ 70 yr (17%) were significantly more likely ($p < 0.05$) to require termination of the procedure because of inadequate bowel preparation.
	Time from patient presentation to physician diagnosis	Marble et al.[46]	No statistically significant difference in time from patient presentation to physician diagnosis for patients < 40 yr compared to > 40 yr.

Table 12. Quality measures used to assess differences in quality of care by patients' age – continued

Question	Quality measure	Study	Results – age
2b	Postsurgical complication rate	Coburn et al.[110]	Controlling for demographic and clinical risk factors, complication rate was 55% for patients > 80 yr compared to 35% for patients < 80 yr.
	Anastomotic leak rate	Coburn et al.[110]	Controlling for demographic and clinical risk factors, postanastomotic leak rate was 6% for patients > 80 yr compared to 3% for patients < 80 yr.
	30-day mortality	Coburn et al.[110]	Controlling for demographic and clinical risk factors, mortality rate was 6.2% for patients over 80 yr compared to 2.4% for patients under 80 yr.
	30-day operative mortality rate	Agarwal et al.[114]	Higher operative mortality rate in > 80 yr vs. < 80 yr (25% vs. 6%), p < 0.01.
	Perioperative mortality rate	Whittle et al.[113]	Age was significantly associated with adjusted rates for perioperative mortality, and 1- and 2-yr postoperative mortality. The odds ratio for 75-84 yrs of age was 1.69 (reference group 66-69 yrs), controlling for sex, and 3.23 for 85 and older.
	Surgery rate for CRC patients	Newcomb and Carbone[86]	Adjusting for disease stage, no statistically significant difference in patients' rates of surgery by age under and over 65 yr.
2c	Adjuvant chemotherapy rate in patients with stage III colon or stages II or III rectal cancer	Ayanian et al.[127]	Patient age inversely related to adjusted adjuvant chemotherapy rates adjusting for socioeconomic status, clinical and other demographic risk factors. 88% of patients > 55 yr received treatment, compared to 11% of patients between 85-89 yr, p = 0.001.
	Adjuvant chemotherapy rate in patients with stage III colon cancer	Schrag et al.[128]	Adjusting for demographics, socioeconomic status, comorbidity and other clinical risk factors, age at diagnosis was the strongest determinant for receipt of chemotherapy, p < 0.001.
	Adjuvant chemotherapy rate in patients with stage III colon cancer	Sundararajan et al.[129]	Controlling for demographic, socioeconomic status, and clinical risk factors, therapy use declined in older vs. younger patients, p = 0.04.
	Rate of adjuvant chemotherapy for CRC	Newcomb and Carbone[86]	41% of patients < 65 yr compared to 26% ≥ 65 yr received therapy, adjusting for disease stage, p = 0.05.
	Adjuvant chemotherapy rate in patients with stage III colon or stage II, III rectal cancer	Potosky et al.[125]	Controlling for demographics, socioeconomic status and clinical risk factors, higher rates were observed among younger compared to older patients, p = 0.003.

Table 12. Quality measures used to assess differences in quality of care by patients' age – continued

Question	Quality measure	Study	Results – age
	Adjuvant chemoradiotherapy rate	Coburn et al.[110]	Controlling for demographic and clinical risk factors, adjuvant therapy rate was 5.1% for patients over 80 yr compared to 20% for patients under 80 yr, p = 0.00001.
	Chemotherapy rate for stage II or III rectal cancer patients	Neugut et al.[133]	Controlling for sociodemographic and clinical factors, younger patients had a higher probability of receiving adjuvant chemotherapy and radiation therapy, p < 0.01.
	Combined chemoradiotherapy rate for stage II, III rectal cancer patients	Neugut et al.[133]	Controlling for sociodemographic and clinical factors, age was inversely associated with receipt of combined chemoradiation therapy.
	Chemoradiotherapy rate stage II or III rectal cancer	Schrag et al.[132]	Adjusting for demographic, socioeconomic status, comorbidity and other clinical risk factors, higher chemoradiation therapy use was observed in younger vs. older patients, p < 0.0001.
	Rate of patients referred to a medical oncologist for adjuvant chemotherapy	Oliveria et al.[137]	Controlling for sex, stage and year at diagnosis, patient age was a significant predictor of referral. Younger patients (< 70 yr) were more likely to be referred to an oncologist, p < 0.0001.
	Chemotherapy rate within 120 days of diagnosis	Rogers et al.[90]	Controlling for sex, nursing home status, socioeconomic status, tumor stage, comorbidity and other potential risk factors, rates of use declined with increasing age. Among those 65 to 74 yr, 75 to 84 yr, 85 and older, rates were 11.3%, 8.4%, and 4.5%, respectively.
	Adjuvant chemotherapy rate of patients with stage III colon cancer	Mahoney et al.[126]	Older patients were less likely than younger patients to receive adjuvant chemotherapy after adjusting for confounding variables, p = 0.003.
2d	Radiotherapy rate in stage II or III rectal cancer	Neugut et al.[133]	Controlling for sociodemographic and clinical factors, the use of radiation therapy declined as age increased, p < 0.01.
	rate of radiation therapy for rectal cancer	Wudel et al.[100]	Older patients may be less likely to receive radiation therapy (unadjusted) compared to younger patients.
	Rate of adjuvant radiotherapy for CRC patients	Newcomb and Carbone[86]	No statistically significant difference found in patients under 65 (14%) and over 65 yr (18%) in therapy, adjusting for disease stage.
	Adjuvant radiation therapy rate for patients with stage II or III rectal cancer	Ayanian et al.[127]	Adjusting for clinical, socioeconomic status and demographic factors, older patients were less likely to receive adjuvant therapy compared to younger patients, p = 0.001.

Table 12. Quality measures used to assess differences in quality of care by patients' age – continued

Question	Quality measure	Study	Results – age
	Percentage of patients diagnosed with colon or rectal cancer who received radiation therapy	Roetzheim et al.[94]	Younger age was a predictor of receipt of radiation therapy, after controlling for demographic socioeconomic status factors, clinical risk factors. p < 0.001.
3	Percentage of patients with non-metastatic CRC who received follow up colonoscopy	Cooper et al.[158,159]	Older patients were less likely than younger patients to receive followup testing after controlling for age, comorbidity, location of tumor and other risk factors, p = 0.001.
	Rate of colonoscopy or flexible sigmoidoscopy with barium enema after diagnosis	Rulyak et al.[157]	Controlling for demographic, clinical, socioeconomic status and site of service covariates, patients > 80 yr of age were less likely to undergo surveillance, p < 0.05.
	Percentage of CRC patients receiving a posttreatment colonoscopy	LaFata et al.[162]	Adjusting for demographic, socioeconomic status, and clinical risk factors, age was inversely related to surveillance, p = 0.01.

Table 13. Quality measures used to assess differences in quality of care by patients' sex

Question	Quality measure	Study	Results – sex
2b	Perioperative mortality rate	Whittle et al.[113]	After adjusting for age, males had a 31% higher perioperative mortality rate compared to female patients, p < 0.05.
2c	Adjuvant chemotherapy rate of patients with stage III colon cancer	Mahoney et al.[126]	After adjusting for age and other potential confounding variables, males had a 5.8 times greater chance of receiving chemotherapy than female patients, p = 0.002.
	Percent of patients diagnosed with stage III colon cancer receiving adjuvant chemotherapy	Schrag et al.[128]	Adjusting for demographic, socioeconomic status, comorbidity and other clinical risk factors, males were slightly more likely to receive treatment compared to female patients, p = 0.06.
	Percent of patients diagnosed with stage III colon cancer receiving adjuvant chemotherapy	Sundararajan et al.[129]	Controlling for demographic, socioeconomic status, and clinical risk factors, males were more likely to receive treatment, p = 0.002.
	Percent of patients diagnosed with stage II, III rectal cancer receiving adjuvant therapy	Potosky et al.[125]	Controlling for demographic, socioeconomic status, and clinical risk factors, females were more likely to receive treatment than males, p = 0.06.

Table 14. Quality measures used to assess differences in quality of care by patients' race/ethnicity

Question	Quality measure	Study	Results – race/ethnicity
2b	Rate of non-receipt of standard surgical treatment of patients diagnosed with colon cancer	Demissie et al.[87]	The disparity between black and white patients with stages I and IV colon cancer was small, but persisted after controlling for risk factors including age, location of cancer, histologic type, and tumor grade. No statistically significant difference was seen for patients with stages II and III. A higher adjusted odds ratio for non-receipt of surgical treatment was observed for stage I, II rectal cancer in black females. An adjusted odds ratio for non-receipt of surgical treatment was higher for black males compared to white males for stages I, III, and IV rectal cancer. For stage I rectal cancer, black males had a lower likelihood of non-receipt of radiation therapy. The black-white disparity in non-receipt was more prominent when actual treatment received vs. intent to treat was considered. Refusal rate was 32.8% among black males compared to 9.2% for white males.
	Surgical resection rate	Cooper et al.[93]	Surgical resection was performed less often in black compared to white patients (68% vs. 78%), after controlling for age, sex, comorbidity, location of tumor, and other potential risk factors.
	30-day mortality rate	Cooper et al.[93]	Black patients had a higher mortality rate (6.1%) than white patients (4.6%), after controlling for age, sex, comorbidity, location of tumor, and other potential risk factors. Differences held at 1 and 2 years postsurgery.
	Rate of sphincter-preserving operation	Morris et al.[105]	Controlling for age, sex, year of disease, geographic location, stage, and anatomic location, lower procedure rate was observed in black (57%) compared to white (63%) population with an adjusted odds ratio of 1.42.
	Surgery rate	Dominitz et al.[88]	Adjusting for demographics, comorbidity, and other clinical factors, no statistically significant difference was found across racial lines in receipt of surgery in the VA population.
	Surgery rate for patients with stages II and III CRC	Govindarajan et al.[102]	Controlling for sex, site, socioeconomic status, and therapeutic modalities, compared to blacks, white patients were more likely to undergo surgery (p = 0.067) at all stages.

Table 14. Quality measures used to assess differences in quality of care by patients' race/ethnicity – continued

Question	Quality measure	Study	Results – race/ethnicity
	Curative resection rate	Wudel et al.[100]	No statistically significant difference in unadjusted rates for curative resection treatment between ethnic groups was observed. Black patients were significantly worse in overall and disease-specific survival in both institutions.
	Surgery rate of CRC patients	Rogers et al.[90]	Controlling for sex, nursing home status, socioeconomic status, tumor stage, comorbidity, and other potential risk factors, 91% of whites compared to 86% of blacks received surgery, p = 0.02. Higher adjusted odds ratio.
2c	Adjuvant chemotherapy rate in patients with stage III colon or stages II or III rectal cancer	Ayanian et al.[127]	Adjusting for demographic, clinical, and socioeconomic status risk factors, treatment was used less in black vs. white population, p = 0.001.
	Chemotherapy rate within 120 days of diagnosis	Rogers et al.[90]	Controlling for sex, nursing home status, socioeconomic status, tumor stage, comorbidity, and other potential risk factors, 7.8% of whites compared to 9.4% of blacks received chemotherapy within 120 days of diagnosis.
	Adjuvant chemotherapy rate in patients with stage III colon cancer	Schrag et al.[128]	Adjusting for demographic, socioeconomic status, comorbidity, and other clinical risk factors, blacks were less likely to receive therapy, p < 0.004.
	Chemotherapy rate	Dominitz et al.[88]	Adjusting for demographic, comorbidity, and other clinical factors, no statistically significant difference was found across racial lines in receipt of chemotherapy in the VA population.
	Chemotherapy rate of patients with stages II and II CRC	Govindarajan et al.[102]	Controlling for sex, site, socioeconomic status, and therapeutic modalities, higher rates of treatment were found among white patients compared to blacks at stages II and III, p = 0.007.
	Adjuvant chemotherapy rate in patients with stage III colon or stage II or III rectal cancer	Potosky et al.[125]	Controlling for demographic, socioeconomic status, and clinical risk factors, higher rates of treatment were observed among whites compared to blacks, p = 0.02.
	Percentage of patients with stage III colon cancer receiving adjuvant chemotherapy	Sundararajan et al.[129]	Controlling for demographic, socioeconomic status, and clinical risk factors, therapy use declined in non-Hispanic black vs. non-Hispanic white patients, p = 0.0001.
	Chemotherapy rate for patients with colon cancer	Wudel et al.[100]	There was no statistically significant difference in unadjusted rates of treatment received along racial lines.

Table 14. Quality measures used to assess differences in quality of care by patients' race/ethnicity – continued

Question	Quality measure	Study	Results – race/ethnicity
	Chemotherapy rate for stage II or III rectal cancer patients	Neugut et al.[133]	Controlling for sociodemographic and clinical factors, non-black patients had a higher probability of receiving adjuvant chemotherapy and radiation therapy.
	Chemoradiotherapy rate stage II or III rectal cancer	Schrag et al.[132]	Adjusting for demographic, socioeconomic status, comorbidity, and other clinical risk factors, higher chemoradiation therapy use in white vs. black patients, p = 0.003.
2d	Non-receipt of standard radiation treatment	Demissie et al.[87]	Stages I and III rectal cancer black patients, when compared to white patients, experienced a significantly greater rate of non-receipt of standard radiation treatment after controlling for age, location of cancer, histological type, and tumor grade. There was no statistically significant difference for patients with stages II and IV rectal cancer.
	Radiation therapy rate	Dominitz et al.[88]	Adjusting for demographic, comorbidity, and other clinical factors, no statistically significant difference across racial lines was found in the receipt of radiation therapy in the VA population.
	Radiation therapy rate for patients with stages II and III CRC	Govindarajan[102]	Controlling for sex, site, socioeconomic status, and therapeutic modalities, higher percent of whites (43%) compared to blacks (26%) received therapy, p = 0.008.
	Rate of radiation therapy use for stage II, III rectal cancer patients	Morris et al.[105]	Controlling for age, sex, year of disease, geographic location, stage, and anatomic location, an adjusted odds ratio for non-receipt of treatment was higher for black (1.47) vs. white (1.15) patients.
	Adjuvant radiotherapy rate for rectal cancer patients	Rogers et al.[90]	Controlling for sex, nursing home status, socioeconomic status, tumor stage, comorbidity, and other potential risk factors, 4% of white patients received therapy compared to 13% of black patients, p = 0.001, adjusting for other factors.
	Rate of radiation therapy	Roetzheim et al.[94]	After adjusting for demographic, socioeconomic status, and clinical risk factors, no statistically significant difference was found in an adjusted odds ratio for receipt of treatment across racial lines.
	Rate of radiation therapy for rectal cancer	Wudel et al.[100]	No statistically significant difference was found in unadjusted rate of receipt of treatment across racial lines.
	Adjuvant radiation therapy rate for patients with stage II or III rectal cancer	Ayanian et al.[127]	Adjusting for demographic, socioeconomic status, and clinical factors, black patients were less likely to receive adjuvant therapy compared to white patients.

Table 14. Quality measures used to assess differences in quality of care by patients' race/ethnicity – continued

Question	Quality measure	Study	Results – race/ethnicity
3	Rate of colonoscopy or flexible sigmoidoscopy with barium enema after diagnosis	Rulyak et al.[157]	Controlling for demographic, clinical, socioeconomic status, and site of service covariates, lower use was observed among black compared to white patients.
	Percentage of patients who received posttreatment colonoscopy	LaFata et al.[162]	Adjusting for demographic, clinical, and socioeconomic status characteristics, whites were slightly more likely than non-white patients to receive followup colonoscopy (p = 0.09).

Table 15. Quality measures used to assess differences in quality of care by patients' socioeconomic status

Question	Quality measure	Study	Results – socioeconomic status (income/insurance status)
2b	Surgery rate for colon or rectal cancer patients	Roetzheim et al.[94]	Controlling for demographic, socioeconomic status factors, and clinical risk factors, the uninsured and Medicaid patients were less likely to undergo surgical treatment compared to FFS patients, p < 0.01.
	Surgery rate	Vernon et al.[92]	No statistically significant difference in treatment use of HMO vs. FFS patients when controlling for demographic, clinical, and socioeconomic status factors.
	Surgical resection rate of colon	Merrill et al.[91]	Controlling for demographic, socioeconomic status, and clinical factors, no difference observed in rectal cancer treatment of HMO vs. FFS patients undergoing surgery. HMO patients with rectal cancer were more likely to receive postsurgical radiation treatment than FFS patients.
2c	Rate of adjuvant chemotherapy use for stage III colon or stage II, III rectal cancer	Ayanian et al.[127]	Controlling for demographic, other socioeconomic status, and clinical risk factors, median household income was a predictor of rate of treatment; the higher the income, the more likely receipt of treatment, p = 0.006.
	Percentage of patients with stage II or III rectal cancer receiving chemoradiotherapy	Schrag et al.[132]	A slight, positive relationship (p = 0.09) was found between median income and odds of receiving adjuvant chemoradiation therapy, adjusting for demographic, socioeconomic status, comorbidity, and other clinical risk factors.
	Percentage of patients diagnosed with stage III colon cancer who received adjuvant chemotherapy	Schrag et al.[128]	Adjusting for demographic, comorbidity, and other clinical risk factors, a positive relationship was observed between median household income and receipt of treatment, p = 0.06.

Table 15. Quality measures used to assess differences in quality of care by patients' socioeconomic status – continued

Question	Quality measure	Study	Results – socioeconomic status (income/insurance status)
	Percent of patients diagnosed with stage II, III rectal cancer receiving adjuvant therapy	Potosky et al.[125]	Controlling for demographic, socioeconomic status, and clinical risk factors, income was found to be inversely related to standard adjuvant therapy (chemotherapy for stage III colon and chemotherapy and radiation therapy for stage II, III rectal cancer) use, p < 0.001.
	Adjuvant chemotherapy rate for patients with stage III colon cancer	Keating et al.[130]	After controlling for age, race, tumor stage and grade, comorbidity, socioeconomic status, and other risk factors, researchers found no statistically significant difference in increased market share penetration associated with lower rates of therapy use.
	Adjuvant chemotherapy rate for patients with stage II or III rectal cancer	Keating et al.[130]	After controlling for age, race, tumor stage and grade, comorbidity, socioeconomic status, and other risk factors, researchers found increased market share of managed care resulted in significant decrease in percent of patients with stage II or III rectal cancer received adjuvant chemotherapy and radiotherapy.
	Chemotherapy rate for patients with colon or rectal cancer	Roetzheim et al.[94]	Controlling for demographic, socioeconomic status factors, and clinical risk factors, patients who are members of a community HMO were less likely to receive treatment compared to those participating in a FFS program.
	Palliative chemotherapy rate	Retchin and Brown[136]	No statistically significant difference between HMO and FFS patients undergoing palliative chemotherapy.
	Rate of adjuvant radiation therapy use for stage II, III rectal cancer	Ayanian et al.[127]	Controlling for demographic, other socioeconomic status, and clinical risk factors, median household income was positively related to receipt of treatment, p = 0.006.
2d	Rate of radiation therapy	Roetzheim et al.[94]	Controlling for demographic and clinical risk factors, lower income level was a predictor of receipt of radiation therapy. Medicare patients enrolled in an HMO with colon cancer were less likely to receive radiation therapy. Among non-Medicare HMO enrollees, no insurance-related differences were observed.

Table 15. Quality measures used to assess differences in quality of care by patients' socioeconomic status – continued

Question	Quality measure	Study	Results – socioeconomic status (income/insurance status)
3	Rate of complete colonoscopy pre- or perioperatively	Keating et al.[130]	After controlling for age, race, tumor stage and grade, comorbidity, socioeconomic status, and other risk factors, researchers found that increased market share of managed care in a given county resulted in significant increase in the percent of patients with complete colonoscopy pre- or perioperatively, p = 0.001.
	Rate of colonoscopy during 7 to 18 mo after diagnosis	Keating et al.[130]	After controlling for age, race, tumor stage and grade, comorbidity, socioeconomic status, and other risk factors, researchers found no statistically significant difference in colonoscopy rates and market share increase of managed care.
	Rate of colonoscopy or flexible sigmoidoscopy with barium enema after diagnosis	Rulyak et al.[157]	Controlling for demographic, clinical, socioeconomic status, and site of service covariates, high median household annual income (≥ $40,000) was positively associated with receipt of first complete exam of the colon.
	Percentage of patients who received posttreatment colonoscopy	LaFata et al.[162]	Adjusting for demographic, socioeconomic status, and clinical risk factors, income was inversely related to receipt of followup colonoscopy (p = 0.03).
	Percentage of CRC patients having a surveillance colonoscopy after surgery	Retchin and Brown[136]	No statistically significant difference found between receipt of surveillance colonoscopy and health plan coverage (HMO vs. FFS).

Abbreviations: FFS = fee-for-service; HMO = health maintenance organization

Conclusions

The question of whether the evidence supports the use of any of the available quality measures ultimately devolves into asking whether the databases in question exhibit differential bias according to the patient subgroups being studied. For example, suppose that patients with stage III colon cancer are followed, and the process measure of interest is the percentage of patients receiving adjuvant chemotherapy. As discussed elsewhere, most but not all of such patients are good candidates for adjuvant chemotherapy, and not all patients that are offered such therapy will accept. If the data source is prospectively collected and designed to be sensitive to such issues (e.g., a form in the patient's medical record that documents whether or not the patient was a good candidate for chemotherapy and, if so, whether the therapy was accepted), then sufficient information is present to make an accurate comparison of, for example, rates of adjuvant chemotherapy use by age. On the other hand, if such information is absent, then the possibility exists that older patients may have more contraindications and/or a greater propensity to refuse therapy, thus biasing the conclusions. The answers to the above question about differential bias depend entirely on the quality measure, the groups to be compared, and the available database, but clearly this is the question that should be of fundamental importance to the analyst.

Chapter 4. Future Research

In brief, we have identified the following gaps in our knowledge, or equivalently, areas of emphasis for future research:

- Developing the two general process measures pertaining to the treatment of polyps (particularly, those polyps with evidence of malignancy) identified in this report.

- Expanding technical process measures for those topics with too few or no such measures; these include operative reports, chemotherapy reports, the treatment of polyps, and surgery.

- For those areas in which technical measures are well developed, identifying and focusing on those measures having the greatest impact on patient outcomes.

- Improving the evidence base on which all quality measures for colorectal cancer (CRC) are based.

- Clarifying and otherwise fine-tuning both the numerator and denominator of various measures (while at the same time addressing the trade-off between increased information requirements and data sources).

- Providing more explicit directions regarding risk-adjustment.

- Capturing data regarding patient preferences.

- Addressing quality of life (which is of immense importance to patients) within the context of quality improvement for CRC.

More detailed discussion regarding these gaps and future research required to fill them is provided under Questions 1 to 4, above.

The progress to date, as reflected by the existing quality measures, lends confidence that such future research will be fruitful.

Chapter 5. Conclusions

This section summarizes the overall conclusions about the quality measures identified in our literature review. More detailed conclusions about individual measures are included in the text of Chapter 3, under Questions 1-4.

Our approach to the classification of measures used as its organizing principle the distinction between structure, process, and outcome. Structural measures tended to be linked with the outcomes of complication rates and survival. An example of a typical application is the comparison of hospitals with different volumes of surgery according to the outcome of major complications associated with colorectal cancer (CRC)-related surgery. In these applications the structural variables tended to be generic (and not specific to CRC as such); for example, hospital volume and hospital type (e.g., urban vs. rural, academic vs. other). One application that used a structural measure that was more specific to CRC was the *proportion of colonoscopies performed by physicians with formal endoscopy training*.

Most applications were quite typical of the literature on structural variables and unremarkable for the purpose of identifying quality measures specific to CRC. The usual caveats to interpretation apply; most particularly, that crucial elements of the pathway between structure and outcome might be missing or incompletely specified. These elements include patient characteristics (e.g., comorbidities, preference for type of treatment, and sometimes even more critical information about stage of disease) and process of care.

Whether part of applications that linked structure to outcome, process to outcome, or focused on outcome alone, outcome variables were of three types: (a) complication rates; (b) survival; and (c) quality of life. Complication rates (e.g., complications of CRC surgery, complications of diagnostic colonoscopy) were straightforwardly defined in the same fashion as the process measures, i.e., as a ratio using a denominator counting the number of eligible patients and a numerator counting the number of such patients with the event of interest; here, a complication of treatment. The points of emphasis were the precise specification of the population at risk in the denominator and the precise specification of the events of interest in the numerator. For example, some outcome measures would most reasonably focus on any complications, whereas others would limit their focus to major complications only.

Survival-related outcome measures were of two types, proportion surviving at a specific point in time (e.g., 30-day mortality rates), and time until event. The former measures can be treated as traditional ratio measures, the main challenge being to select the time period that is most appropriate to the question at hand. For example, mortality rates associated with CRC surgery might reasonably be defined as either in-hospital mortality or 30-day mortality, 30-day mortality being a bit more pertinent but also inducing somewhat more stringent data requirements, as a mechanism for following patients that are discharged before 30 days post-surgery would be required. Time-to-event measures can be, and were, analyzed using traditional techniques of survival analysis such as Kaplan-Meier curves, and Cox models with hazard ratio estimators. Neither version of a survival-related outcome measure involves methodological issues that are unique to CRC.

The final type of outcome measure pertains to quality of life. While quality of life is of immense importance to patients with CRC, it was seldom used in the context of quality improvement, perhaps because of the large number of steps between the leverage points on which an intervention can be performed and the outcome of quality of life (and also because of the large number of other things, besides quality of care, that can affect CRC-related quality of life). Quality-of-life measures are also unique in that they are usually most naturally presented as continuous variables rather than on a ratio scale. A brief discussion of quality-of-life measures is provided in an Appendix A[*].

The primary focus of this report was on measures of CRC-related processes of care. Here, the main distinction is between those measures that are general versus technical.

The formula for creating a general process measure is to take the sequence of steps describing the optimal pattern of care for patients with CRC (i.e., as graphically summarized in Figures 1 and 2 in Chapter 1, or as described in more detail throughout the document), identify each of these steps as both a leverage point and a potential quality measure, and then define such a measure. For example, one of the earliest steps in the process involves the proper diagnosis of patients with a suspicion of CRC. A well-developed and well-tested measure associated with this step is *percentage of patients who underwent appropriate evaluation for a positive fecal occult blood test (FOBT)*. As with all ratio-based measures, it is critical to carefully define both the numerator and denominator of the measure. Here, the numerator can be based on a guideline and involves colonoscopy with complete visualization of the colon, although the literature did discuss various nuances, such as the precise definition of what complete visualization entails, how soon the colonoscopy should be performed after the positive FOBT, and so forth. The numerators of some general process measures will have a stronger evidence base than others, with those that are based on guidelines (especially those guidelines that are consistent across professional societies, when multiple such guidelines have been proffered) having the strongest evidence base, and those that are derived from basic first principles supported by some research findings being relatively weaker, but often quite sufficient for the task at hand.

Regarding the denominator, “patients with positive FOBT” comprise only a subset of those patients of ultimate interest, namely, “all patients with sufficiently high clinical suspicion of CRC to require followup testing.” These patients would include those with positive tests according to other modalities (e.g., barium enema, flexible sigmoidoscopy), and also those who come to the provider’s attention because of symptoms such as bleeding. Often, a clinically precise statement of the denominator involved deleting various patients; for example, those that would be ineligible because of comorbid conditions or other clinical issues, patients that refuse a form of therapy such as chemotherapy, and so forth.

A consistent source of tension is the distinction between the clinically derived fine-tuning of the definition of the denominator of a quality measure and the limitations of available data sources (which often do not contain sufficient information to act on such distinctions). Our approach here has been to encourage the definition of denominators that are as precise as possible, even if the available data sources might not meet all their requirements. In practice, it is crucially important to assess both the strengths and weaknesses of available data sources. Formal validation efforts are encouraged, but are not always strictly necessary. The assessment of data sources should include the differential impact of data quality on patient subgroups. For example, older patients tend to have more comorbidity and might thus be less likely to tolerate adjuvant chemoradiation therapy; an analysis that does not take this tendency into account could incorrectly lead to the conclusion that an age-related bias exists in the provision of such therapy. A similar caveat applies to analyses comparing patients by race and ethnicity, hospitals according to type, and so forth.

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[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/colocanqm/colocanqm.pdf

Overall, the coverage of general process measures (i.e., across the various leverage points in the sequence of care) is extensive. At least some process measures are available for the steps involving diagnostic imaging, staging, surgical therapy, adjuvant chemotherapy, adjuvant radiation therapy, and colonoscopic surveillance. Additional general process measures might be developed for polyp assessment and removal, although it must be recognized that the proper clinical course of action when presented with a malignant polyp is not always clear. While the above formula could be followed to generate even more general process measures within the above categories, perhaps the task of greater importance is to continue to refine those measures that already exist. The continued expansion of the evidence base, and the continued updating of guidelines, should assist this process. Moreover, the basic structure of general process measures facilitates such updating. For example, if future research suggests that the optimal interval for colonoscopic surveillance should be changed, then the structure of the existing quality measures related to surveillance need not be changed; all that would require change is the replacement of one recommended interval with another.

General process measures were used in both formal quality improvement applications as well as more general research applications, the distinction being that these latter applications did not tend to specify information such as the users and uses of the measure (i.e., the quality improvement context), as well as various other details about databases and other procedures that reflect the specificity required for quality improvement. Chapter 3 did not always explicitly maintain the distinction between these types of application, the main and quite encouraging reason being that it appeared that many of those measures that were used outside the quality improvement context could be rather straightforwardly modified to fit into this context. Overall, the general state of the science regarding general process measures was encouraging.

In contrast to general process measures, as might be anticipated, technical measures tended to be used in a quality improvement context. Although some excellent technical measures were found, the overall development of technical measures seems somewhat less advanced than that of the general process measures. In particular, for some elements of the care pathway, such as operative reports and chemotherapy reports, no technical measures were found. Various technical measures for quality of colonoscopy were found (e.g., cecal intubation rate). These were guideline-based, well developed, but less well tested, and the linkage between the technical measures and patient outcomes, although intuitive, was not always explicitly provided. To the extent that *complication rates of colonoscopy* can be considered a technical measure, this area of inquiry is relatively well developed. *Adequate lymph node retrieval and evaluation* is an excellent technical measure related to disease staging, although residual areas requiring clarification remain (e.g., optimal number of lymph nodes to examine, consideration that the optimal number of lymph node depends to some extent on patient characteristics). Technical measures associated with surgery are underdeveloped. Chemoradiation therapy has a number of potential and well-justified technical measures; here, the challenge is to identify and focus on those measures having the most impact on patient outcomes. Regarding reporting, technical measures for pathology reporting are well developed, reflecting among other things the areas of emphasis among the relevant professional societies. As noted above, no such technical process measures were identified for operative reports or chemotherapy reports, although it can quite reasonably presumed that with sufficient attention from professional societies and other stakeholders such measures could be developed.

Perhaps the most important areas for future development of technical measures are (a) developing such measures in those areas for which they are lacking; and (b) in areas where such measures exist, identifying and focusing on those measures having the greatest impact on outcome. As with the general measures, clarifying and otherwise fine-tuning the technical measures is a process that should be ongoing.

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Weaver P, Harrison B, Eskander G, et al. Colon cancer in blacks: a disease with a worsening prognosis. J Natl Med Assoc 1991;83(2):133-6.

Wei JT, Miller EA, Woosley JT, et al. Quality of colon carcinoma pathology reporting: a process of care study. Cancer 2004;100(6):1262-7.

Whittle J, Steinberg EP, Anderson GF, et al. Results of colectomy in elderly patients with colon cancer, based on Medicare claims data. Am J Surg 1992;163(6):572-6.

Wudel LJ Jr, Chapman WC, Shyr Y, et al. Disparate outcomes in patients with colorectal cancer: effect of race on long-term survival. Arch Surg 2002;137(5):550-4; discussion 554-6.

Acronyms and Abbreviations

5-FU	5-Fluorouracil
AAAHC	Accreditation Association for Ambulatory Health Care
ACS	American Cancer Society
ACS-COC	American College of Surgery Commission on Cancer
ADASP	Association of Directors of Anatomic and Surgical Pathology
AGA	American Gastroenterological Association
AHRQ	Agency for Healthcare Research and Quality
AJCC	American Joint Committee on Cancer
APR	Abdominal perineal resection
ASCO	American Society of Clinical Oncology
ASCRS	American Society of Colon and Rectal Surgeons
ASGE	American Society for Gastrointestinal Endoscopy
BE	Barium enema
CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention
CEA	Carcinoembryonic antigen
CMS	Centers for Medicare & Medicaid Services
CORI	Clinical Outcomes Research Initiative
CPT	*Current Procedural Terminology*
CRC	Colorectal cancer
CT	Computed tomography/tomographic
DCBE	Double contrast barium enema
EUS	Endoscopic ultrasound
FFS	Fee-for-service
FOBT	Fecal occult blood test
Gy	Gray
HCUP	Hospital Cost and Utilization Project
HMO	Health maintenance organization
HSCRC	Health Services Cost Review Commission
IOM	Institute of Medicine
MeV	Million electron volts
MRI	Magnetic resonance imaging
NCCS	North Carolina Cancer Study
NCDB	National Cancer Data Base
NCCN	National Comprehensive Cancer Network
NCI	National Cancer Institute
NCPB	National Cancer Policy Board
NCQA	National Committee for Quality Assurance
NIH	National Institutes of Health
NIS	Nationwide Inpatient Sample
NQF	National Quality Forum
NQMC	National Quality Measures Clearinghouse
PCS	Patterns of Care Study

RTOG	Radiation Therapy Oncology Group
SEER	Surveillance, Epidemiology, and End Results
SLN	Sentinel lymph node
TME	Total mesorectal excision
TNM	Tumor, Node, Metastasis Staging System
UICC	International Union Against Cancer
VA	Veterans Administration

APPENDIXES

to

“Cancer Care Quality Measures:
Diagnosis and Treatment of Colorectal Cancer”

Prepared by the Duke Evidence-based Practice Center
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Appendix A: Quality of Life

Methods of Assessing Quality of Life for Patients With Colorectal Cancer

When measuring quality of life for persons with colorectal cancer (CRC), most authors recommend the use of several instruments including a general instrument (e.g., SF-36, EQ-5D) that allows benchmarking against other conditions and a cancer-specific instrument that focuses on those aspects that are most salient to cancer. Ideally, the cancer-specific instrument would appropriately account for those aspects that are unique to CRC. Sprangers[1] and Provenzale and Gray[2] provide excellent reviews of the overall topic of how to assess quality of life in patients with CRC.

We describe various instruments that have been used in patients with CRC, including general health measures, cancer-specific measures, and CRC-specific measures. The general health measures and cancer-specific measures are listed and/or given only a very brief description. The CRC-specific measures are described, any validation efforts are noted, and the measures are rated.

General Health Status Measures

Various American researchers (e.g., Anthony et al.[3]) have tended to characterize the general health status of CRC patients using the Medical Outcome Study Short Form Health Survey (SF-36).[4] European researchers have also used the EQ-5D (e.g., Johnson et al.[5]). Other general health status measures, such as the Sickness Impact Profile and the Nottingham Health Profile, have also been used from time to time.[1] Various studies (e.g., Weeks et al.[6]) also use a single-item global measure of quality of life (e.g., “On a scale of 0-100, how do you rate your quality of life today?”), this latter measurement having the advantages of minimal respondent burden and being easily translated into a utility value usable within a cost-effectiveness analysis.

By design, it can reasonably be presumed that the validation efforts of these general health status instruments apply equally well to patients with CRC. For example, the eight dimensions of the SF-36 are physical functioning, physical role, pain, general health, vitality, social functioning, emotional role, and mental health, all of which are relevant to patients with CRC. Although it is helpful for many reasons to include a generic assessment of health-related quality of life, for the purposes of quality measurement its connection with the process of care is likely to be weaker than would be the corresponding connection with a measure that is more specific to CRC.

Cancer-Related Measures

Sprangers[1] notes that among the cancer-specific measures most commonly applied to patients with CRC are the Functional Living Index-Cancer (FLIC),[7] the Rotterdam Symptom Checklist (RSCL),[8] and the European Organization for Research and Treatment of Cancer (EORTC) Core Quality of Life Questionnaire (QLQ-C30),[9] these latter two measures tending to be used in

Europe and, as documented by Provenzale and Gray,[2] the most commonly used in practice. Additional cancer-specific measures include the Symptom Distress Scale,[6] the Quality of Life Index,[6] and the Functional Assessment of Cancer Therapy-General (FACT-G).[10]

As an illustration of the nature of typical cancer-specific instruments, the 13-item Symptom Distress Scale[6] measures symptom frequency and distress in the domains of nausea, appetite, insomnia, pain, fatigue, bowel function, concentration, appearance, breathing, outlook, and cough, all with five response categories and a summary score using all items. The 5-item Quality of Life Index[6] measures quality of life in the domains of activity, daily living, health, support and outlook, all with three response categories, and a summary score using all items. The 22-item FLIC instrument[7] addresses physical well-being, social well-being, hardship due to cancer and nausea (all items are coded on a 1-7 scale). The FACT-G[10] is subdivided into seven items on physical well-being, seven items on social well-being, six items on emotional well-being, and seven items on functional well-being.

Chapman et al.[11] measured quality of life for 2,202 patients with ileal pouch-anal anastomosis (not all from cancer-related surgery) and applied a reasonable but not formally validated instrument to measure quality of life. The instrument measures constructs (sexual life, social, sports and work activities, family relationships) not on an absolute scale, but relative to the patient's status before surgery.

Ayanian et al.[12] conducted phone interviews of CRC patients obtained from a cancer registry in northern California using a 34-item instrument addressing emotional, social, physical and functional well-being. The instrument, with the exception of one question pertaining to bowel function, appears to be equally applicable to other cancer patients. The instrument successfully measures differences in satisfaction with care according to age, race, and sex, among other factors. With the possible exception of the instrument from which the candidate items were originally derived, the current version of this instrument has not been validated outside the context of this study.

As above, it can reasonably be presumed that the validation efforts of these cancer-specific quality-of-life instruments apply equally well to patients with CRC. It can also be presumed that the connection between quality of life as measured by these instruments and process of care is stronger than would be the case for general health instruments, but weaker than would be the case for CRC-specific instruments.

CRC-Related Measures

Most investigators have adopted what Spangers[1] terms the "modular approach" to CRC-specific measures; that is, beginning with a general cancer-specific scale and adding items relevant to CRC. The most noteworthy examples are the FACT-C and the QLQ-CR38.

The FACT-C begins with the 27-item FACT-G scale (described in brief above), then adds a 9-item Colorectal Cancer Subscale (CCS). Two of the nine CCS items pertain to ostomy appliances and thus are not relevant to most CRC patients. In many applications, only the remaining seven items are used. Thus, the usual version of the FACT-C has 34 items (27 from the FACT-G and 7 from the CCS). Ward et al.[10] describe the validation of the FACT-C in 60 patients with advanced CRC and 156 patients with CRC but without distant metastases, these patients being sub-divided into 63 English-speakers and 93 Spanish-speakers. Separate analyses were also performed on the 29 patients in this latter sample. Standard techniques of psychometric analysis were applied, including an examination of internal consistency, convergent validity, divergent validity, the ability to distinguish among known groups, and sensitivity to change. Overall, the results strongly support the validity of the FACT-C.

The QLQ-CR38 uses the QLQ-C30 (discussed above), and adds 38 CRC-specific questions. Nineteen of these questions are answered by all respondents, and 19 depend on circumstances. Items are combined into sub-scales of micturition problems, gastrointestinal symptoms, side effects of chemotherapy, bowel problems, stoma-related problems, sexual problems, body image, and future-looking orientation. Validation was performed on 117 Dutch patients with CRC, and an English version is available. Overall, the results strongly support the validity of the instrument.

Schwenk et al.[13] compared results from the EORTC QLQ-C30 and the Gastrointestinal Quality of Life Index (GIQLI). Although the research was performed outside the United States (116 German patients undergoing surgery for CRC), to our knowledge this is the first formal comparison between the scales. The level of agreement between the instruments was low; the EORTC QLQ-C30 was found to be more sensitive in the detection of impairment of quality of life in the early post-operative period, causing the authors to recommend the EORTC QLQ-C30 as the preferred instrument.

Gupta et al.[14] validated the use of the subjective global assessment (SGA), a clinical technique that combines data from subjective and objective aspects of medical history and physical examination, in stage III and IV colorectal cancer patients, finding those with poorer SGA also had poorer survival.

Temple et al.[15] report on the development and initial validation of an instrument to evaluate bowel function after sphincter-preserving surgery for rectal cancer. Elements of validation, as applied to 184 patients undergoing sphincter-preserving surgery, included internal consistency, discriminant and construct validity, test-retest, and reliability. This 18-item, 5-response-category scale shows promising psychometric properties.

In addition to these formal CRC-related measures, various investigators have applied the above module-based thinking on an ad hoc basis. For example, Caffo et al.[16] created a self-administered diary card, recorded daily by 32 patients with rectal cancer, consisting of 10 clinically derived questions, nine of which (e.g., “Did you feel any nausea today?”) are coded on a scale of 1 to 4; the final question (“How many times have you had bowel movements today?”) is coded as an integer. Results were analyzed at the item level, and there was no total score. No formal validation of the measure was provided.

In a study comparing the quality-of-life experience of 44 patients undergoing surgery for benign colonic disease, 61 patients with CRC undergoing surgery alone, and 53 CRC patients undergoing both surgery and adjuvant therapy, Anthony et al.[3] added five CRC-specific questions to the SF-36, asking about appetite, weight, bowel function, urinary function, and whether the patient would repeat the same therapy as before. No formal validation was provided.

Ratings

Rating only those measures that were formally developed in order assess CRC-related quality of life, both the FACT-C and the QLQ-CR38 can be rated as Importance 4, Usability 4, and Validity 4. Regarding importance, the salience of the items to quality of life with CRC is clear, the only negative for the purpose of quality measurement being the possibly weak link between process of care and quality of life. All measures are usable, except for very sick patients for whom respondent burden is a major issue, in which case a single-item general health scale might be preferred. In both cases, the validation of the parent measure has been extensive, and the validation of the CRC-related subscale less comprehensive but nevertheless quite encouraging.

References

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2. Provenzale D, Gray RN. Colorectal cancer screening and treatment: review of outcomes research. J Natl Cancer Inst Monogr 2004;(33):45-55.

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4. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30(6):473-83.

5. Johnson J, Luo N, Shar J, et al. Valuations of EQ-5D Health States: Are the United States and United Kingdon Different? Med Care 2005;43(3):221-8.

6. Weeks J, Nelson H, Gelber S, et al. Short-term quality of life outcomes following laparoscopic-assisted colectomy vs open colectomy for colon cancer: a randomized trial. JAMA 2002;287(3):321-8.

7. Schipper H, Clinch J, McMurray A, et al. Measuring the quality of life of cancer patients: The Functional Living Index-Cancer: development and validation. J Clin Oncol 1984;2(5):472-83.

8. de Haes JC, van Knippenberg FC, Neijt JP. Measuring psychological and physical distress in cancer patients: structure and application of the Rotterdam Symptom Checklist. Br J Cancer 1990;62(6):1034-8.

9. Aaronson NK, Ahmedzai S, Bergman B, et al. The EORTC QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst 1993;85(5):365-76.

10. Ward WL, Hahn EA, Mo F, et al. Reliability and validity of the Functional Assessment of Cancer Therapy-Colorectal (FACT-C) quality of life instrument. Qual Life Res 1999;8(3):181-95.

11. Chapman JR, Larson DW, Wolff BG, et al. Ileal pouch-anal anastomosis: does age at the time of surgery affect outcome? Arch Surg 2005;140(6):534-9; discussion 539-40.

12. Ayanian JZ , Zaslavsky AM , Guadagnoli E , et al. Patient perceptions of quality of care for colorectal cancer by race, ethnicity, and language. J Clin Oncol 2005;23(27):TBD.

13. Schwenk W, Neudecker J, Haase O, et al. Comparison of EORTC quality of life core questionnaire (EORTC-QLQ-C30) and gastrointestinal quality of life index (GIQLI) in patients undergoing elective colorectal cancer resection. Int J Colorectal Dis 2004;19(6):554-60.

14. Gupta D, Lammersfeld CA, Vashi PG, et al. Prognostic significance of Subjective Global Assessment (SGA) in advanced colorectal cancer. Eur J Clin Nutr 2005;59(1):35-40.

15. Temple LK, Bacik J, Savatta SG, et al. The development of a validated instrument to evaluate bowel function after sphincter-preserving surgery for rectal cancer. Dis Colon Rectum 2005;48(7):1353-65.

16. Caffo O, Amichetti M, Romano M, et al. Evaluation of toxicity and quality of life using a diary card during postoperative radiotherapy for rectal cancer. Dis Colon Rectum 2002;45(4):459-65; discussion 465-7.

Appendix B: Exact Search String

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Database: Ovid MEDLINE(R) <1966 to January Week 1 2005>
Search Strategy:
--------------------------------------------------------------------------------
1     exp colorectal neoplasms/ or colonic neoplasms/ (83,325)
2     exp *"Quality of Health Care"/ (286,107)
3     exp *"Patient care management"/ (162,883)
4     exp *"Organization and Administration"/ (326,572)
5     exp *"health care quality, access, and evaluation"/ (521,870)
6     or/72,82,85,87 (810,834)
7     95 or age factors/ or african americans/ or specialties, surgical/ (1,067,364)
8     99 and 68 (5742)
9     limit 100 to (human and english language and yr=1990-2005) (3644)
```

Appendix C: List of Excluded Studies

All excluded studies list below were reviewed in their full-text version. Following each reference, in italics, is the reason for exclusion. Reasons for exclusion signify only the usefulness of the articles for this study and are not intended as criticisms of the articles.

Aaltonen LA, Sankila R, Mecklin JP, et al. A novel approach to estimate the proportion of hereditary nonpolyposis colorectal cancer of total colorectal cancer burden. Cancer Detect Prev 1994;18(1):57-63. *Exclude non-U.S. data.*

Abel U, Wollermann C. Methodological aspects of the evaluation of postoperative cancer surveillance. Part II: Efficacy. Clin Lab 2003;49(7-8):379-98. *Exclude non-U.S. data*.

Abulafi AM, Williams NS. Local recurrence of colorectal cancer: the problem, mechanisms, management and adjuvant therapy. Br J Surg 1994;81(1):7-19. *Exclude review*.

Achkar E. Colorectal cancer screening in primary care: the long and short of it. Am J Gastroenterol 2004;99(5):837-8. *Exclude falls outside Task Order scope*.

Adair A, Bennis M, Clifton MA. Referral guidelines for colorectal cancer--do they work? Ann R Coll Surg Engl 2004;86(2):144. *Exclude non-U.S. data*.

Adam IJ, Mohamdee MO. Role of Circumferential Margin Involvement in the Local Recurrence of Rectal Cancer. Lancet 1994;344(8924). *Exclude non-U.S. data*.

Adams J, White M, Barker G, et al. Are there socio-economic inequalities in age of resection of colorectal cancer in people with HNPCC? Fam Cancer 2003;2(3-4):169-73. *Exclude non-U.S. data.*

Adams T, Dufton R, Lamb C, et al. Hospital secondments of community nurses to improve stoma care. Br J Community Nurs 2003;8(12):539-43. *Exclude non-U.S. data.*

Adler GS, Shatto A. Screening for osteoporosis and colon cancer under Medicare. Health Care Financ Rev 2002;23(4):189-200. *Exclude falls outside Task Order scope.*

Afridi SA, Jafri SF, Marshall JB. Do gastroenterologists themselves follow the American Cancer Society recommendations for colorectal cancer screening?. Am J Gastroenterol 1994;89(12):2184-7. *Exclude falls outside Task Order scope.*

Agrez MV, Coory M, Cockburn J. Population screening for colorectal carcinoma with fecal-occult blood testing: are we sufficiently informed? Cancer 1998;82(10):1803-7. *Exclude falls outside Task Order scope.*

Ahlquist DA. Fecal occult blood testing for colorectal cancer. Can we afford to do this? Gastroenterol Clin North Am 1997;26(1):41-55. *Exclude review.*

Ahlquist DA, Shuber AP. Stool screening for colorectal cancer: evolution from occult blood to molecular markers. Clin Chim Acta 2002;315(1-2):157-68. *Exclude falls outside Task Order scope.*

Ahmad NA, Hoops TC. The role of colonoscopy for screening of colorectal cancer. Semin Roentgenol 2000;35(4):404-8. *Exclude review*.

Ahnen DJ, Lynch KL. Colorectal cancer screening in average - and high-risk groups. Adv Intern Med 2001;46:77-106. *Exclude review.*

Aihara H, Kawamura YJ, Konishi F. Reduced medical costs achieved after elective oncological colorectal surgery by early feeding and fewer scheduled examinations. J Gastroenterol 2003;38(8):747-50. *Exclude non-U.S. data.*

Akerley WL 3rd, Moritz TE, Ryan LS, et al. Racial comparison of outcomes of male Department of Veterans Affairs patients with lung and colon cancer. Arch Intern Med 1993;153(14):1681-8. *Exclude no explicit QM.*

Alexander D, Chatla C, Funkhouser E, et al. Postsurgical disparity in survival between African Americans and Caucasians with colonic adenocarcinoma. Cancer 2004;101(1):66-76. *Exclude survival only.*

Alexander D, Jhala N, Chatla C, et al. High-grade tumor differentiation is an indicator of poor prognosis in African Americans with colonic adenocarcinomas. Cancer 2005;103(10):2163-70. *Exclude review.*

Alici S, Aykan NF, Sakar B, et al. Colorectal cancer in young patients: characteristics and outcome. Tohoku J Exp Med 2003;199(2):85-93. *Exclude non-U.S. data.*

Allal AS, Mermillod B, Roth AD, et al. The impact of treatment factors on local control in T2-T3 anal carcinomas treated by radiotherapy with or without chemotherapy. Cancer 1997;79(12):2329-35. *Exclude no explicit QM.*

Allenmersh TG, Earlam S. Quality of Life and Survival with Continuous Heaptic-Artery Floxuridine Infusion for Colorectal Liver Metastases. Lancet 1994;344(8932). *Exclude no explicit QM.*

American Society of Clinical Oncology. Outcomes of cancer treatment for technology assessment and cancer treatment guidelines: outcomes for technology assessments and guideline development. Available at: http:www.asco.org/ac/. Accessed: April 6, 2005. 1995. *Exclude review.*

Andreoni B, Biffi R, Torri V. Follow-up in colorectal cancer. Tumori 1997;83(1 Suppl):S19-20. *Exclude non-U.S. data.*

Ang YS, Macaleenan N, Mahmud N, et al. The yield of colonoscopy in average-risk patients with non-specific colonic symptoms. Eur J Gastroenterol Hepatol 2002;14(10):1073-7. *Exclude non-U.S. data*

Angelo N, Dreyer L. Colorectal carcinoma--a new threat to black patients? A retrospective analysis of colorectal carcinoma received by the Institute for Pathology, University of Pretoria. S Afr Med J 2001;91(8):689-93. *Exclude non-U.S. data*

Anonymous. Recommendations for the reporting of resected large intestinal carcinomas. Association of Directors of Anatomic and Surgical Pathology. Mod Pathol 1996;9(1):73-6. *Exclude review.*

Anonymous. Screening for colorectal cancer--United States, 1992-1993, and new guidelines. MMWR Morb Mortal Wkly Rep 1996;45(5):107-10. *Exclude falls outside Task Order scope.*

Anonymous. AHCPR releases evidence report on colorectal cancer screening. Oncology (Huntingt). 1997;11(3):342-4. *Exclude review.*

Anonymous. Clinical pathways for general surgeons: elective colectomy for cancer. Am Surg 1998;64(5):481-4. *Exclude no explicit QM.*

Anonymous. Colonoscopy in the screening and surveillance of individuals at increased risk for colorectal cancer. American Society for Gastrointestinal Endoscopy. Gastrointest Endosc 1998;48(6):676-8. *Exclude review.*

Anonymous. Guidelines for colorectal cancer screening and surveillance. Gastrointest Endosc 2000;51(6):777-82. *Exclude review.*

Anonymous. Surgery for colorectal cancer in elderly patients: a systematic review. Colorectal Cancer Collaborative Group. Lancet 2000;356(9234):968-74. *Exclude review.*

Anonymous. Colonoscopy benchmarks suggest less invasive tack not always most productive. Data Strateg Benchmarks 2001;5(8):116-9, 113. *Exclude review.*

Anonymous. Summaries for patients. Choice of statistical analysis can change the results of studies of the relationship between hospital and surgeon volume and outcomes of cancer surgery. Ann Intern Med 2003;139(8):I44. *Exclude no explicit QM.*

Anonymous. Summaries for patients. Relationships between the amount of colon cancer surgery a hospital performs and patient outcomes. Ann Intern Med 2003;139(8):I28. *Exclude no explicit QM.*

Anonymous. Summaries for patients. Using risks to tailor screening for colorectal cancer. Ann Intern Med 2003;139(12):I10. *Exclude non-U.S. data.*

Anonymous. Summaries for patients. What is the best way to test for colorectal cancer?[original report in Ann Intern Med. 2005 Jan 18;142(2):81-5; PMID: 15657155]. Ann Intern Med 2005;142(2):I23. *Exclude wrong population*

Anthony T, Fleming JB, Bieligk SC, et al. Postoperative colorectal cancer surveillance. J Am Coll Surg 2000;190(6):737-49. *Exclude review.*

Anthony T, Jones C, Antoine J, et al. The effect of treatment for colorectal cancer on long-term health-related quality of life. Ann Surg Oncol 2001;8(1):44-9. *Exclude review.*

Anthony T, Simmang C, Hyman N, et al. Practice parameters for the surveillance and follow-up of patients with colon and rectal cancer. Dis Colon Rectum 2004;47(6):807-17. *Exclude review.*

Aparicio T, Desrame J, Lecomte T, et al. Oxaliplatin- or irinotecan-based chemotherapy for metastatic colorectal cancer in the elderly. Br J Cancer 2003;89(8):1439-44. *Exclude non-U.S. data.*

Apolone G, Cavuto S, Torri V, et al. Effectiveness of adjuvant fluorouracil in elderly colon cancer patients: the internal and external validity of nonrandomized research design. J Clin Oncol 2003;21(9):1892; author reply 1893. *Exclude non-U.S. data.*

Apolone G, Filiberti A, Cifani S, et al. Evaluation of the EORTC QLQ-C30 questionnaire: a comparison with SF-36 Health Survey in a cohort of Italian long-survival cancer patients. Ann Oncol 1998;9(5):549-57. *Exclude non-U.S. data.*

Apse KA, Biesecker BB, Giardiello FM, et al. Perceptions of genetic discrimination among at-risk relatives of colorectal cancer patients. Genet Med 2004;6(6):510-6. *Exclude falls outside Task Order scope.*

Archer SB, Burnett RJ, Flesch LV, et al. Implementation of a clinical pathway decreases length of stay and hospital charges for patients undergoing total colectomy and ileal pouch/anal anastomosis. Surgery 1997;122(4):699-703; discussion 703-5. *Exclude falls outside Task Order scope.*

Arenal JJ, Benito C, Concejo MP, et al. Colorectal resection and primary anastomosis in patients aged 70 and older: prospective study. Eur J Surg 1999;165(6):593-7. *Exclude non-U.S. data.*

Armbrecht U, Manus B, Bragelmann R, et al. Acceptance and outcome of endoscopic screening for colonic neoplasia in patients undergoing clinical rehabilitation for gastrointestinal and metabolic diseases. NZ Gastroenterol 1994;32(1):3-7. *Exclude non-U.S. data.*

Arnaud JP, Schloegel M, Ollier JC, et al. Colorectal cancer in patients over 80 years of age. Dis Colon Rectum 1991;34(10):896-8. *Exclude non-U.S. data*.

Arndt V, Merx H, Stegmaier C, et al. Quality of life in patients with colorectal cancer 1 year after diagnosis compared with the general population: a population-based study.[erratum appears in J Clin Oncol 2005 Jan 1;23(1):248]. J Clin Oncol 2004;22(23):4829-36. *Exclude non-U.S. data*

Arora A, Singh P. Colonoscopy in patients 80 years of age and older is safe, with high success rate and diagnostic yield. Gastrointest Endosc 2004;60(3):408-13. *Exclude non-U.S. data.*

Ashley OS, Nadel M, Ransohoff DF. Achieving quality in flexible sigmoidoscopy screening for colorectal cancer. Am J Med 2001;111(8):643-53. *Exclude review.*

Atkin W, Rogers P, Cardwell C, et al. Wide variation in adenoma detection rates at screening flexible sigmoidoscopy. Gastroenterology 2004;126(5):1247-56. *Exclude non-U.S. data.*

Audisio RA, Filiberti A, Geraghty JG, et al. Personalized surgery for rectal tumours: the patient's opinion counts. Support Care Cancer 1997;5(1):17-21. *Exclude no explicit QM*.

Audisio RA, Robertson C. Colorectal cancer follow-up: perspectives for future studies. Eur J Surg Oncol 2000;26(4):329-37. *Exclude review.*

Austin D, Russell EM. Is there ageism in oncology? Scott Med J 2003;48(1):17-20. *Exclude non-U.S. data*

Ayanian JZ , Zaslavsky AM , Guadagnoli E , et al. Patient perceptions of quality of care for colorectal cancer by race, ethnicity, and language. Jl Clin Oncol 2005;23(27):TBD. *Exclude QOL.*

Baier M, Calonge N, Cutter G, et al. Validity of self-reported colorectal cancer screening behavior. Cancer Epidemiol Biomarkers Prev 2000;9(2):229-32. *Exclude falls outside Task Order scope.*

Baig MK, Marks CG. Referral guidelines for colorectal cancer: a threat or a challenge? Hosp Med 2000;61(7):452-3. *Exclude review.*

Bailes J. Final report of the national initiative on cancer care quality. American Society of Clinical Oncology. Slide presentation. Available at: http://www.asco.org/ac/. Accessed: April 6, 2005. 2004. *Exclude review.*

Bailey C, Corner J, Addington-Hall J, et al. Older patients' experiences of treatment for colorectal cancer: an analysis of functional status and service use. Eur J Cancer Care (Engl) 2004;13(5):483-93. *Exclude non-U.S. data.*

Bailey C, Corner J, Addington-Hall J, et al. Treatment decisions in older patients with colorectal cancer: the role of age and multidimensional function. Eur J Cancer Care (Engl). 2003;12(3):257-62. *Exclude non-U.S. data.*

Baker D. Current surgical management of colorectal cancer. Nurs Clin North Am 2001;36(3):579-92, xi-xii. *Exclude review.*

Balducci L. Believing is seeing: a new parameter to study cancer prevention and cancer treatment in older individuals. Cancer 2004;100(5):881-2. *Exclude no explicit QM.*

Balducci L, Mowry K. Pharmacology and organ toxicity of chemotherapy in older patients. Oncology (Huntingt) 1992;6(2 Suppl):62-8. *Exclude review.*

Ball JK, Elixhauser A. Treatment differences between blacks and whites with colorectal cancer. Med Care 1996;34(9):970-84. *Exclude no explicit QM.*

Bampton PA, Sandford JJ, Cole SR, et al. Interval faecal occult blood testing in a colonoscopy based screening programme detects additional pathology. Gut 2005;54(6):803-6. *Exclude non-U.S. data.*

Bampton PA, Sandford JJ, Young GP. Applying evidence-based guidelines improves use of colonoscopy resources in patients with a moderate risk of colorectal neoplasia. Med J Aust 2002;176(4):155-7. *Exclude non-U.S. data.*

Baquet CR, Commiskey P. Colorectal cancer epidemiology in minorities: a review. J Assoc Acad Minor Phys 1999;10(3):51-8. *Exclude falls outside Task Order scope.*

Barkun AN, Jobin G, Cousineau G, et al. The Quebec Association of Gastroenterology position paper on colorectal cancer screening - 2003. Can J Gastroenterol 2004;18(8):509-19. *Exclude non-U.S. data.*

Baron PL, Sigurdson ER. Local surgical treatment of rectal cancer. Cancer Invest 1995;13(6):612-6. *Exclude review.*

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Turner B, Myers RE, Hyslop T, et al. Physician and patient factors associated with ordering a colon evaluation after a positive fecal occult blood test. J Gen Intern Med 2003;18(5):357-63. *Exclude no explicit QM.*

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Tyldesley S, Zhang-Salomons J, Groome PA, et al. Association between age and the utilization of radiotherapy in Ontario. Int J Radiat Oncol Biol Phys 2000;47(2):469-80. *Exclude non-U.S. data.*

Ubhi SS, Kent SJ. Which surgeons in a district general hospital should treat patients with carcinoma of the rectum? J R Coll Surg Edinb 1995;40(1):52-4. *Exclude non-U.S. data.*

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Wakefield SE, Baigrie RJ, MacLeod AJ, et al. Colorectal cancer surgery in a district general hospital. J R Coll Surg Edinb 1996;41(6):374-8. *Exclude non-U.S. data.*

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Whittle J, Steinberg EP, Anderson GF, et al. Accuracy of Medicare claims data for estimation of cancer incidence and resection rates among elderly Americans. Med Care 1991;29(12):1226-36. *Exclude data sources.*

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Wullenweber HP, Sutter C, Autschbach F, et al. Evaluation of Bethesda guidelines in relation to microsatellite instability. Dis Colon Rectum 2001;44(9):1281-9. *Exclude non-U.S. data.*

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Yamamoto S, Watanabe M, Hasegawa H, et al. Prospective evaluation of laparoscopic surgery for rectosigmoidal and rectal carcinoma. Dis Colon Rectum 2002;45(12):1648-54. *Exclude non-U.S. data.*

Yancik R, Wesley M, Ries L, et al. Comorbidity and Age s Predictors of Risk for Early Mortality of Male and Female Colon Carcinoma Patients. Cancer 1998;82(11):2123-34. *Exclude survival only.*

Yancik R, Wesley MN, Ries LA, et al. Comorbidity and age as predictors of risk for early mortality of male and female colon carcinoma patients: a population-based study. Cancer 1998;82(11):2123-34. *Exclude no explicit QM.*

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Yoong KK, Heymann T. Colonoscopy in the very old: why bother? Postgrad Med J 2005;81(953):196-7. *Exclude falls outside Task Order scope.*

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Zauber AG, Winawer SJ. Initial management and follow-up surveillance of patients with colorectal adenomas. Gastroenterol Clin North Am 1997;26(1):85-101. *Exclude review.*

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Zieren HU, Muller JM, Zieren J, et al. The impact of patient's age on surgical therapy of colorectal liver metastases. Int Surg 1993;78(4):288-91. *Exclude non-U.S. data.*

Ziogas A, Anton-Culver H. Validation of family history data in cancer family registries. Am J Prev Med 2003;24(2):190-8. *Exclude no explicit QM.*

Zorcolo L, Covotta L, Carlomagno N, et al. Safety of primary anastomosis in emergency colo-rectal surgery. Colorectal Dis 2003;5(3):262-9. *Exclude non-U.S. data*.

Appendix D: Sample Data Abstraction Forms*

Blank Data Abstraction Form/ET for CRC Care Quality Evidence Report (to be used for *published* quality measures only)

General instructions:

1) If an article includes more than one quality measure, please complete a separate evidence table entry (row) for each measure.

2) If an article includes a quality measure having to do with the *quality of a data source*, please note this under "General comments" in the Comments column, but do not abstract the data pertaining to this measure (we will do that separately).

3) If an article reports on *long-term survival/mortality* as a quality measure, please note this under "General comments" in the Comments column, but do not abstract the data pertaining to this measure (we will do that separately). Please *do* abstract data on short-term post-surgical mortality.

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
First author, date, Pro-Cite#	**Quality measure (QM):** [include formal name of measure, if any, or give description ("the percentage of …")] **Basis of QM:** [delete all but one] Clinical practice guideline Other (please specify): None If basis was *clinical practice guideline* or *"other,"* was this named/cited in the article? Yes/No If yes, please specify here: If no, do you think you know what it was?: Yes (please specify): No **Type of QM:** [delete all but one in each line] (a) Structure/Process/Outcome (b) General/Technical For *structure* and *process* measures, please indicate the **Outcome to which the QM is linked:** **Intent of QM:** [delete as appropriate] Quality improvement Accountability Research Other (please specify):	**Study population:** N: Age: Race: Sex: Tumor stage: Performance status: Other: **Geographic location:** **Dates:** **Healthcare setting:** **Is this a formal validation study?:** Yes/No If no, does it cite a formal validation study?: Yes (give citation #)/No **Results:**	**If article should be EXCLUDED, please indicate why:** [delete as appropriate] Non-US data Review article Wrong study population: [delete as appropriate] Screening of asymptomatic individuals Familial polyposis syndrome Ulcerative colitis Colorectal CA with hereditary nonpolyposis Multiple metastases (majority not colorectal CA) Other (please specify): No explicit QM with positive colorectal CA diagnosis No data source testing of validity/reliability Other (falls outside scope of Task Order) **General comments:** **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: - Usability: - Scientific acceptability (five criteria): Precise specifications: Reliability: Validity: Adaptability: Adequacy of risk adjustment:

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
	Not specified: **Definition of denominator/numerator:** Denominator: Numerator: **Data sources:** **Recommended frequency of data collection:**		**This QM is relevant to:** [please delete as appropriate] Question 1a (imaging, visualization, biopsy) Question 1b (pathologic staging) Question 2a (polypectomy, eval surgical margins) Question 2b (surgical therapy) Question 2c (adj chemo and metastatic CRC) Question 2d (radiation therapy) Question 3 (colonoscopic surveillance) Question 4 (documentation of reporting) Question 5a (patient populations and purposes) Question 5b (demographic differences)

* The data abstraction form reproduced here was used for *published* quality measures. The form used for *unpublished* measures was identical to the above, except that it omitted the center column, on “Testing of Quality Measure.”

Appendix E: Evidence Tables

Evidence Table 1 – Question 1a (Published Literature): *What quality-of-care measures are available and what evidence is available for these measures to assess the quality of diagnosis of colorectal cancer, including appropriate use of colon imaging, endoscopic visualization, and biopsy?*

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Baig, Myers, Turner, et al., 2003 **#33210**	**Quality measure (QM):** Percentage of patients with a positive fecal occult blood test (+FOBT) who underwent a complete diagnostic evaluation (colonoscopy or double contrast barium enema [DCBE]) **Basis of QM:** Clinical practice guideline; not cited, but appears to be Multi-Society Task Force (Winawer et al., Gastroenterology 1997, updated 2003; maybe also U.S. Preventive Services Task Force (Pignone et al., Ann Intern Med ~2002) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Mortality in prior trials – no link within this particular paper **Intent of QM:** Not specified (aim of the study was to determine reasons for non-performance of a complete diagnostic evaluation) **Definition of denominator/numerator:** Denominator: Number of Aetna Health (an HMO in greater Philadelphia, PA) participants aged 50 and older who had a +FOBT from Aug-Nov 1998 Numerator: Number above subjects who had a colonoscopy or DCBE at 60 days from the +FOBT, as indicated by mailed survey and claims data **Data sources:** Provider survey, MCO claims data **Recommended frequency of data collection:** No recommendation	**Study population:** HMO patients; primary care practices N: 544 Age: ≥ 50 Race: NR Sex: NR Tumor stage: NA **Geographic location:** Greater Philadelphia, PA **Dates:** FOBT result, Aug-Nov 1998; follow up at 60 days **Healthcare setting:** HMO primary care practices **Results:** Of the 544 +FOBT patients, 46% did not receive colonoscopy or DCBE.	**General comments:** Measure has face validity because follow up of +FOBT with colonoscopy (or DCBE) is supported by practice guidelines, which themselves are supported by large well-designed RCTs with (disease-specific) mortality as the end point. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 4 Validity: 4 Adaptability: 4 Adequacy of risk adjustment: 1

Evidence Table 1 – Question 1a (Published Literature) – continued

Study

Beart, Steele Jr., Menck, et al., 1995

#990

Characteristics of Quality Measure

Quality measure (QM): Percentage of patients with colon (or rectal) cancer undergoing colonoscopy as part of their initial evaluation

Basis of QM: None

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: None is specified, but presumably it would be the finding of synchronous lesions that should be dealt with during surgery as well as the primary tumor

Intent of QM: Not specified (aim of the study was to identify current trends in the management of patients with carcinoma of the colon or rectum and to identify changes in patterns of care and survival)

Definition of denominator/numerator:
Denominator:
Number of cases of colon and rectal cancer (up to 25 per program or facility) reported by over 1,200 approved cancer programs and 800 other facilities on the Commission on Cancer mailing list that were invited to participate.

Numerator:
Number of above cases having colonoscopy as part of their initial evaluation.

Data sources: Hospitals sent in up to 25 consecutive cases from their medical records

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 39,502 (29,209 colon; 10,293 rectal)

	Colon		Rectum	
	1983	1988	1983	1988
Cases	12,682	16,527	4,597	5,696
< 50 yrs	5.6	5.3	6.1	6.1
50-69	39.4	37.4	46.1	46.0
70-79	33.4	33.9	31.5	31.2
80+	2106	23.4	16.2	16.7
Male %	47.8	49.3	55.9	57.2
Tumor Stage				
0	3.7	5.5	5.6	6.1
I	21.2	22.9	27.4	28.3
II	29.9	28.6	22.7	21.6
III	22.4	22.1	21.9	22.0
IV	20.1	17.7	17.0	16.7
Unkown	2.7	3.3	5.4	5.4
Non-hispanic white		86.1		87.0
Hispanic		2.7		3.5
AA		9.1		6.5
Asian		1.1		1.6

Performance status: NR

Geographic location: Entire U.S.

Dates: Calendar years 1983 and 1988

Healthcare setting: Hospitals

Results:
44% of colon cancer patients in 1983 and 63.8 in 1988 underwent colonoscopy.

30.1% of rectal cancer patients in 1983 and 54.6% in 1988 underwent colonoscopy.

Comments/Quality Scoring

General comments:
The data for this study were generated prior to 1990 so it may not reflect more modern recommendations for management.

This study reports the frequency of use for a number of diagnostic tests (chest x-ray, colonoscopy, biopsy of primary site, barium enema, preoperative CEA, LFTs, CT scan of primary site or liver, IVP, chest CT, etc.) that were performed for patients with colon and rectal cancer, but it is never stated which ones should have been considered components of quality care. Therefore, it is not possible to determine which are quality measures, and none of these are reported in this abstraction except colonoscopy, which seems to have face validity as a quality measure.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 4
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 2
  - Reliability: 4
  - Validity: 4
  - Adaptability: 4
  - Adequacy of risk adjustment: 2

Evidence Table 1 – Question 1a (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Harewood, Sharma, and de Garmo, 2003 **#33050**	**Quality measure (QM):** Percentage of patients with adequate preparation of bowel prior to colonoscopy **Basis of QM:** None **Type of QM:** (a) Process (b) Technical **Outcome to which the QM is linked:** Detection of colonic lesions **Intent of QM:** Not specified (aim of the study was to characterize the impact of bowel preparation adequacy on detection of colonic lesions) **Definition of denominator/numerator:** Denominator: Number of colonoscopies performed from January 1, 2000, to December 31, 2001, that were completed and had complete documentation of age, sex, preparation quality, and endoscopic findings. Numerator: Number of above colonoscopies for which bowel preparation was rated as adequate. **Data sources:** Clinical Outcomes Research Initiative (CORI) database, which collects data from endoscopic procedures from a consortium of 580 specialists in GI diseases at 88 sites in 24 states **Recommended frequency of data collection:** No recommendation	**Study population:** N: 93,004 Age: NR Race: NR Sex: NR Tumor stage: NR; most cases were not colorectal cancer Performance status: NR **Geographic location:** 88 sites in 24 states **Dates:** Jan 1, 2000 to Dec 31, 2001 **Healthcare setting:** Varied (community, academic, and VA institutions) **Results:** 76.9% of colonoscopies with complete data were rated as having an adequate preparation. Regarding the relationship of adequacy of bowel preparation to ability to detect colonic polyps/cancers: Suspected neoplasia was detected in 29.1% of colonoscopies with adequate preparation and 26.4% with inadequate preparation ($P < 0.0001$). Polyps > 9 mm were identified with equal frequency (7.3%) regardless of adequacy of preparation. Polyps ≤ 9mm were identified in 21.8% of colonoscopies with adequate preparation and 19.0% with inadequate preparation ($P < 0.0001$). After adjusting for age and sex, adequate preparation was predictive of detection of suspected neoplasia.	**General comments:** The ability to achieve adequate colonoscopic preparation is predominantly patient-dependent. This paper also does not exclusively deal with colon cancer and does not discuss the reasons the colonoscopy was performed. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 2 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: NA

Evidence Table 1 – Question 1a (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Haseman, Lemmel, Rahmani, et al., 1997 **#35910**	**Quality measure (QM):** Percentage of colon cancers not detected by colonoscopy in symptomatic patients. (Only 7% of the patients in this study had routine screening colonoscopies.) **Basis of QM:** None **Type of QM:** (a) Process (b) Technical **Outcome to which the QM is linked:** Not stated but presumably linked to stage of colon cancer that a patient is ultimately diagnosed with **Intent of QM:** Not specified, but presumably to help with future quality improvement projects (aim of the study was to understand the reasons for colonoscopic failures to detect colon cancer and polyps) **Definition of denominator/numerator:** Denominator: Number of cases of colorectal cancer in which colonoscopy was used within 3 years of diagnosis. Numerator: Number of above cases of colon cancer that were missed by the colonoscopy. **Data sources:** Data were collected from 20 hospitals that agreed to participate in this project **Recommended frequency of data collection:** No recommendation	**Study population:** N: 941 Age: 69.8 Race: NR Sex: NR Tumor stage: Various Performance status: NR **Geographic location:** Hospitals in central Indiana **Dates:** 1988-1993 **Healthcare setting:** Hospitals **Results:** Failure to detect colorectal cancer by colonoscopy occurred in 5%. All undetected tumors were “missed” rather than not reached.	**General comments:** Data for this study were collected from hospitals that “agreed to participate,” which raises concern about whether bias may occur. Only hospitals with low “miss” rates might want to participate; others might not to avoid “bad publicity.” Cecal intubation rates were not calculated, but would be relevant because failure to reach the cancer is a factor in failed detection. Data on size of tumors were not collected. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 4 Validity: 3 Adaptability: 4 Adequacy of risk adjustment: 3

Evidence Table 1 – Question 1a (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Levin, Hess, and Johnson, 1997 **#11880**	**Quality measure (QM):** Number of participants undergoing adequate diagnostic follow up of positive fecal occult blood test (+FOBT) **Basis of QM:** Clinical practice guideline (ACS guidelines [ref 16]) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Detection of colonic neoplasms **Intent of QM:** Not specified (aim of the study was to compare three FOBTs and assess patient and physician compliance with ACS guidelines on recommended diagnostic workup of participants with a +FOBT) **Definition of denominator/numerator:** Denominator: Number of participants with +FOBT tests for whom followup information was available. Numerator: Number of above participants undergoing adequate diagnostic follow up (colonoscopy or double-contrast barium enema with flexible sigmoidoscopy) **Data sources:** Telephone calls to participants; questionnaires sent to physicians **Recommended frequency of data collection:** No recommendation	**Study population:** N: 934 Age: 50-94 Race: 90% white, 4.8% black, 2.9% Hispanic, 1.4% Asian, < 1% American Indian Sex: 43.3% male, 56.7% female Tumor stage: NR Performance status: NR **Geographic location:** Houston, TX **Dates:** 4-week period in October 1993 **Healthcare setting:** Not stated; all were outpatients when participating in the study **Results:** Rate of adequate diagnostic followup was 59% overall and varied depending on specialty of the physician who was consulted: Family physician: 45% Other physician: 55% Gastroenterologist: 85% Neoplasia was discovered in 56/553 (10%) participants who received adequate diagnostic follow up regardless of physician type, but in only 4/553 (1%) participants who did not get adequate followup care. This difference was statistically significant ($p < 0.001$).	**General comments:** The purpose of this paper was to compare three different hemoccult tests for detecting fecal occult blood, but it also obtained information on whether diagnostic followup was obtained. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 1 – Question 1a (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td>Mandel, Church, Bond, et al., 2000

#16070</td>
<td>Quality measure (QM): Percentage of patients who have a followup evaluation of a positive fecal occult blood test (+FOBT)

Basis of QM: Clinical practice guideline

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Positive diagnosis of colorectal cancer

Intent of QM: Quality improvement, research

Definition of denominator/numerator:
Denominator:
Number of patients with a +FOBT.

Numerator:
Number of above patients who had appropriate diagnostic evaluation.

Data sources: Database of the Minnesota Colon Cancer Control study

Recommended frequency of data collection: No recommendation</td>
<td>Study population:

<table>
<tr><th></th><th>Annual Screening</th><th>Biennial Screening</th></tr>
<tr><td>Male</td><td>7,474</td><td>7,430</td></tr>
<tr><td>Female</td><td>8,058</td><td>8,120</td></tr>
<tr><td>Total</td><td>15,532</td><td>15,550</td></tr>
</table>

Average age: 50-80 years old

Geographic location: Minnesota

Dates: 1976-1992

Healthcare setting: Randomized trial

Results:
83% of patients in the annual-screening group and 84% of patients in the biennial-screening group underwent diagnostic followup, including a complete examination of the large bowel by colonoscopy or the combination of double-contrast enema and flexible sigmoidoscopy. In each group about 11% of the subjects with positive screening tests underwent flexible sigmoidoscopy or barium enema or underwent another FOBT. Five percent of the subjects with positive tests declined to consult a physician.</td>
<td>General comments:
The purpose of this paper was to present data on the cumulative incidence of colorectal cancer in the individual groups who were screened by annual, biennial, or usual care. It does report the percentage of patients who had follow up of a positive FOBT.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
Precise specifications: 5
Reliability: 5
Validity: 5
Adaptability: 3
Adequacy of risk adjustment: 1</td>
</tr>
</table>

Evidence Table 1 – Question 1a (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Marble, Banerjee, and Greenwald, 1992 **#4910**	**Quality measure (QM):** Time from patient presentation to physician diagnosis **Basis of QM:** None **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** More rapid diagnosis presumed to be linked to earlier stage at diagnosis and hence improved cure rates. (Unlikely that there are data to support this idea over the typical range of time between presentation and diagnosis.) **Intent of QM:** Not specified (aim of the study was to determine whether younger patients with colorectal cancer had a poorer prognosis than their older counterparts, and if they did, the reasons underlying this) **Definition of denominator/numerator:** Denominator: Numerator: **Data sources:** Saint Francis Hospital and Medical Center Tumor Registry **Recommended frequency of data collection:** No recommendation	**Study population:** N: 50/50 Age: ≤ 40/ > 40 Race: 94% white/98% white Sex: 58% female/52% female Tumor stage: NR Performance status: NR **Geographic location:** Hartford, CT **Dates:** 1935-1988 **Healthcare setting:** Hospital **Results:** There was no difference in the interval from presentation to diagnosis in older vs. younger patients (the appropriate diagnosis was made in < 1 week in > 90% of the patients in both groups).	**General comments:** A small study of limited use in quality measurement. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 3 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 2 Reliability: 1 Validity: 1 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 1 – Question 1a (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td>Myers, Turner, Weinberg, et al., 2004

#30300</td>
<td>Quality measure (QM): Percentage of patients receiving complete diagnostic evaluation (CDE) for positive fecal occult blood test (+FOBT), defined as colonoscopy or barium enema + flexible sigmoidoscopy (BEFS)

Basis of QM: Clinical practice guideline (Winawer et al., Gastroenterology, 2003)

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Reduced colorectal cancer-related mortality

Intent of QM: Not specified (aim of the study was to evaluate the impact of a guideline on CDE performance rates in primary care practices)

Definition of denominator/numerator:
Denominator:
Number of +FOBT patients eligible for CDE recommendation and performance. Exclusion criteria: CDE procedures completed within 3 years prior to +FOBT result; patient had a medical condition that contraindicated CDE; patient deceased; patient unknown to practice and patient left practice before CDE could be recommended.

Numerator:
Number of above patients whose physicians had recommended CDE; number of patients who underwent CDE within 180 days after the +FOBT result. Results were coded as dichotomous variables, yes or no (recommendation was made or treatment was provided).

Data sources: ICA forms; MCO administrative claims data

Recommended frequency of data collection: No recommendation</td>
<td>Study population:
N: 2,992
Age: ≥ 50

Geographic location: Southern PA and NJ

Dates: 1994-2000, 3 study periods

Healthcare setting: Aetna U.S. Healthcare and various MCO-based cancer screening sites

Results:

<table>
<tr><th></th><th>Intervention group</th><th>Control group</th></tr>
<tr><td>CDE recommendation rate</td><td>79.6</td><td>67.3</td></tr>
<tr><td>CDE performance rate</td><td>63.3</td><td>53.7</td></tr>
</table>

For study period 3 (5/99 to 2/00), the differences in CDE recommendation and performance rates between the intervention group and control group was statistically significant. Use of a physician-oriented intervention substantially and significantly increased CDE recommendation and performance in intervention group practice as compared to control group practices. Targeting PCPs for delivery of a combined CDE reminder feedback and educational outreach intervention can have a meaningful impact on physician behavior and patient followup in colorectal cancer screening.</td>
<td>General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 4
- Scientific acceptability (five criteria):
Precise specifications: 4
Reliability: 4
Validity: 4
Adaptability: 4
Adequacy of risk adjustment: 1</td>
</tr>
</table>

Evidence Table 1 – Question 1a (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td>**Nelson, McQuaid, Bond, et al., 2002**

#45970</td>
<td>**Quality measure (QM):** Postprocedural complication rate

Basis of QM: Not specified

Type of QM:
(a) Outcome
(b) Technical

Intent of QM: Not specified (aim of the study was to report and identify predictive variable for procedural success and complication rates of screening colonoscopy in a large asymptomatic cohort)

Definition of denominator/numerator:
Denominator:
Number of asymptomatic patients between 50 and 75 years undergoing a screening colonoscopy at 13 VAMCs between 2/1994-1/1997.

Exclusion criteria: Patients were excluded if they reported symptoms of lower GI tract disease, including rectal bleeding on more than one occasion in the prior 6 months, significant change in bowel habits or lower abdominal pain that would require evaluation. Also excluded were those with prior colonic disease; prior colon examination within 10 years; significant medical problems that would increase risk of colonoscopy, or a medical condition that would preclude benefit from screening; need for special precautions for colonoscopy; women with childbearing potential.

Numerator:
Number of above cases where postprocedural complications within 30 days occurred, including perforation, GI bleeding with hospitalization, new arrhythmia, MI/CVA, death within 30 days.

Data sources: Medical chart

Recommended frequency of data collection: No recommendation</td>
<td>**Study population:** n = 3,196

<table>
<tr><td>Mean age</td><td>63.0</td></tr>
<tr><td>% male</td><td>96.8</td></tr>
<tr><td>% white</td><td>83.5</td></tr>
<tr><td>Comorbidities:</td><td></td></tr>
<tr><td>Coronary heart disease</td><td>21.1%</td></tr>
<tr><td>CVA/TIA</td><td>8.2%</td></tr>
<tr><td>Diabetes</td><td>20.8%</td></tr>
<tr><td>COPD</td><td>8.5%</td></tr>
</table>

Geographic location: 13 VAMCs across U.S.

Dates: 1994-1997

Healthcare setting: General medicine clinics

Results:
No statistically significant complications occurred.</td>
<td>**General comments:** None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 3
- Scientific acceptability (five criteria):
Precise specifications: 5
Reliability: 4
Validity: 4
Adaptability: 4
Adequacy of risk adjustment: 4</td>
</tr>
</table>

Evidence Table 1 – Question 1a (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td>Nelson, McQuaid, Bond, et al., 2002

#45970</td>
<td>Quality measure (QM): Percent of patients with “adequate” or better bowel preparation

Basis of QM: Not specified

Type of QM:
(a) Outcome
(b) Technical

Outcome to which the QM is linked:

Intent of QM: Not specified (aim of the study was to report and identify predictive variable for procedural success and complication rates of screening colonoscopy in a large asymptomatic cohort)

Definition of denominator/numerator:
Denominator:
Number of asymptomatic patients between 50 and 75 years undergoing a screening colonoscopy at 13 VAMCs between 2/1994-1/1997.

Exclusion criteria: Patients were excluded if they reported symptoms of lower GI tract disease, including rectal bleeding on more than one occasion in the prior 6 months, significant change in bowel habits or lower abdominal pain that would require evaluation. Also excluded were those with prior colonic disease; prior colon examination within 10 years; significant medical problems that would increase risk of colonoscopy, or a medical condition that would preclude benefit from screening; need for special precautions for colonoscopy; women with childbearing potential.

Numerator:
Number of above cases where bowel preparation was rated by the endoscopist as “good” (mucosa well seen throughout), “fair” (liquid, contents; exam adequate); or ”poor” (solid contents, exam compromised).

Data sources: Medical chart

Recommended frequency of data collection: No</td>
<td>Study population: n = 3,196

<table>
<tr><td>Mean age</td><td>63.0</td></tr>
<tr><td>% male</td><td>96.8</td></tr>
<tr><td>% white</td><td>83.5</td></tr>
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<tr><td>Diabetes</td><td>20.8%</td></tr>
<tr><td>COPD</td><td>8.5%</td></tr>
</table>

Geographic location: 13 VAMCs across U.S.

Dates: 1994-1997

Healthcare setting: General medicine clinics

Results:
By using a polyethylene glycol-based electrolyte solution, the bowel preparation was described as good in 81.4%, fair in 15.8% and poor in 2.7% of patients.</td>
<td>General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 3
- Scientific acceptability (five criteria):
Precise specifications: 5
Reliability: 4
Validity: 4
Adaptability: 4
Adequacy of risk adjustment: 4</td>
</tr>
</table>

Evidence Table 1 – Question 1a (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr><td></td><td>recommendation.</td><td></td><td></td></tr>
<tr><td>Nelson, McQuaid, Bond, et al., 2002

#45970</td><td>Quality measure (QM): Percent of patients with a colonoscopy with successful cecal intubation

Basis of QM: Not specified

Type of QM:
(a) Process
(b) Technical

Outcome to which the QM is linked:

Intent of QM: Not specified (aim of the study was to report and identify predictive variable for procedural success and complication rates of screening colonoscopy in a large asymptomatic cohort)

Definition of denominator/numerator:
Denominator:
Number of asymptomatic patients between 50 and 75 years undergoing a screening colonoscopy at 13 VAMCs between 2/1994-1/1997.

Exclusion criteria: Patients were excluded if they reported symptoms of lower GI tract disease, including rectal bleeding on more than one occasion in the prior 6 months, significant change in bowel habits or lower abdominal pain that would require evaluation. Also excluded were those with prior colonic disease; prior colon examination within 10 years; significant medical problems that would increase risk of colonoscopy, or a medical condition that would preclude benefit from screening; need for special precautions for colonoscopy; women with childbearing potential.

Numerator:
Number of above cases where colonoscopy with procedure was successful; that is, confirmation of cecal intubation.

Data sources: Medical chart

Recommended frequency of data collection: No</td><td>Study population: n = 3,196

<table><tr><td>Mean age</td><td>63.0</td></tr><tr><td>% male</td><td>96.8</td></tr><tr><td>% white</td><td>83.5</td></tr><tr><td>Comorbidities:</td><td></td></tr><tr><td>Coronary heart disease</td><td>21.1%</td></tr><tr><td>CVA/TIA</td><td>8.2%</td></tr><tr><td>Diabetes</td><td>20.8%</td></tr><tr><td>COPD</td><td>8.5%</td></tr></table>
Geographic location: 13 VAMCs across U.S.

Dates: 1994-1997

Healthcare setting: General medicine clinics

Results:
Colonoscopy with cecal intubation was successful on the first attempt in 97.2% of the cases. This includes 69 cases in which the quality of the preparation was felt to be inadequate to visualize the entire colonic mucosa. 53.8% of these cases had at lest 1 polyp resected.</td><td>General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 3
- Scientific acceptability (five criteria):
Precise specifications: 5
Reliability: 4
Validity: 4
Adaptability: 4
Adequacy of risk adjustment: 4

:</td></tr>
</table>

Evidence Table 1 – Question 1a (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
	recommendation.		
Shehadeh, Rebala, Kumar, et al., 2002 **#18520**	**Quality measure (QM):** Miss rate for followup colonoscopy after polypectomy **Basis of QM:** None **Type of QM:** (a) Process (b) Technical **Outcome to which the QM is linked:** Presumably, improved survival via earlier detection of malignancy **Intent of QM:** Not specified (aim of the study was to evalute the miss rates of advanced adenomas) **Definition of denominator/numerator:** Denominator: Number of patients who had polypectomy on initial colonoscopy and who had at least one followup colonoscopy from July 1, 1992 to June 30, 1999 at the Dayton VAMC. Colonoscopy had to be complete and bowel prep had to be satisfactory. Numerator: Number of patients with missed advanced adenomas (≥10 mm) found on repeat colonoscopy. **Data sources:** Computerized database and paper charts at VAMC **Recommended frequency of data collection:** No recommendation	**Study population:** N: 122 Age: NR Race: NR Sex: 100% male Tumor stage: NA Performance status: NR **Geographic location:** Dayton, Ohio **Dates:** 1992-1999 **Healthcare setting:** Veteran's Affairs Medical Center (VAMC) **Results:** 122 patients had 338 colonoscopies. Miss rates were calculated as in the National Polyp Study. Missed adenomas were defined as adenomas (especially big ones) found on repeat colonoscopy. 122 patients had 2 colonoscopies and 60 patients had a third colonoscopy. The calculated miss rate of advanced adenomas for the second colonoscopy was 2.5% (4/122); for the third colonoscopy, it was 3.3 %(2/60).	**General comments:** Because fellows in training performed most of the colonoscopies (albeit with gastroenterologist supervision), the results may not be reflective of routine clinical practice. Miss rates could be used for internal quality improvement purposes (as was done in this case). **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 3 Validity: 5 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 1 – Question 1a (Published Literature) – continued

Study

Shields, Weiner, Henry, et al., 2001

#23040

Characteristics of Quality Measure

Quality measure (QM): Percentage of patients aged 40 or older participating in a mass screening program who had an "adequate evaluation" (colonoscopy or barium enema + flexible sigmoidoscopy [BEFS]) for a positive fecal occult blood test (+FOBT; Hemeoccult II)

Basis of QM: Clinical practice guideline (American Cancer Society [ref 14, 15 1980 CA, 1996 JAMA])

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Reduced mortality from colorectal cancer

Intent of QM: Not specified (aim of the study was to determine whether factors like age, sex, and family history [among others] influence adequate evaluation of a +FOBT)

Definition of denominator/numerator:
Denominator:
Number of patients who participated in a 1986 mass screening program with FOBT (pharmacy-based, processed at Beth Israel Hospital (Boston MA), who returned their cards, had at least 1 positive window (out of 6) and who provided (or their physician provided) followup data (90%).

Numerator:
Number of the above subjects who in addition had an "adequate evaluation" (colonoscopy or barium enema + flexible sigmoidoscopy [BEFS])

Data sources: Physician survey "checklist," patient or physician phone call (if survey/checklist not returned), pathology reports, patient survey at 3 years

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population: N: 940

	percent
40-49 yrs	11
50-59 yrs	18
60-69 yrs	37
70-79 yrs	28
80+ yrs	6
male	48
female	47
unspecified	5

Race: NR

Geographic location: Boston area, MA

Dates: 1986-1988

Healthcare setting: Variety

Results:
59% of patients with a +FOBT were adequately evaluated. 11.2% of adequately evaluated patients had new colon cancers discovered.

The effects of age and sex on the adequacy of follow up were considered, but no significant differences were found by age group or between men and women.

Comments/Quality Scoring

General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 4
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 3
  - Validity: 4
  - Adaptability: 3
  - Adequacy of risk adjustment: 1

Evidence Table 1 – Question 1a (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Ure, Dehghan, Vernava 3rd, et al., 1995 **#960**	**Quality measure (QM):** Complication rate of colonoscopy in the elderly and non-elderly **Basis of QM:** None **Type of QM:** (a) Outcome (b) Technical **Intent of QM:** Not specified (aim of the study was to evaluate the utility, morbidity, and patient tolerance of colonoscopy in elderly patients as compared to a similar group of younger patients) **Definition of denominator/numerator:** Denominator: Number of elderly/non-elderly patients undergoing colonoscopy. Numerator: Number of the above patients with resulting complications. **Data sources:** Not specified **Recommended frequency of data collection:** No recommendation	**Study population:** Eldlerly/Non-elderly N: 354/302 Age: ≥ 70 / 50-70 Race: NR Sex: NR Tumor stage: NA Performance status: NR **Geographic location:** St. Louis area **Dates:** "A recent 48-month period" **Healthcare setting:** University Hospital **Results:** Overall morbidity was similar in elderly and non-elderly patients (24% vs. 16%, p = NS). Elderly patients were significantly more likely to require termination of the procedure because of inadequate bowel preparation or pain (17% vs. 1%, p < 0.05). Colonoscopy was successful to the cecum or ileocolic anastomosis in 85% (555/656). No patient had a perforation; 2% postprocedure hemorrhage in those undergoing polypectomy.	**General comments:** This paper reports the rate of the following quality measures of the performance of colonoscopy: colonoscopy completion, rate of perforations, and postpolypectomy bleeding, but some patients were undergoing colonoscopy for screening (16%). **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 5 Validity: 5 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 2 – Question 1a (Grey Literature): *What quality-of-care measures are available and what evidence is available for these measures to assess the quality of diagnosis of colorectal cancer, including appropriate use of colon imaging, endoscopic visualization, and biopsy?*

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Colon Cancer Workgroup, 2003 **#36650**	**Quality measure (QM):** Colonoscopy to the ileocecal valve is performed prior to surgical resection of colorectal cancer **Basis of QM:** Clinical practice guideline (National Comprehensive Cancer Network [NCCN] guidelines) **Type of QM:** (a) Process (b) Technical **Outcome to which the QM is linked:** Better surgical outcome **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of patients having colon cancer surgery. Numerator: Number of above patients with documentation of colonoscopy of the entire colon to the ileocecal valve before surgery except in cases of obstructing carcinoma or perforation. **Data sources:** Medical records (operative report, history and physical, or other preoperative testing documentation) **Recommended frequency of data collection:** No recommendation	**General comments:** It should be noted that colonoscopy will not be performed prior to surgery for cases of obstructing or perforated carcinoma. **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 2 – Question 1a (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Minnesota Gastro-enterology PA, 2004 **#36590**	**Quality measure (QM):** Percentage of colonoscopy cases performed by physicians completing residency/fellowship training in gastroenterology, colorectal surgery, general surgery or pediatric surgery **Basis of QM:** Practice guideline (ASGE recommendation) **Type of QM:** (a) Structure (b) General **Outcome to which the QM is linked:** Improved health status **Intent of QM:** Quality improvement, accountability **Definition of denominator/numerator:** Denominator: Number of patients undergoing endoscopy. Numerator: Number of above patients undergoing endoscopy by a physician having completed residency or fellowship training in gastroenterology, colorectal surgery, general surgery or pediatric surgery and who have specific proctored training in endoscopy. Reference (Feb 2002, ASGE Policy and Procedure Manual) **Data sources:** Physician credentials, endoscopy notes **Recommended frequency of data collection:** No recommendation	**General comments:** None **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 2 – Question 1a (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Minnesota Gastro-enterology PA, 2004 **#36590**	**Quality measure (QM):** Unplanned reversal of sedation medication **Basis of QM:** Internal quality assurance committee **Type of QM:** (a) Process (b) Technical **Outcome to which the QM is linked:** Survival **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of endoscopies performed. Numerator: Number of above cases where sedation medication was reversed. **Data sources:** Medical chart **Recommended frequency of data collection:** Continually	**General comments:** None **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 2 – Question 1a (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Minnesota Gastro-enterology PA, 2004 **#36590**	**Quality measure (QM):** Postendoscopic procedure complication rates **Basis of QM**: Internal quality assurance committee **Type of QM** (a) Outcome (b) Technical **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of endoscopies performed. Numerator: Number of above cases where postendoscopic procedure complications occurred, including death within 30 days, perforation, bleeding with transfusion, cardiopulmonary arrest, unplanned surgery. **Data sources:** Medical chart **Recommended frequency of data collection:** Continually	**General comments:** None **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 2 – Question 1a (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Minnesota Gastro-enterology PA, 2004 **#36590**	**Quality measure (QM):** Effectiveness of bowel prep prior to colonoscopy **Basis of QM:** Internal quality assurance committee **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** High-quality exam **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of endoscopies performed. Numerator: Number of above cases where no fecal material obscured a lesion 5 mm or more in diameter and a high quality exam takes place. **Data sources:** Electronic chart **Recommended frequency of data collection:** Continually	**General comments:** None **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 2 – Question 1a (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Minnesota Gastro-enterology PA, 2004 **#36590**	**Quality measure (QM):** Percent of examinations complete to the end of colon (cecal intubation rate) **Basis of QM:** Internal quality assurance committee (goal is less than > 90 percent) **Type of QM:** (a) Process (b) Technical **Outcome to which the QM is linked:** Improved health outcomes **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of endoscopies performed, Numerator: Number of above cases where end of colon was reached. **Data sources:** Medical chart **Recommended frequency of data collection:** Continually	**General comments:** None **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 2 – Question 1a (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Minnesota Gastro-enterology PA, 2004 **#36590**	**Quality measure (QM):** Rate of adenomas removed for patients > 50 years of age **Basis of QM:** Clinical practice guideline (Multi-Society Task Force on Colon Cancer); goal: men > 50, 25%; women > 50, 15% **Type of QM:** (a) Process (b) Technical **Outcome to which the QM is linked:** Survival **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of endoscopies performed. Numerator: Number of above cases where one or more adenomas (polyps > 1 cm or with advanced histology) were removed. **Data sources:** Medical chart **Recommended frequency of data collection:** Continually	**General comments:** None **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 2 – Question 1a (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Minnesota Gastroenterology PA, 2004 **#36590**	**Quality measure (QM):** Acceptable cycle time for colonoscopic examination **Basis of QM:** No national, internal goals **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Quality improvement **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of endoscopies performed. Numerator: Number of above cases where exam was completed in a timely fashion acceptable to patient and referring physician according to internal practice standards. **Data sources:** Medical chart **Recommended frequency of data collection:** Continually	**General comments:** None **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 2 – Question 1a (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
National Quality Measures Clearinghouse (measure proposed by Accreditation Association for Ambulatory Health Care Institute for Quality Improvement), 2003 **#36640**	**Quality measure (QM):** Intraprocedure colonoscopy complication rate (percentage of patients who developed one or more intraprocedure complications) **Basis of QM:** None **Type of QM:** (a) Outcome (b) Technical **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of patients undergoing colonoscopy procedure (CPT codes 45378-45385) at the ambulatory health care organization. Numerator: Number of above patients who developed one or more intraprocedure complications (including arrhythmia, bleeding requiring treatment, extended recovery, hospital transfer, hypotension, hypoxia, noted perforations, respiratory arrest). **Data sources:** Patient survey **Recommended frequency of data collection:** No recommendation	**General comments:** Patients could be undergoing colonoscopy for screening or postoperative surveillance. **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 2 – Question 1a (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
National Quality Measures Clearinghouse (measure proposed by Accreditation Association for Ambulatory Health Care Institute for Quality Improvement), 2003 **#36640**	**Quality measure (QM):** Patient understanding of colonoscopy procedure (percentage of patients answering “yes” to the postprocedure telephone interview question, “Did you have an adequate understanding of your procedure?”) **Basis of QM:** None **Type of QM:** (a) Outcome (b) General **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of patients undergoing colonoscopy procedure (CPT codes 45378-45385) at the ambulatory health care organization who were reached for the telephone survey and who responded to the question “Did you have an adequate understanding of your procedure?” Numerator: Number of above patients answering “yes” to the postprocedure telephone interview question “Did you have an adequate understanding of your procedure?” **Data sources:** Patient survey **Recommended frequency of data collection:** No recommendation	**General comments:** Patients could be undergoing colonoscopy for screening or postoperative surveillance. **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 3 – Question 1b (Published Literature): *What quality-of-care measures are available and what evidence is available for these measures to assess the quality of diagnosis of colorectal cancer, including availability and accuracy of pathologic staging?*

Study

Baxter, Virnig, Rothenberger, et al., 2005

#35800

Characteristics of Quality Measure

Quality measure (QM): Adequate lymph node evaluation

Basis of QM: Clinical practice guideline (American Joint Committee on Cancer, International Union against Cancer)

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Recurrence

Intent of QM: Not specified (aim of the study was to determine the proportion of colorectal cancer patients in the U.S. who receive adequate lymph node evaluation)

Definition of denominator/numerator:
Denominator:
Number of patients ≥ 18 yr, diagnosed with localized invasive adenocarcinoma of colon or rectum from Jan 1988-Dec 2001.

Exclusion criteria: Patients with cancer colon not otherwise localized, patients who underwent radical surgical resection, and postoperative radiation.

Numerator:
Number of above patients with adequate lymph node evaluation (adequate = at least 12 nodes examined) .

Data sources: NCI's SEER registry

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 116,995

		Anatomic site of tumor		
Characteristics	All pts (N = 116,995)	Right colon (49,613)	Left colon (50,536)	Rectum (16,846)
Median age (yr)	71	74	69	68
Males	50%	44%	53%	58%
Race/ ethnicity				
White	83%	84%	82%	84%
Non-white	17%	16%	18%	16%
Tumor stage				
Stage I	25%	19.5%	27%	33%
Stage II	40%	45.5%	39%	29%
Stage III	35%	35%	34%	38%
Tumor Grade				
Well or mod diff.	82%	76%	87%	83%
Poorly diff.	18%	24%	13%	17%
Node No. (Median)	9	11	7	8

Geographic location: U.S.

Dates: Jan 1988-Dec 2001

Healthcare setting: Multiple

Results:
No lymph nodes were examined in 6.5% patients.

(continued on next page)

Comments/Quality Scoring

General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
    - Precise specifications: 5
    - Reliability: 3
    - Validity: 3
    - Adaptability: 4
    - Adequacy of risk adjustment: 3

Evidence Table 3 – Question 1b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring

Characteristic	% of all pts	Rates among pts with stage I disease (N = 27,323)	Rates among pts with stage II disease (N = 44,771)	Rates among pts with stage III disease (N = 38,660)
Overall rates	37%	25%	41%	46%
Patient age (yr)				
≤ 50	51%	35%	56%	57%
51-60	40%	27%	46%	48%
61-70	36%	23%	41%	45%
≥ 71	35%	25%	37%	43%
Year of diagnosis				
1988-90	33%	22%	37%	40%
1991-3	35%	23%	38%	44%
1994-6	36%	24%	40%	45%
1997-9	40%	26%	43%	49%
2000-1	43%	31%	45%	52%

Evidence Table 3 – Question 1b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Chiaverini, Fulton, and Darcy, 2002 **#17720**	**Quality measure (QM):** Percentage of newly diagnosed CRC cases that were staged using the AJCC system **Basis of QM:** Clinical practice guideline (implicit that AJCC staging system would follow the American Joint Committee on Cancer guidelines but these are not actually cited in the article. The authors do mention the rules and regulations of the Rhode Island Cancer Registry and the Rhode Island Cancer Control Plan [ref 4]). **Type of QM:** (a) Structure (b) Process and technical **Outcome to which the QM is linked:** No outcome linked, but measure is said to be important for choosing appropriate treatments **Intent of QM:** NA (aim of the study was to describe progress in the control of colorectal cancer in Rhode Island, 1987-2000) **Definition of denominator/numerator:** Denominator: Number of Rhode Island men and women newly diagnosed with colorectal cancer in 1989-1999 compared to 2000. Numerator: Number of above patients who were staged using the AJCC system. **Data sources:** Rhode Island Cancer Registry **Recommended frequency of data collection:** No recommendation	**Study population:** N: NR Age: NR Race: NR Sex: NR Tumor stage: NR Performance status: NR **Geographic location:** Rhode Island **Dates:** 1989-2000 **Healthcare setting:** Multiple **Results:** The proportion of cases staged with AJCC staging methodology increased from 65% in 1989 to 92% in 2000 for men, and from 65% in 1989 to 90% in 2000 for women.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 4 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: 4

Evidence Table 3 – Question 1b (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td>**Galvis, Raab, D’Amico, et al., 2001**

#20330</td>
<td>**Quality measure (QM):** Lymph node retrieval rate

Basis of QM: None (but see refs 1-10)

Type of QM
(a) Process
(b) Technical

Outcome to which the QM is linked: Recurrence

Intent of QM: Not specified (aim of the study was to measure the quality of pathologists’ assistants’ surgical gross examination [vs. that of pathology residents])

Definition of denominator/numerator:
Denominator:
Number of colorectal specimens submitted for tumor from Dec 1997-Nov 1999 (all cases for which 5 or more cassettes of tissue were initially submitted for histologic examination).

Numerator:
Number of positive lymph nodes retrieved from above specimens.

Data sources: Retrospective review of surgical pathology reports

Recommended frequency of data collection: No recommendation</td>
<td>**Study population:**
N: 176 specimens

Geographic location: PA

Dates: Dec 1997-Nov 1999

Healthcare setting: University hospital

Results:

<table>
<tr><th rowspan="2">Examiner</th><th rowspan="2">Total number of cases</th><th colspan="2">Mean # of lymph nodes</th></tr>
<tr><th>Retrieved per specimen</th><th>Positive per specimen</th></tr>
<tr><td>Pathologist’s assistant</td><td>50</td><td>31.3</td><td>1.1</td></tr>
<tr><td>Pathology resident</td><td>126</td><td>18.7</td><td>2.2</td></tr>
</table>
</td>
<td>**General comments:** None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 4
- Scientific acceptability (five criteria):
Precise specifications: 1
Reliability: 2
Validity: 4
Adaptability: 4
Adequacy of risk adjustment: 3</td>
</tr>
</table>

Evidence Table 3 – Question 1b (Published Literature) – continued

Study | **Characteristics of Quality Measure** | **Testing of Quality Measure** | **Comments/Quality Scoring**

Steele, 1994, #35840

Quality measure: Percentage of newly diagnosed CRC cases who were staged using the AJCC system

Basis of QM: Clinical practice guideline (implicit that the AHCC guidelines be followed but these are not actually cited)

Type of QM:
(a) Process
(b) Technical

Outcome to which the QM is linked: No outcome is exactly linked to the above but is said to be a marker of appropriate cancer diagnosis and treatment. No citation is provided for this statement.

Intent of QM: Not specified (aim of the study was to assess cancer patient care and outcomes on a national basis)

Definition of denominator/numerator:
Denominator:
Number of patients in the National Cancer Data Base (NCDB) with a new diagnosis of colon cancer or rectal cancer (rectosigmoid junction, rectum and anal canal) in the years 1985-1986 or 1991.

Numerator:
Number of the above patients who were staged using the AJCC system.

Data sources: National Cancer Data Base (NCDB)

Recommended frequency of data collection: No recommendation

Study population:

	Colon		Rectal	
	1985-86	1991	1985-86	1991
cases	40384	39751	18418	17348
Age				
≤54	10.6	11.2	13.5	14.8
55-64	19.8	17.2	23.8	21.6
65-74	32.3	21.9	33.9	32.9
≥75	37.3	39.7	28.8	30.7
%male	48.7	49.6	55.3	55.7
race				
White	86.9	85.9	88.0	86.9
hispanic	1.1	1.8	1.6	2.3
AA	6.6	8.1	4.7	6.3
Asian	0.9	1.5	1.2	2.2
Unk.	4.5	2.7	4.5	2.3
Tumor stage				
0	3.7	6.5	5.8	5.0
1	14.4	19.3	15.2	18.6
2	13.8	26.2	10.5	17.4
3	12.9	20.3	12.2	20.0
4	9.2	15.8	5.0	7.8
Unk.	46.0	11.9	51.3	31.2

Geographic location: National sample; note that the sample is not probabilistic and represented different hospitals in different years

Dates: 1991 and outcomes for 1985-86

Healthcare setting: 464 hospital in 1985, 474 hospitals in 1986, 937 hospitals in 1991

Results: The percent of cases reported as having an “unknown stage” decreased from 46% to 11.9% and 51.3% to 31.2% for colon and rectal cancer cases respectively, between 1985-86 and 1991.

General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 3
- Usability: 4
- Scientific acceptability (five criteria):
    - Precise specifications: 4
    - Reliability: 4
    - Validity: 3
    - Adaptability: 3
    - Adequacy of risk adjustment: 1

Evidence Table 4 – Question 1b (Grey Literature): *What quality-of-care measures are available and what evidence is available for these measures to assess the quality of diagnosis of colorectal cancer, including availability and accuracy of pathologic staging?*

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Colon Cancer Workgroup, 2003 **#36650**	**Quality measure (QM):** Surgical resection includes at least 8 lymph nodes **Basis of QM:** Clinical practice guideline (CAP, National Comprehensive Cancer Network [NCCN] guidelines, NCI guidelines) **Type of QM:** (a) Process (b) Technical **Outcome to which the QM is linked:** Improved staging and subsequent treatment planning **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of patients having colon cancer surgery. Numerator: Number of above patients in whom 8 or more lymph nodes were resected. **Data sources:** Pathology, surgery reports **Recommended frequency of data collection:** No recommendation	**General comments:** Measure notes that some patients would have fewer than 8 lymph nodes. Measure mentions only “surgical resection,” but the entire description implies that “number of lymph nodes positive” is important for staging, and that pathology data are important for staging. **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 4 – Question 1b (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Institute of Medicine, 2005 **#36680**	**Quality measure (QM):** Appropriate histological assessment of colorectal cancer **Basis of QM:** Clinical practice guideline (National Comprehensive Cancer Network [NCCN] guidelines) NCCN recommends that a minimum of 14 regional lymph nodes be removed during surgical resection. CAP recommends removal of at least 12 nodes and urges that additional techniques (i.e., visual enhancement) be considered if fewer than 12 nodes are found. **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Staging **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of colorectal cancer surgery patients. Numerator: Number of above patients with a surgical resection that included at least 12 lymph nodes. **Data sources:** Surveillance, Epidemiology and End results Program (SEER)-GCCR, baseline studies of pathology reports and medical records **Recommended frequency of data collection:** No recommendation	**General comments:** Numerous studies reveal that surgical and pathology reporting practices are of variable quality. Information on margins and the number and status of nodes is often missing. Key references cited: Compton (CAP), 2004 Compton, 2003 LeVoyer et al., 2003 NCCN, 2004 Stocchi et al., 2001 **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 4 – Question 1b (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
National Committee for Quality Assurance, 2005 **#36580**	**Quality measure (QM):** Percent of colon cancer patients receiving surgical treatment that had at least 14 lymph nodes examined **Basis of QM:** Clinical practice guideline (National Comprehensive Cancer Network [NCCN] guidelines) **Type of QM:** (a) Process (b) Technical **Outcome to which the QM is linked:** Improved health status **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of patients with colon cancer surgery over a 12-month period. Numerator: Number of above patients who had 14 or more lymph nodes examined at the time of surgery. **Data sources:** Cancer registry, claims data **Recommended frequency of data collection:** No recommendation	**General comments:** Not all data may be available. **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 5 – Question 2b (Published Literature): *As appropriate to specific stages of colorectal cancer, what quality-of-care measures are available and what evidence is available for measures of quality of care of treatment of colorectal cancer, including surgical therapy for colon and rectal cancers?*

Study

Agarwal, Leighton, Mandile, et al., 1990

#7530

Characteristics of Quality Measure

Quality measure (QM): 30-day operative mortality rate

Basis of QM: None

Type of QM:
(a) Outcome
(b) General

Intent of QM: Quality improvement (aim of the study was to determine the relationship between age and 5-year survival, taking into consideration the site, stage, and type of surgical treatment rendered)

Definition of denominator/numerator:
Denominator:
Number of patients treated for colorectal cancer during 1975-1980 with histologically confirmed adenocarcinoma.

Exclusion criteria: Carcinoma in situ.

Numerator:
Number of above patients who died within 30 days following operation.

Data sources: Tumor registry

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 271

	30-day mortality n = 29 (%)	P value
Age		< 0.001
< 80	6	
≥ 80	25	
Tumor stage		< 0.05
I	5	
II	8	
III	4	
IV	19	
Treatment		< 0.01
Colectomy	9	
Low anterior	2	
Abdominoperineal	0	
Colostomy	24	
Miscellaneious	23	

Geographic location: New York

Dates: 1975-1980

Healthcare setting: Medical center

Results:
30-day mortality was related significantly to stage and treatment but not to site of cancer. An increased proportion of patients who had stage IV cancers or who received colostomy and miscellaneous treatment died within 1 month. Patients ≥ 80 yr had a significantly higher 30-day mortality compared with patients < 80 yr (p < 0.0010).

Comments/Quality Scoring

General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 4
  - Validity: 4
  - Adaptability: 3
  - Adequacy of risk adjustment: 3

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Coburn, Pricolo, and Soderbert, 1994

#2920

Characteristics of Quality Measure

Quality measure (QM): Anastomotic leak rate

Basis of QM: None

Type of QM:
(a) Outcome
(b) Technical

Intent of QM: Not specified (aim of the study was to perform univariate and multivariate analyses of poor indicators in the elderly undergoing colorectal operation, and to compare clinical, pathologic, and therapeutic factors in patients younger than and older than 80 years of age)

Definition of denominator/numerator:
Denominator:
Number of subjects who had received operative treatment for colon and rectal cancer between 1961 and 1987.

Numerator:
Number of above subjects that had an anastomotic leak after surgery (within a unspecified period).

Comparisons were made between patients under and over 80 years.

Data sources: Inpatient, outpatient, and office records

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 800

	< 80 yr	> 80 yr
N	177	623
Sex (%F/M)	48/52	56/44
Rectal lesions	36	23
Duke stage		
A	9.0	6.0
B1	16.7	12.8
B2	31.2	42.7
C1	4.5	0
C2	21.5	21.8
D	17.1	16.7

Geographic location: Rhode Island, U.S.

Dates: 1961 and 1987

Healthcare setting: Academic institute

Results:
Postanastomotic leak rate was 6% for patients > 80 yr and 3% for patients < 80 yr.

Long-term survival (at 5 and 8 yrs) and rate of recurrence after curative therapy used to validate the measure.

There was a statistically significant difference in survival rates: 48% for patients < 80 vs. 32% for patients > 80.

There was no statistically significant difference between the groups with regard to recurrence after curative therapy.

Comments/Quality Scoring

General comments:
Data collected between 1961 and 1987.

Other factors that affect mortality rates in the elderly include: more aggressive biologic behavior of cancer of the colon and rectum in the elderly, with aggressive local disease and less tendency towards distant dissemination, greater tendency of cancer of the colon to be right-sided, rarity of adjuvant therapy administered to older patients, higher complication rate in elderly patients due to comorbid conditions and greater frequency of obstructing and perforated lesions.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 4
  - Validity: 4
  - Adaptability: 4
  - Adequacy of risk adjustment: 2

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Coburn, Pricolo, and Soderbert, 1994

#2920

Characteristics of Quality Measure

Quality measure (QM): 30-day mortality

Basis of QM: None

Type of QM:
(a) Outcome
(b) General

Outcome to which the QM is linked: Mortality

Intent of QM: Not specified (aim of the study was to perform univariate and multivariate analyses of poor indicators in the elderly undergoing colorectal operation, and to compare clinical, pathologic, and therapeutic factors in patients younger than and older than 80 years of age)

Definition of denominator/numerator:
Denominator:
Number of subjects who had received operative treatment for colon and rectal cancer between 1961 and 1987.

Numerator:
Number of above subjects that died within 30 days of operation

Comparisons were made between patients under and over 80 years.

Data sources: Inpatient, outpatient, and office records

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 800

	< 80 yr	> 80 yr
N	177	623
Sex (%F/M)	48/52	56/44
Obstruction/ Perforation	12	22
Normal CEA at diagnosis	77	68
Rectal lesions	36	23
Duke stage		
A	9.0	6.0
B1	16.7	12.8
B2	31.2	42.7
C1	4.5	0
C2	21.5	21.8
D	17.1	16.7

Geographic location: Rhode Island, U.S.

Dates: 1961 and 1987

Healthcare setting: Academic institute

Results:
30-day mortality rate was:
6.2% for patients > 80 yr and
2.4% for patients < 80 yr

Long-term survival (at 5 and 8 yrs) and rate of recurrence after curative therapy used to validate the measure.

There was a statistically significant difference in survival rates: 48% for patients < 80 vs. 32% for patients > 80.

There was no statistically significant difference between the groups with regard to recurrence after curative therapy.

Comments/Quality Scoring

General comments:
Data collected between 1961 and 1987.

Other factors that affect mortality rates in the elderly include: more aggressive biologic behavior of cancer of the colon and rectum in the elderly, with aggressive local disease and less tendency towards distant dissemination, greater tendency of cancer of the colon to be right-sided, rarity of adjuvant therapy administered to older patients, higher complication rate in elderly patients due to comorbid conditions and greater frequency of obstructing and perforated lesions.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 4
  - Validity: 4
  - Adaptability: 4
  - Adequacy of risk adjustment: 2

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Coburn, Pricolo, and Soderbert, 1994

#2920

Characteristics of Quality Measure

Quality measure (QM): Surgical complication rate

Basis of QM: None

Type of QM:
(a) Outcome
(b) General

Intent of QM: Not specified (aim of the study was to perform univariate and multivariate analyses of poor indicators in the elderly undergoing colorectal operation, and to compare clinical, pathologic, and therapeutic factors in patients younger than and older than 80 years of age)

Definition of denominator/numerator:
Denominator:
Number of subjects who had received operative treatment for colon and rectal cancer between 1961 and 1987.

Numerator:
Number of above subjects that had postsurgical complications (within a unspecified period) received adjuvant therapy (chemo- or radiotherapy).

Comparisons were made between patients under and over 80 years.

Data sources: Inpatient, outpatient, and office records

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 800

	< 80 yrs	> 80 yrs
N	177	623
Sex (%F/M)	48/52	56/44
Obstruction/ Perforation	12	22
Normal CEA at diagnosis	77	68
Rectal lesions	36	23
Right sided lesions	9	19
Mucin producing tumors	13	23
Invasion adjacent organs	13	23
Single liver metastasis	20	38
Duke stage		
A	9.0	6.0
B1	16.7	12.8
B2	31.2	42.7
C1	4.5	0
C2	21.5	21.8
D	17.1	16.7

Geographic location: Rhode Island, U.S.

Dates: 1961 and 1987

Healthcare setting: Academic institute

Results:
Complication rate was 55% for patients > 80 yr and 35% for patients < 80 yr.

There was a statistically significant difference in survival rates: 48% for patients < 80 vs. 32% for patients > 80.

There was no statistically significant difference between the groups with regard to recurrence after curative therapy.

Comments/Quality Scoring

General comments:
Data collected between 1961 and 1987.

Long-term survival (at 5 and 8 yrs) and rate of recurrence after curative therapy used to validate the three measures.

Other factors that affect mortality rates in the elderly include: more aggressive biologic behavior of cancer of the colon and rectum in the elderly, with aggressive local disease and less tendency towards distant dissemination, greater tendency of cancer of the colon to be right-sided, rarity of adjuvant therapy administered to older patients, higher complication rate in elderly patients due to comorbid conditions and greater frequency of obstructing and perforated lesions.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 2
  - Reliability: 4
  - Validity: 4
  - Adaptability: 4
  - Adequacy of risk adjustment: 2

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Cooper, Yuan, Landefeld, et al., 1996

#14030

Characteristics of Quality Measure

Quality measure (QM): 30-day mortality

Basis of QM: None

Type of QM:
(a) Outcome
(b) General

Outcome to which the QM is linked: Survival

Intent of QM: Not specified (aim of the study was to determine whether race was associated with differences in two aspects of treatment of colorectal cancer: potentially curative surgical resections and survival after surgery)

Definition of denominator/numerator:
Denominator:
Number of Medicare beneficiaries with a first documented discharge diagnosis of colon or rectal cancer.

Exclusion criteria: Patients less than 65 yr of age enrolled in Medicare for ESRD or chronic disability, or whose race was not specified, and those with ulcerative colitis, hospital identifier not matching an Americal Hospital Association number and preexisting colorectal malignancy according to the 1984 through 1987 files.

Numerator:
Number of above patients with deaths within 30 days postadmission.

Data sources: 1987 Medicare provider analysis and review files

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:

	% White patients (n = 75,865)	% Black patients (n = 5714)	% Total (n = 81,579)
Age, y			
65-69	20.9	24.0	21.1
70-74	23.0	23.0	23.0
75-79	22.8	22.2	22.8
80-84	17.6	16.2	17.5
> 85	15.7	14.6	15.6
Female	53.7	57.6	54.0
Male	46.3	42.4	46.0

Geographic location: Nationwide

Dates: 1984-1987

Healthcare setting: Mixed

Results:
Death rates at 30 days were higher for black patients (6.1% vs. 4.6% for white patients).

Death rates were also higher for black patents at 1 year (26.6%% vs. 21.7% for white patients) and at 2 years (40% vs. 33.5% for white patients). The disparity persisted after controlling for sex, age, number of comorbidities, and extent and location of cancer.

Comments/Quality Scoring

General comments:
Race-related differences in patient preferences for management of colon cancer including adjuvant therapy and surveillance procedures may have contributed to the observed differences. The observed survival differences may also be related to peri- and postoperative care.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 3
  - Validity: 3
  - Adaptability: 4
  - Adequacy of risk adjustment: 3

Evidence Table 5 – Question 2b (Published Literature) – continued

Study | **Characteristics of Quality Measure** | **Testing of Quality Measure** | **Comments/Quality Scoring**

Cooper, Yuan, Landefeld, et al., 1996

#14030

Quality measure (QM): Surgical resection rate

Basis of QM: None

Type of QM:
(a) Outcome
(b) General

Outcome to which the QM is linked: Survival

Intent of QM: Not specified (aim of the study was to determine whether race was associated with differences in two aspects of treatment of colorectal cancer: potentially curative surgical resections and survival after surgery)

Definition of denominator/numerator:
Denominator:
Number of Medicare beneficiaries with a first documented discharge diagnosis of colon or rectal cancer.

Exclusion criteria: Patients less than 65 yr of age enrolled in Medicare for ESRD or chronic disability, or whose race was not specified, and those with ulcerative colitis, hospital identifier not matching an Americal Hospital Association number and preexisting colorectal malignancy according to the 1984 through 1987 files.

Numerator:
Number of above patients who underwent surgical resection.

Data sources: 1987 Medicare provider analysis and review files

Recommended frequency of data collection: No recommendation

Study population:

	% White patients (n = 75,865)	% Black patients (n = 5714)	% Total (n = 81,579)
Age, y			
65-69	20.9	24.0	21.1
70-74	23.0	23.0	23.0
75-79	22.8	22.2	22.8
80-84	17.6	16.2	17.5
>-85	15.7	14.6	15.6
Gender			
Female	53.7	57.6	54.0
Male	46.3	42.4	46.0

Geographic location: Nationwide

Dates: 1984-1987

Healthcare setting: Mixed

Results:
Surgical resection of colon cancer was performed less often in black patients (68%) than in white patients (78%). After controlling for sex, age, number of comorbidities, and extent and location of cancer, black patients were less likely to undergo surgical resection.

Surgical resection was performed less often for black patients than white patients in teaching hospitals, non-teaching hospitals, private hospitals and public hospitals.

Death rates were also higher for black patents at 1 year (26.6%% vs. 21.7% for white patients) and at 2 years (40% vs. 33.5% for white patients). The disparity persisted after controlling for gender, age, number of comorbidities, and extent and location of cancer.

General comments:
Race-related differences in patient preferences for management of colon cancer including adjuvant therapy and surveillance procedures may have contributed to the observed differences. The observed survival differences may also be related to peri- and postoperative care.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 3
  - Validity: 3
  - Adaptability: 4
  - Adequacy of risk adjustment: 3

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Demissie, Oluwole, Balasubramanian, et al., 2004

#31380

Characteristics of Quality Measure

Quality measure (QM): Non-receipt of standard surgical treatment

Basis of QM: Clinical practice guideline (NIH guidelines)

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Survival

Intent of QM: Not specified (aim of the study was to examine colorectal cancer treatment differences between races with comparable disease at presentation)

Definition of denominator/numerator:
Denominator:
Number of white or black subjects diagnosed with rectal cancer between Jan 1, 1988 and Dec 31, 1997.

Exclusion criteria: Subjects neither white nor black, unknown treatment history, cancer diagnosed at autopsy, in-situ tumor or carcinoid tumor, rare histological types.

Numerator:
Number of above subjects not receiving standard surgical treatment.

Comparisons were made between blacks and whites.

Data sources: SEER database

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:

Charac-teristic	Male		Female	
	White	Black	White	Black
n	49,359	4383	47,803	4832
< 84 yr	92.5	95.3	84	92
AJJCC Tumor Stage				
II	26.84	23.07	24.18	20.99
II	29.54	26.44	32.49	28.04
III	22.66	23.02	23.77	24.71
IV	16.76	22.36	15.70	20.88
Un-known	4.2	5.11	3.87	5.38

Geographic location: SEER geographic regions

Dates: 1988-1997

Healthcare setting: Mixed

Results:
The black-to-white disparities in surgical treatment for stage I and IV colon cancer were small, but persisted controlling for age, location of cancer, histologic type, and tumor grade. No significant racial disparities in receipt of surgical treatment were apparent for stage II and III and unstaged colon cancer patients.

Odds of non-receipt of surgical treatment were higher for black males compared with white males for stages I, III, and IV rectal cancer. A higher likelihood of non-receipt of surgical treatment was also seen for stage I and II rectal cancer among black females.

Black-to-white disparity in non-receipt was more prominent when actual treatment received rather than intent-to-treat was considered.

Patients refused cancer-directed surgery: Stage I: 32.8% black and 9.2% white males.19.4% black and 12.8% white females.

Comments/Quality Scoring

General comments:
Intent-to-treat was considered; therefore all exploratory surgical procedures with and without the actual removal of tumor were considered “standard surgical treatment.” “Standard surgical treatments” for rectal and colon cancer are well defined in the study.

Report states that higher proportion of non-receipt of standard treatment in blacks could be because of higher treatment refusal.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  Precise specifications: 4
  Reliability: 3
  Validity: 3
  Adaptability: 4
  Adequacy of risk adjustment: 4

Evidence Table 5 – Question 2b (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td>**Dimick, Cowan, Upchurch, et al., 2003**

#33220</td>
<td>**Quality measure (QM):** In-hospital mortality

Basis of QM: None

Type of QM:
(a) Structure
(b) General

Outcome to which the QM is linked: Mortality

Intent of QM: Not specified (aim of the study was to determine the impact of hospital volume on mortality for patients of different age groups to determine whether elderly patients would derive more benefit from selective referral policies)

Definition of denominator/numerator:
Denominator:
Number of patients who underwent colon resection for cancer by hospital volume.

Numerator:
Number of above patients who died while in hospital.

Comparisons were made across hospitals:
Quartiles of hospitals: Low volume = < 55/yr
Medium volume= 55-100/yr
High volume = 101-150/yr
Very high volume = > 150/yr

Data sources: Nationwide Inpatient Sample (NIS)

Recommended frequency of data collection: No recommendation</td>
<td>**Study population:**
<table>
<tr><th></th><th colspan="4">Volume</th></tr>
<tr><td></td><td>Low</td><td>Medium</td><td>High</td><td>V high</td></tr>
<tr><td>No.of hospitals</td><td>536 (64%)</td><td>149 (18%)</td><td>97 (12%)</td><td>60 (7%)</td></tr>
<tr><td>Bed size</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Small</td><td>271 (51%)</td><td>21 (14%)</td><td>12 (12%)</td><td>2 (3%)</td></tr>
<tr><td>Med.</td><td>190 (35%)</td><td>57 (38%)</td><td>32 (33%)</td><td>11 (18%)</td></tr>
<tr><td>Large</td><td>75 (14%)</td><td>69 (46%)</td><td>53 (55%)</td><td>47 (78%)</td></tr>
</table>
Geographic location: U.S.

Dates: 1997

Healthcare setting: Mixed

Results:
Adjusting for several significant patient covariates, low hospital volume was associated with a 50% (95% CI, 10-100%, p = 0.005) increased risk of in-hospital mortality compared to very high volume hospitals.

In the multivariate analysis adjusting for several significant patient covariates, low hospital volume was associated with increased risk of in-hospital mortality compared to very high volume hospitals. Other significant independent variables in the multivariate analysis included patient age, nature of admission (urgent or emergent), comorbid disease, annual income, and patient sex.</td>
<td>**General comments:**
Risk-adjustment is essential for drawing accurate conclusions regarding the impact of hospital volume on surgical outcomes.

Study suggests that older patients are an easily identifiable high-risk group that would benefit from referral to high-volume hospitals. Such a selective strategy would realize the most from regionalization, and will not affect low-volume hospitals.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
Precise specifications: 3
Reliability: 3
Validity: 1
Adaptability: 2
Adequacy of risk adjustment: 4</td>
</tr>
</table>

Evidence Table 5 – Question 2b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Dominitz, Samsa, Landsman, et al., 1998 **#9380**	**Quality measure (QM):** Percentage of patients with colorectal cancer undergoing surgery **Basis of QM:** None **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Survival **Intent of QM:** Not specified (aim of the study was to assess the influence of race on the treatment and survival of patients with colorectal carcinoma) **Definition of denominator/numerator:** Denominator: Number of white/black patients with colorectal cancer identified from the VA Patient Treatment File (PTF) who were discharged from VA hospitals with a diagnosis of CRC (ICD-9-CM codes 153.0-153.4, 153.6-154.1) during fiscal year 1989. To exclude prevalent cases, any patient with a diagnosis of CRC (ICD-9-CM codes 153.0-153.4, 153.6-154.1, V10.05-V10.06) for hospitalization during FY 1984-1988, or a personal history of CRC (ICD-9-CM codes V10.05-V10.06) during the index hospitalization, was excluded. Male veterans only. No ulcerative colitis or Crohn's disease. Numerator: Number of above white/black patients treated with surgery, as indicated by specific ICD-9-CM codes in the PTF. **Data sources:** VA PTF **Recommended frequency of data collection:** No recommendation	**Study population:** N: 2607 whites + 569 blacks Age: 67.1 ± 9.1 (whites); 66.4 ± 9.9 (blacks) Race: See above Sex: 100% male Tumor stage: All stages Performance status: NR **Geographic location:** VA Medical Centers **Dates:** 1989 **Healthcare setting:** VA Hospitals **Results:** No statistically significant differences in rates of surgical resection in blacks vs. whites. No difference in 5-year relative survival or overall survival in blacks vs. whites.	**General comments:** The article compares rates of surgery, radiotherapy, and chemotherapy among blacks and whites. No attempt is made to compare to a gold standard (e.g., a guideline) to determine whether the rates in blacks or whites are optimal. The study is limited because of its use of an administrative database that lacked clinical details and did not allow for adjustment to disease severity. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 3 Reliability: 3 Validity: 1 Adaptability: 1 Adequacy of risk adjustment: 1

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Govindarajan, Shah, Erkman, et al., 2003

#35310

Characteristics of Quality Measure

Quality measure (QM): Percentage of patients with stage II, III colorectal cancer undergoing surgery

Basis of QM: None

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Not firmly linked to any outcome, but presumably to survival, quality of life, or rates of local recurrence

Intent of QM: Not specified (aim of the study was to analyze disease stage, treatment received, and socioeconomic factors to better understand the factors influencing survival differences between African-Americans and Caucasians with colorectal cancer)

Definition of denominator/numerator:
Denominator:
Number of African-Americans (AAs)/Caucasians, aged 18 older, with CRC treated between 1984 and 1997 at a state-funded University hospital located in Arkansas, identified through the hospital tumor registry using appropriate tumor registry codes.

Numerator:
Number of above AAs/Caucasians treated with surgery.

Data sources: Tumor registry at Univ. of Arkansas.

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 617

Colorectal	Caucasian	AA
N	427	190
Median age	60.0	61.5
Male (%)	47.1	39.5
Tumor stage (%)		
0-I	23.4	21.6
II	20.5	15.3
III	26.2	26.7
IV	30.0	36.4

Performance status: NR

Geographic location: Arkansas

Dates: 1984-1997

Healthcare setting: University hospital

Results:
Authors show that significantly higher percentages of Caucasians received surgery, compared with AAs, for patients with all stages of CRC, and for patients with only stages II and III disease.

Cancer-specific mortality was higher in African-Americans than in Caucasians for all stages.

Comments/Quality Scoring

General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
    - Precise specifications: 3
    - Reliability: 3
    - Validity: 1
    - Adaptability: 1
    - Adequacy of risk adjustment: 1

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Harmon, Tang, Gordon, et al, 1999

#35570

Characteristics of Quality Measure

Quality measure (QM): In-hospital death rate

Basis of QM: None

Type of QM:
(a) Outcome
(b) General

Outcome to which the QM is linked: Mortality

Intent of QM: Not specified (aim of the study was to examine the association of surgeon and hospital case volumes with the short-term outcomes in-hospital death, total hospital charges, and length of stay for resection of colorectal carcinoma)

Definition of denominator/numerator:
Denominator:
Number of patients who underwent colorectal resection (partial colectomy, total colectomy, abdominoperineal resection, other rectal resections including anterior resection).

Numerator:
Number of above patients who died in hospital.

Comparisons were made across hospital and surgeon volume. Surgeon case volume groups: low = < 5 cases/yr, medium = 5-10 cases/yr, high = >10 cases/yr. Hospital volume groups: low = <40 cases/yr, medium = 40-70 cases/yr, high => 70 cases/yr.

Data sources: Health Services Cost Review Commission

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:

Characteristics	Surgeon Volume Groups	Hospital Volume Groups
	Low/ Med/ High	Low/ Med/ High
Mean age (years)	68.7/ 69.2/ 69.3	69.1/ 69.5/ 68.8
Sex (% male)	47.0/ 48.6/ 47.2	47.8/46.6/ 48.7
Race-%white	74.4/ 83.8/ 84.1	74.9/ 81.7/ 84.7
Race-% black	23.8/ 14.8/ 13.7	23.3/ 16.5/ 13.5

Geographic location: Maryland

Dates: 1992-1996

Healthcare setting: Mixed

Results:

Characteristics	State Total	Surgeon Volume Groups	Hospital Volume Groups
		Low/ Med/ High	Low/ Med/ High
Mortality			
Crude %	3.5	4.5/ 3.3/ 2.6	4.7/ 3.0/ 3.0
Adjusted relative risk		1.00/0.79/ 0.64	1.00/0.79/ 0.78

A positive relation between high surgeon case volume and favorable outcomes was observed.

Medium volume surgeons achieved excellent outcomes similar to high-volume surgeons when operating in medium- or high-volume hospitals, but not in low-volume hospitals.

Comments/Quality Scoring

General comments:
Hospital case volume can serve as a surrogate for surgeon case volume. Surgeons in medium-volume hospitals had indistinguishable results.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
    - Precise specifications: 3
    - Reliability: 4
    - Validity: 4
    - Adaptability: 3
    - Adequacy of risk adjustment: 4

Evidence Table 5 – Question 2b (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr><td></td><td></td><td>Results of low-volume surgeons improved with increasing hospital volume, but never equated those of high-volume surgeons

Besides surgeon and hospital volume, other independent variables had a significant impact: an urgent or emergent admission, increased age, presence of organ metastasis, increased comorbidity index, male sex, undergoing a total colectomy or rectal resection and Medicaid payer status were associated with poorer outcomes.</td><td></td></tr>
<tr><td>Hodgson, Zhang, Zaslavsky, et al., 2003

#34120</td><td>Quality measure (QM): Postoperative (30-day) mortality

Basis of QM: None

Type of QM:
(a) Outcome
(b) General

Intent of QM: Not specified (aim of the study was to assess the association between hospital volume and colostomy rates, postoperative mortality, and overall survival for patients with rectal cancer)

Definition of denominator/numerator:
Denominator:
Number of patients diagnosed with rectal cancer or rectosigmoid cancer (ICD for Oncology codes 20.9 and 19.9), stage I-III, in California who underwent a major surgical procedure and had available hospital, demographic, and followup data.

Numerator:
Number of above patients who died within 30 days of the surgical procedure.

Data sources: California Cancer Registry

Recommended frequency of data collection: No recommendation</td><td>Study population:
N: 7,257

<table>
<tr><td>Median age</td><td>68.1</td></tr>
<tr><td>Male (%)</td><td>55.5</td></tr>
<tr><td>Race (%)</td><td></td></tr>
<tr><td>White</td><td>75.0</td></tr>
<tr><td>Black</td><td>4.9</td></tr>
<tr><td>Hispanic</td><td>10.9</td></tr>
<tr><td>Asian</td><td>8.8</td></tr>
<tr><td>Tumor stage (%)</td><td></td></tr>
<tr><td>I</td><td>34.0</td></tr>
<tr><td>II</td><td>33.3</td></tr>
<tr><td>III</td><td>32.7</td></tr>
</table>
Performance status: NR

Geographic location: California

Dates: January 1, 1994-December 31, 1997

Healthcare setting: Hospital

Results:
The 30-day mortality rate varied from 1.6% at high-volume hospitals to 4.8% at low-volume hospitals.</td><td>General comments:
30-day mortality seems to have face validity as an indicator of quality of surgery although there are a number of factors that may account for this other than hospital volume. The investigators performed multivariate analysis and found hospital volume still remained a significant indicator, but of course, there are some factors that might not be accounted for in the model.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
Precise specifications: 4
Reliability: 4
Validity: 4
Adaptability: 3
Adequacy of risk adjustment: 2</td></tr>
</table>

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Hodgson, Zhang, Zaslavsky, et al., 2003

#34120

Characteristics of Quality Measure

Quality measure (QM): Rate of colostomy for patients with rectal and rectosigmoid cancers

Basis of QM: None

Type of QM:
(a) Outcome
(b) General

Intent of QM: Not specified (aim of the study was to assess the association between hospital volume and colostomy rates, postoperative mortality, and overall survival for patients with rectal cancer)

Definition of denominator/numerator:
Denominator:
Number of patients diagnosed with rectal cancer or rectosigmoid cancer (ICD for Oncology codes 20.9 and 19.9), stage I-III, in California who underwent a major surgical procedure and had available hospital, demographic, and followup data.

Numerator:
Number of above patients requiring a colostomy.

Data sources: California Cancer Registry

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 7,257

Median age	68.1
Male (%)	55.5
Race (%)	
White	75.0
Black	4.9
Hispanic	10.9
Asian	8.8
Tumor stage (%)	
I	34.0
II	33.3
III	32.7

Performance status: NR

Geographic location: California

Dates: January 1, 1994-December 31, 1997

Healthcare setting: Hospital

Results:
33.1% of patients underwent a permanent colostomy, and the rate increased statistically as hospital volume decreased.

Comments/Quality Scoring

General comments:
The relation of colostomy rate to hospital volume seems to have face validity, but having a colostomy may not indicate poor quality care because some patients have tumors that are so low they cannot be excised with a reanastamosis. In other patients, the colostomy could be temporary to protect the anastomosis. The authors do try to account for temporary colostomies by excluding those with ICD codes for reversal within 1 year (but this could still misplace some patients).

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
    - Precise specifications: 5
    - Reliability: 5
    - Validity: 2
    - Adaptability: 2
    - Adequacy of risk adjustment: 2

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Hyman, Labow, and Vermont Chapter of the American College of Surgeons, 2002

#18980

Characteristics of Quality Measure

Quality measure (QM): Curative resection rate

Basis of QM: Not specified

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Mortality

Intent of QM: Quality improvement (aim of the study was to assess the feasibility of performing a quality study of the surgical management of colorectal cancer using a voluntary registry)

Definition of denominator/numerator:
Denominator:
Number of colorectal cancer patients reported to registry.

Numerator:
Number of above patients curatively resected. Curative resection defined as “no residual disease and no unresected metastatic disease.”

Data sources: Prospective statewide voluntary registry created by the Vermont chapter of ACS with the Vermont Program for Quality Health Care

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 364 (33 surgeons)
Age: Mean 68.7
Stage of tumor: Stage I = 24%, stage II = 32%, stage II = 28%, stage IV = 16%

Operative Procedures Performed in 364 Patients with Colorectal Cancer

Procedure	Patients, No.
Right hemicolectomy	125
Transverse colectomy	14
Left hemicolectomy	23
Sigmoid resection	55
Subtotal colectomy	13
Total proctocolectomy	4
Anterior resection	58
Coloanal anastomosis	11
Abdominoperineal resection	15
Local excision	20
Diverting stoma only	13
Intestinal bypass	3
Exploratory laparotomy only	2
Other/multiple procedures	8
Total	364

Geographic location: Vermont

Dates: April 1 1999 to March 31, 2001

Healthcare setting: Mixed

Results:
85% patients had a potentially curative resection (no residual local disease and no unresected metastatic disease).

Comments/Quality Scoring

General comments:
The study was not designed with an explicit intention to compare quality of care among participating surgeons (although it could potentially do so), but for comparison with national benchmarks.

A voluntary registry was used as the source of data.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
    - Precise specifications: 3
    - Reliability: 2
    - Validity: 4
    - Adaptability: 3
    - Adequacy of risk adjustment: 3

Evidence Table 5 – Question 2b (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td>Ko, Chang, Chaudhry, et al., 2002

#17540</td>
<td>Quality measure (QM): In-hospital death by hospital volume

Basis of QM: None

Type of QM:
(a) Structure
(b) General

Outcome to which the QM is linked: In-hospital mortality

Intent of QM: Not specified (aim of the study was to evaluate the importance of volume variables relative to other factors in an attempt to target specific areas for improving outcomes for colon cancer resections)

Definition of denominator/numerator:
Denominator:
Number of patients with colon cancer resection.

Numerator:
Number of above patients who died in hospital.

Comparisons were made by hospital volume.

Data sources: 1996 HCUP nationwide inpatient sample

Recommended frequency of data collection: No recommendation</td>
<td>Study population:
N: 22,408

<table>
<tr><td>Average age</td><td>70.4 +/- 12.2</td></tr>
<tr><td>male</td><td>51%</td></tr>
<tr><td>Caucasian</td><td>86%</td></tr>
<tr><td>black</td><td>8%</td></tr>
<tr><td>Hispanic</td><td>4%</td></tr>
<tr><td>Asian</td><td>1%</td></tr>
<tr><td>Average discharges</td><td>15,437 +/- 11,000</td></tr>
<tr><td>Colorectal cases</td><td>60 +/- 41</td></tr>
<tr><td>Surgeon cases</td><td>10.8 +/- 7.8</td></tr>
</table>

Geographic location: U.S.

Dates: 1996

Healthcare setting: Inpatient hospital setting

Results:
Significant predictors of mortality were age, sex, comorbid disease and volume (both hospital and surgeon). The predicted decrease in mortality by going to a high-volume hospital was 0.13%. Overall, the volume variables, although statistically significant, have a relatively smaller effect on outcome compared with other factors.</td>
<td>General comments:
The analysis suggests that the variables that resulted in the greatest increase in the probability of in-hospital mortality included having liver disease (4.45%), and having an emergency operation (4.35%), each with more than a 3-fold increase over the baseline (1.22%). Female sex, increased hospital procedure volume and increased surgeon volume were associated with a decreased probability of mortality.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
Precise specifications: 3
Reliability: 4
Validity: 3
Adaptability: 3
Adequacy of risk adjustment: 3</td>
</tr>
</table>

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Ko, Chang, Chaudhry, et al., 2002

#17540

Characteristics of Quality Measure

Quality measure (QM): In-hospital death by surgeon volume

Basis of QM: None

Type of QM:
(a) Structure
(b) General

Outcome to which the QM is linked: In-hospital mortality

Intent of QM: Not specified (aim of the study was to evaluate the importance of volume variables relative to other factors in an attempt to target specific areas for improving outcomes for colon cancer resections)

Definition of denominator/numerator:
Denominator:
Number of patients with colon cancer resection.

Numerator:
Number of above patients who died in hospital.

Comparisons were made by surgeon volume.

Data sources: 1996 HCUP nationwide inpatient sample

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 22,408

Average age	70.4 +/- 12.2
male	51%
Caucasian	86%
black	8%
Hispanic	4%
Asian	1%
Average discharges	15,437 +/- 11,000
Colorectal cases	60 +/- 41
Surgeon cases	10.8 +/- 7.8

Geographic location: U.S.

Dates: 1996

Healthcare setting: Mixed

Results:
Significant predictors of mortality were age, sex, comorbid disease and volume (both hospital and surgeon). The predicted decrease in mortality by going to a high-volume surgeon was 0.17%.

Overall, the volume variables, although statistically significant, have a relatively smaller effect on outcome compared with other factors.

Comments/Quality Scoring

General comments:
The analysis suggests that the variables that resulted in the greatest increase in the probability of in-hospital mortality included having liver disease (4.45%), and having an emergency operation (4.35%), each with more than a 3-fold increase over the baseline (1.22%). Female sex, increased hospital procedure volume and increased surgeon volume were associated with a decreased probability of mortality.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 3
  - Reliability: 4
  - Validity: 3
  - Adaptability: 3
  - Adequacy of risk adjustment: 3

Evidence Table 5 – Question 2b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Merrill, Brown, Potosky, et al., 1999 **#27110**	**Quality measure (QM):** Percentage of CRC patients who had surgical resection **Basis of QM:** None **Type of QM:** (a) Structure (b) General **Outcome to which the QM is linked:** Presumably survival **Intent of QM:** Not specified (aim of the study was to compare treatment utilization and long-term survival in HMO and fee-for-service [FFS] settings for Medicare colorectal cancer cases) **Definition of denominator/numerator:** Denominator: Number of CRC patients in each subgroup of the dataset (see Data sources, below). Numerator: Number of above patients who had surgical resection. **Data sources:** 1. Two tumor registries on colon and rectum cancer patients diagnosed 1985-92 and followed up through 31 December 1994. Both registries are part of SEER. 2. Medicare inpatient claims data. 3. Databases of two HMO plans, Kaiser Permanente of Northern California and Group Health Cooperative of Puget Sound. 4. 1990 U.S. Census **Recommended frequency of data collection:** No recommendation	**Study population:** N: 15,352 total Age: ≥ 65 Race: 81.2 to 95.3% white depending on subgroup Sex: 46.8 to 54.3% male, depending on subgroup Tumor stage: 0-IV Performance status: NR Comorbidity Index: 0-2+ **Geographic location:** San-Francisco-Oakland area, Seattle-Puget Sound area **Dates:** 1985-1992 **Healthcare setting:** 2 tumor registries participating in the SEER Program augmented with Medicare data along with HMOs KPNC and GHC. **Results:** Only statistical difference in rates of surgical resection between HMO and FFS cases was observed for stage I cases, in which the percentage receiving resection was 75% (95% CI 70-79%) for HMO cases and 82% (95% CI 80-84%) for FFS cases. Standardizing to the FFS cases gave an adjusted HMO rate of 74% (95% CI 70-79%), which was no longer statistically different. No differences were seen in the use of surgical resection for rectal cases. Cancer-specific mortality rates were similar in both settings.	**General comments:** A very high-quality study by experienced researchers. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 4 Adaptability: 4 Adequacy of risk adjustment: 4

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Morris, Billingsley, Baxter, et al., 2004

#32200

Characteristics of Quality Measure

Quality measure (QM): Rate of sphincter-preserving procedures (SSP)

Basis of QM: Not specified, but appears to be NIH Consensus conference

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: No explicit outcome link, but presumably to decreased rates of LRR or improved OS

Intent of QM: Aim of the study was to investigate racial variation in the performance of sphincter-sparing procedures for patients with stage II and III rectal cancer who underwent surgery, and to study race and delivery of any surgical treatment, neoadjuvant therapy, and radiation therapy to these patients, with implications for quality of care.

Definition of denominator/numerator:
Denominator:
Number of blacks/whites diagnosed with rectal cancer and entered into the SEER database 1988-1999.

Exclusion criteria: Prior diagnosis of CRC, prior diagnosis of cancer requiring surgery or radiotherapy in the pelvis, or < age 35.

Numerator:
Number of above patients who received various treatments for CRC including surgery (also type of operation) and radiation (timing of RT also evaluated).

Data sources: SEER registry

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N = 52,864

	White	Black
n	44,010	3,851
Age (%)		
35-64	35	49
65-79	46	40
80+	20	12
Male (%)	55	52
Tumor stage (%)		
In situ	9	8
I	3	28
II	21	20
III	19	18
IV	14	17
Unstaged	8	10

Geographic location: SEER regions

Dates: 1988-1999

Healthcare setting: U.S. healthcare facilities

Results:

N = 15,351	Rate of operation		Adjusted OR (95% CI)
	Any	None	
White	96	4	1.30 (1.12-1.95)
Black	94	6	

N = 14,405	SSP	APR	Adjusted OR (95% CI)
White	63	37	1.42 (1.23-1.65)
Black	57	43	

Comments/Quality Scoring

General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 4
- Usability: 4
- Scientific acceptability (five criteria):
  - Precise specifications: 3
  - Reliability: 3
  - Validity: 4
  - Adaptability: 4
  - Adequacy of risk adjustment: 3

Evidence Table 5 – Question 2b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Newcomb and Carbone, 1993 **#3760**	**Quality measure (QM):** Rate of surgery for colorectal cancer **Basis of QM:** None mentioned, but presumably practice guideline **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Not specified, but presumably survival or rate of bleeding or obstruction **Intent of QM:** Not specified (aim of the study was to evaluate the selection of cancer treatment among the elderly) **Definition of denominator/numerator:** Denominator: Number of women residents of Wisconsin aged 20-74 at the time of diagnosis with a new diagnosis of carcinoma of the large bowel during 1989-1991, and who had a listed telephone number and spoke English, and whose physician consented to their participation, and who agreed to a telephone interview, and were among the 628 consecutive participants interviewed September 1, 1990 through November 30, 1990. Numerator: Number of above subjects having surgery. **Data sources:** Registry for staging information and patient interviews (for the treatment information) **Recommended frequency of data collection:** No recommendation	**Study population:** N: 121 with colorectal Age: 20-74 Race: NR Sex: Female Tumor stage: All stages Performance status: NR **Geographic location:** Wisconsin **Dates:** Sep 1 through Nov 30, 1990 **Healthcare setting:** None (all participants were outpatients contacted by phone) **Results:** 98% of patients less than 65 and 94% ≥ 65 received surgery.	**General comments:** Relying on recall of patients for whether they received a treatment is open to bias. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 3 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 4 Validity: 4 Adaptability: 5 Adequacy of risk adjustment: 1

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

O'Connell, Maggard, Liu, et al., 2004

#45210

Characteristics of Quality Measure

Quality measure (QM)
Cancer-directed surgery (CDS) rate

Basis of QM: NIH Consensus Conference Guidelines for adjuvant therapy for colorectal cancer

Type of QM:
(a) Process
(b) General

Intent of QM: Not specified (aim of the study was to compare rectal cancer patient outcomes between young and older populations)

Definition of denominator/numerator:
Denominator:
Patients in the SEER database diagnosed with rectal cancer between 1991 and 1999. Tumors identified as "rectum" in location were selected. Specific histologies were chosen to include only adenocarcinomas.

Exclusion criteria: Patients with tumors identified as rectosigmoid. Mucinous, signet ring cell, carcinoid, sarcoma and lumphoma histologies were excluded, along with those tumors classified as benign or in situ.

Numerator:
Number of above patients who received CDS subsequent to diagnosis.

Data sources: SEER database

Frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N = 11,778

	20-40 yrs (young) N = 466	60-80 yrs (old) N = 11,312	P-value
Age	34.1± 4.5	70± 5.5	
Male %	54.9	60	0.03
Race			
White	62.6	82.3	< 0.001
Black	12.7	6.1	< 0.001
Hispanic	8.8	3.7	< 0.001
Asian	7.5	6.4	NS
other	8.4	1.5	< 0.001
AJCC stage			
I	17	23.7	< 0.001
II	15.5	17.8	NS
III	27	20	< 0.001
IV	17.4	13.6	0.02
Grade			
Well	7.5	9.4	NS
Moderate	50.4	61.2	< 0.001
Poorly	24.3	14	< 0.001
Anaplastic	1.7	.7	0.008
unknown	16.1	14.7	NS

Geographic location: U.S.

Dates: 1991- 1999

Healthcare setting: Hospital

Results:
Young patients overall were as likely to receive CDS as their older counterparts (85.4% vs. 85.5%). Similar findings were seen for stages I, II and III disease (96.2-99.2% received CDS). However, both young and older patients with stage IV disease were less likely to receive CDS (51.9 vs. 51.8; p = NS).

Median survival was 24 months for the young group and 27 months for the older group. Univariate

Comments/Quality Scoring

General comments:
The SEER registry maintains stringent quality control measures to prevent coding errors and is regarded as one of the best population based databases; however, miscoding and inaccurate data may be present. The registry does not contain all clinically relevant data, such as family history, predisposing factors, etc. A third limitation of the SEER data is that tumor stage or grade was unknown for a number of patients. Another limitation of the study is the substantially smaller sample of young rectal cancer patients compared with the large number of older patients, leading to overestimation of differences.

Rating of quality measures as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
Importance: 4
Usability: 5
Scientific acceptability
- Precise specifications: 4
- Reliability: 3
- Validity: 3
- Adaptability: 3
- Adequacy of risk adjustment: 3

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
		analysis revealed overall 5-year survival was similar for the young group compared with the older (63.2 vs. 62.1%; p = NS). Five-year, stage-specific survival also was similar for all stages. Multivariate Cox regression analysis revealed that young, rectal cancer patients had a lower hazard of dying (hazard ratio, 0.693, p = 0.0004) when controlling for tumor stage, patient demographics, tumor characteristics, and stage and treatment.	

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

O'Connell, Maggard, Liu, et al., 2004

#29710

Characteristics of Quality Measure

Quality measure (QM): Percentage of patients with colon cancer who underwent cancer-directed surgery

Basis of QM: None

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Mortality

Intent of QM: Not specified (aim of the study was to analyze differences in patient demographics, cancer-related data, and survival between young and older colon cancer patients)

Definition of denominator/numerator:
Denominator:
Number of patients with colon cancer diagnosed between 1991 and 1999 in a SEER database (which included only those patient living in a SEER area at the time of diagnosis) who were either aged 20-40 or aged 60-80.

Exclusion criteria: In situ cancers, rectal cancers.

Numerator:
Number of the above subjects who also underwent "cancer-directed surgery" (a variable in the SEER database).

Data sources: SEER database

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 47,791

	Young (20-40 yrs)	Older (60-80 yrs)
N	1,334	46,457
Age	34.1	70.8
Male (%)	52.1	51.5
Race (%)		
White	64.2	81.2
Black	16.4	9.0
Hispanic	6.5	3.0
Asian	7.4	5.6
Other	5.5	1.2
AJCC Stage (%)		
I	10.6	18.6
II	23.0	29.0
III	31.5	22.8
IV	24.5	17.3
Unstaged	10.4	12.3

Geographic location: SEER regions not specifically listed in this publication)

Dates: Diagnosis 1991-1999; followed through 2004 (?)

Healthcare setting: Variety, Medicare, non-HMO

Results:
Young patients were as likely to undergo cancer-directed surgical resection as their older counterparts, with 91.4% of young patients and 91.2% of older patients having cancer-directed surgery (p = NS). Similar findings were seen specifically for surgery for stage I, II, and III disease (99.2-99.7% underwent surgery). However, older patients with stage IV disease had surgery significantly less often than young patients (74.6% vs. 83.2%, p < 0.001). Overall 5-year cancer-specific survival for young patients was poorer than for older patients (62% vs. 65%).

Comments/Quality Scoring

General comments:
The data for other potential QMs (% received surgery) are much weaker, poorly defined and do not necessarily follow guidelines. Data presented for radiation therapy are too inadequate to abstract as a QM (i.e., not stratified by stage) and are not indicated for colon cancer anyway (rectal cancers were excluded from this study).

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 4
- Usability: 4
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 3
  - Validity: 2
  - Adaptability: 3
  - Adequacy of risk adjustment: 1

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Purves, Pietrobon, Hervey, et al. 2005

#43660

Characteristics of Quality Measure

Quality measure (QM): Rate of sphincter-sparing procedures (SSP) and abdominoperineal resection (APR) procedures performed among surgeons, by caseload volume

Basis of QM: Not specified

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: No explicit outcome link, but presumably to decreased rates of LRR or improved OS.

Intent of QM: Not specified (aim of the study was to determine whether the rate of SSP increased among surgeons who performed a larger number of rectal cancer surgeries in one year, while controlling for patient characteristics, including comorbidity)

Definition of denominator/numerator:
Denominator:
Patients with a diagnostic ICD-9 code of 154.1 (malignant neoplasm of the rectum) as primary diagnosis.

Exclusion criteria: Patients with anal cancer (154.2, 154.3); patients with rectum or colon cancer (154.0) or patients with rectal cancer contiguous with the rectosigmoid junction or anus (154.8). Also excluded were patients who were not surgically treated for their rectal cancer during the hospital admission of record. Prior diagnosis of CRC, prior diagnosis of cancer requiring surgery or radiotherapy in the pelvis, or < age 35.

Numerator:
Number of above patients who underwent either APR or SSP procedure.

Data sources: 1997 National Inpatient Sample (NIS) of the Healthcare Cost and Utilization Project (HCUP) database

Testing of Quality Measure

Study population:
N = 477

	SSP	APR
n	259	218
Surgeons	120	109
Patient Age (%)		
≤ 59	26.3	22.0
60-69	26.6	29.8
≥ 70	47.1	47.2
Male (%)	56	60
White (%)	70	71.1
Non-White (%)	12.6	10.1

Geographic location: 22 states in U.S.

Dates: 1997

Healthcare setting: U.S. community hospitals

Results:

	SSP	APR	
Deyo score (%)			P<.05
0-7	29.8	18.2	
I8-15	20.1	23.5	
≥ 16	4.4	4.0	
Surgeon volume (%)			P<.05
1-3	12.4	16.4	
4-9	9.4	7.1	
≥ 10	9.0	2.7	
Missing	23.5	19.5	
mean	1.27	.73	

(continued on next page)

Comments/Quality Scoring

General comments:
Investigators did not have access to information about specific characteristics of each patient's rectal cancer, such as grading, tumor size and height, lymph node metastases and other tumor characteristics important to staging.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
    - Precise specifications: 4
    - Reliability: 4
    - Validity: 3
    - Adaptability: 4
    - Adequacy of risk adjustment: 3

Evidence Table 5 – Question 2b (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr><td></td><td>Recommended frequency of data collection: No recommendation</td><td>
<table>
<tr><th>Surgeon case-load volume</th><th>Adjusted for age, sex, race, comorbidity, income odds ratio</th><th>Reduced adjusted (race only) odds ratio</th></tr>
<tr><td>1-3</td><td>1.00</td><td>1.00</td></tr>
<tr><td>4-9</td><td>1.73</td><td>2.02</td></tr>
<tr><td>≥ 10</td><td>5.05</td><td>4.55</td></tr>
</table>
<p>SSP accounted for 259 o 54.3 percent of all resections. APR accounted for 45.7%. SSP patients did not differ from those undergoing APR in terms of age, race, sex or income. Patients undergoing SSP, however, had a lower average Deyo comorbidity score than those undergoing APR (6.4 vs. 7.7, p = 0.01).</p>
<p>The mean surgeon caseload volume for patients undergoing SSP was significantly more than that for APR patients (7.7 vs. 4.6, p = 0.0002). Rectal cancer patients treated by a high-caseload surgeon (≥ 10 outcome procedures per year) are more likely to receive an SSP than are patients treated by low-caseload surgeons (1-3 outcome procedures per year).</p>
<p>In a multivariable analysis, patients undergoing procedures performed by surgeons in the highest volume category were five times more likely to undergo SSP than patients treated by surgeons in the lowest volume category, when analysis was controlled for age, race, sex, and Deyo comorbidity score. In a reduced model, controlling only for race, the odds ratio of SSP for patients treated by surgeons in the highest-volume category compared with lowest-volume category was 4.55.</p>
</td><td></td></tr>
</table>

Evidence Table 5 – Question 2b (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td>Rabeneck, Davila, Thompson, et al., 2004

#44670</td>
<td>Quality measure (QM): 30 day operative mortality rate

Basis of QM: None

Type of QM:
(a) Outcome
(b) General

Intent of QM: Not specified (aim of the study was to compare 30-day and 5-year mortality in elderly vs. younger patients following surgical resection for colorectal cancer)

Definition of denominator/numerator:
Denominator:
Patients admitted to VA hospitals with a new diagnosis of CRC who underwent surgical resection within 6 months from discharge date of first hospitalization between October 1990 and September 2000.

Exclusion criteria: Patients with previous CRC diagnosis within last 5 years, those with a prior diagnosis of ulcerative colitis or Crohn’s disease.

Numerator:
Number of above patients who died within 30 days of surgery.

Data sources: National VA Patient Treatment File (PTF)

Frequency of data collection: No recommendation</td>
<td>Study population:
N = 22,633
Mean age: 68, with two-thirds ≥ 65
Sex: 98% male
Race: 75% white; 17% black, 4% Hispanic
57% comorbidity score of 0; 12% had metastatic disease

Geographic location: U.S.

Dates: FY 1991- 2000

Healthcare setting: 172 VA medical centers

Results:

<table>
<tr><th colspan="5">Hazard Ratio</th></tr>
<tr><th></th><th>Rectal cancer</th><th>P-value</th><th>Colon cancer</th><th>P-value</th></tr>
<tr><td>< 65</td><td>1.00</td><td></td><td></td><td></td></tr>
<tr><td>≥ 65</td><td>2.64</td><td><.0001</td><td>2.43</td><td><.0001</td></tr>
<tr><td>Deyo score</td><td></td><td></td><td></td><td></td></tr>
<tr><td>0</td><td>1.00</td><td></td><td></td><td></td></tr>
<tr><td>1-2</td><td>1.77</td><td>0.0002</td><td>1.58</td><td><.0001</td></tr>
<tr><td>3-4</td><td>3.33</td><td><.0001</td><td>2.51</td><td><.0001</td></tr>
<tr><td>>5</td><td>5.59</td><td><.0001</td><td>2.56</td><td>.0002</td></tr>
</table>

Results show 30-day postoperative mortality for patients with rectal cancer following surgical resection was more than 2.5 times greater among older patients than among younger when adjusting for sex, race, comorbidity score, marital status, and hospital surgical volume.

The analysis was repeated for patients with colon cancer who underwent surgical resection during 1991-2000 and the results were similar (2.5 times greater in elderly).</td>
<td>General comments:
Some misclassification of variables may exist because of coding errors. Given that the study population was predominantly male, the results may not be generalized to women with CRC. The quality of ascertainment of chemotherapy and radiotherapy is unknown. Therefore, our adjustment for these variables might be incomplete. Our adjustments for comorbidity may be incomplete because of the use of administrative data, and our adjustment for disease severity may be incomplete. The lack of staging information is an important limitation.

Rating of quality measures as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
Importance: 5
Usability: 5
Scientific acceptability
Precise specifications: 4
Reliability: 4
Validity: 4
Adaptability:3
Adequacy of risk adjustment 4</td>
</tr>
</table>

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Read, Myerson, Fleshman, et al., 2002

#17970

Characteristics of Quality Measure

Quality measure (QM): Local control rate

Basis of QM: Clinical practice guideline (NIH Consensus Statement)

Type of QM:
(a) Structure
(b) General

Outcome to which the QM is linked: Local tumor recurrence (not well defined)

Intent of QM: Quality improvement (aim of the study was to determine the effect of surgeon specialty on disease-free survival and local control in patients with adenocarcinoma of the rectum)

Definition of denominator/numerator:
Denominator:
Number of patients undergoing curative treatment for primary rectal adenocarcinoma with neoadjuvant radiotherapy followed by proctectomy. Patients undergoing endocavitary radiation or transanal local excision were excluded.

Numerator:
Number of above patients who failed to have local tumor recurrence (not well specified).

Data sources: Medical records

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 213
Age: 64 mean (19-97)
Race: NR
Sex: 100% male
Tumor stage: NR
Performance status: NR

Geographic location: U.S. (multi-institutional)

Dates: 1977-1995

Healthcare setting: Hospital

Results:
Background of the surgeon and the pathologic stage were significantly correlated with local control (and disease- free survival) at 5 years.

	No. of cases	% without relapse at 5 yr	% local control at 5 yr
Surgeon			
Colorectal specialist	251	77	93
Other	133	68	84
P value		0.004	0.005
Histologic stage			
I	145	83	95
II	137	75	91
III	102	57	81
P value		< 0.001	0.005

Comments/Quality Scoring

General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 4
- Scientific acceptability (five criteria):
  - Precise specifications: 2
  - Reliability: 4
  - Validity: 4
  - Adaptability: 5
  - Adequacy of risk adjustment: 1

Evidence Table 5 – Question 2b (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td>Roetzheim, Pal, Gonzalez, et al., 2000

#23910</td>
<td>Quality measure (QM): Percentage of patients with a colon or rectal cancer diagnosis who received cancer-directed surgery (i.e., performed for cure not palliation)

Basis of QM: None stated

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Mortality

Intent of QM: Not specified (aim of the study was to explore the influence of race/ethnicity and insurance payer on the treatment of and outcomes for colorectal cancer patients in Florida)

Definition of denominator/numerator:
Denominator:
Number of incident cases of colon or rectal cancer occurring in Florida in 1994 as listed in the state tumor registry.

Numerator:
Number of the above patients who also received cancer-directed surgery within 4 months of initiation of therapy.

Data sources: Florida state cancer registry (Florida Cancer Data System = FCDS); Florida Agency for Health Care Administration AHCA discharge abstracts (admissions to all nonfederal acute care hospitals and patient visits to ambulatory surgical centers, freestanding radiation therapy centers and diagnostic imaging centers)

Recommended frequency of data collection: No recommendation</td>
<td>Study population:
N: 9,548

<table>
<tr><th>Patient characteristic</th><th>Percent</th></tr>
<tr><td>Male</td><td>51</td></tr>
<tr><td>Race</td><td></td></tr>
<tr><td>White</td><td>85</td></tr>
<tr><td>Black</td><td>6</td></tr>
<tr><td>Hispanic</td><td>8</td></tr>
<tr><td>Diagnosis stage</td><td></td></tr>
<tr><td>In situ</td><td>6</td></tr>
<tr><td>Local</td><td>30</td></tr>
<tr><td>Regional</td><td>42</td></tr>
<tr><td>Distant</td><td>16</td></tr>
<tr><td>Unstaged</td><td>6</td></tr>
<tr><td>Anatomic site</td><td></td></tr>
<tr><td>Colon</td><td>84</td></tr>
<tr><td>Rectal</td><td>16</td></tr>
<tr><td>Comorbidity index</td><td></td></tr>
<tr><td>0</td><td>71</td></tr>
<tr><td>1</td><td>21</td></tr>
<tr><td>≥ 2</td><td>8</td></tr>
</table>

Geographic location: Florida

Dates: 1994

Healthcare setting: Multiple

Results:
Used 2 sources for the procedure data: the cancer registry and the state AHCA discharge summaries and in 94.2% there was agreement regarding surgical treatments performed.

Treatments received varied according to insurance payer. Patients with CRC who were uninsured or insured by Medicaid or commercial HMO's had higher mortality rates than patients with commercial FFS insurance. Mortality was also higher among non-Hispanic African-American patients even after controlling for stage of disease at diagnosis and treatment modality. Patients who needed co-directed</td>
<td>General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 4
- Usability: 3
- Scientific acceptability (five criteria):
Precise specifications: 3
Reliability: 4
Validity: 3
Adaptability: 3
Adequacy of risk adjustment: 3</td>
</tr>
</table>

Evidence Table 5 – Question 2b (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr><td></td><td></td><td>surgery were similar in age to those who did not. There were no differences between races in receipt of definitive surgical treatment. Among Medicare patients, those with HMO insurance were more likely to receive definitive surgical treatment, the differences increased with advancing cancer stage. Among non-Medicare patients those having Medicaid, those were uninsured, and those having other forms of health insurance were less likely to receive surgical treatment than were private FFS patients. Use of definitive surgery was more common in younger patients, those with higher levels of education, and those who were married.</td><td></td></tr>
<tr><td>Rogers, Ray, and Smalley, 2004

#30130</td>
<td>Quality measure (QM): Percentage of patients with a diagnosis of colorectal cancer receiving surgery

Basis of QM: Not stated

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Not stated, but presumably survival or recurrence of colorectal cancer

Intent of QM: Not specified (aim of the study was to examine the effect of race on CRC outcomes in patients who had identical health care coverage)

Definition of denominator/numerator:
Denominator:
Number of patients enrolled in both Tennessee Medicaid and Medicare and hospitalized with a diagnosis of colorectal cancer.

Numerator:
Number of above patients who received surgery.

Data sources: Medical records, administrative files from the Tennessee Medicaid program, Tennessee death certificates, and the National Death Index

Recommended frequency of data collection: No recommendation</td>
<td>Study population:
N: 969 total (19.3% rectal cancer)
<table>
<tr><th></th><th>White</th><th>Black</th></tr>
<tr><td>Cases (%)</td><td>72</td><td>28</td></tr>
<tr><td>Age</td><td>78.9</td><td>78.9</td></tr>
<tr><td>Male (%)</td><td>26.1</td><td>27.6</td></tr>
<tr><td>Tumor stage</td><td></td><td></td></tr>
<tr><td>I</td><td>16.4</td><td>9.2</td></tr>
<tr><td>II</td><td>39.7</td><td>36.0</td></tr>
<tr><td>III</td><td>24.4</td><td>27.9</td></tr>
<tr><td>IV</td><td>9.8</td><td>12.9</td></tr>
<tr><td>Unknown</td><td>9.8</td><td>14.0</td></tr>
<tr><td>Charlson-Deyo score (%)</td><td>64</td><td>69</td></tr>
</table>

Geographic location: Tennessee

Dates: 1984-1994

Healthcare setting: Patients identified from hospitalizations

Results:
91% of whites and 86% of blacks had surgery.</td>
<td>General comments:
Study concluded that when there was equal access to care, outcomes were equal in whites and blacks.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
Precise specifications: 5
Reliability: 5
Validity: 5
Adaptability: 3
Adequacy of risk adjustment: 1</td></tr>
</table>

Evidence Table 5 – Question 2b (Published Literature) – continued

Study | **Characteristics of Quality Measure** | **Testing of Quality Measure** | **Comments/Quality Scoring**

Schrag, Cramer, Bach, et al., 2000

#23710

Quality measure (QM): 30-day mortality in low- and high-volume hospitals

Basis of QM: Not stated

Type of QM:
(a) Structure
(b) General

Outcome to which the QM is linked: Mortality

Intent of QM: Quality improvement (aim of the study was to determine whether hospital procedure volume predicts short- and long-term survival following primary colon cancer surgery)

Definition of denominator/numerator:
Denominator:
Number of patients with stage III tumors who survived 3 months postoperatively, were enrolled in Medicare Part B, were 65 years and older, were diagnosed as having primary adenocarcinoma of the colon in a SEER area, and underwent surgery followed by at least one claim for chemotherapy.

Exclusion criteria: Patients were excluded if diagnoses were exclusively noted on death certificates or at autopsy; month of diagnosis was unknown; or patient was enrolled in an HMO. Also, patients who were operated on exclusively for local resection or creation of an ostomy were excluded.

Numerator:
Number of patients who died within 30 days following surgery.

Data sources: SEER for patients 65 and older Medicare Claims Part B

Recommended frequency of data collection: No recommendation

Study population:

Overall

	No. or %
Total patients	27,986
Total hospitals	611
Sex	
Male	44.8
Female	55.2
Age	
65-69	19.5
70-74	23.7
75-79	23.2
80+	33.6
Race	
White	84.6
Black	7.1
Other	8.3
AJCC stage	
I	19.2
II	36.2
III	25.6
IV	13.9
Unstaged	5.1
Romano Charlson comorbid	
0	65.2
1	24.3
2	10.5

(continued on next page)

General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
    - Precise specifications: 4
    - Reliability: 3
    - Validity: 4
    - Adaptability: 4
    - Adequacy of risk adjustment: 4

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring

By hospital volume (figures are numbers or %)

	Low	Med	High	Very high
Total patients	6,837	7,105	6,947	7,097
Total hospitals	440	89	51	31
Sex				
Male	44.9	44.9	45.6	44.0
Female	55.1	55.1	54.4	56.0
Age				
65-69	20.8	18.9	19.2	19.2
70-74	23.9	24.0	23.2	23.9
75-79	22.1	23.3	24.1	23.3
80+	33.2	33.8	33.6	33.7
Race				
White	80.3	83.6	86.1	88.4
Black	7.1	7.2	5.5	8.6
Other	12.6	9.2	8.4	3.0
AJCC stage				
I	18.0	18.4	20.0	20.4
II	35.5	36.3	35.5	37.5
III	24.8	26.3	25.0	26.1
IV	13.9	13.6	14.4	13.6
Unstaged	7.8	5.3	5.0	2.5
Romano Charlson comorbid				
0	64.8	64.8	65.5	65.9
1	24.4	24.6	24.3	23.8
2	10.8	10.6	10.2	10.3

Geographic location: U.S.

Dates: 1991-1996

Healthcare setting: All U.S.

Results:
Adjusting for age, sex, race, cancer stage, comorbid illness, socioeconomic status, and acuity of hospitalization, very high-volume hospitals had a

Evidence Table 5 – Question 2b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
		lower 30-day mortality than low-volume hospitals. A consistent association between higher postoperative mortality and lower surgical volume was evident; this persisted after inclusion of potential confounders. This association was evident for stages I-III, but not for patients with stage IV or unstaged disease (due to smaller sample sizes). The survival curves illustrate a clear association between procedure volume and overall survival. The difference in 5-year mortality for patients operated on at very high- vs. low-volume hospitals was 4.4%.	

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Schrag, Panageas, Riedel, et al., 2002

#17000

Characteristics of Quality Measure

Quality measure (QM): 30-day mortality rate

Basis of QM: None

Type of QM:
(a) Outcome
(b) General

Intent of QM: Research (aim of the study was to compare surgeon and hospital procedure volume as predictors of outcomes for patients with rectal cancer)

Definition of denominator/numerator:
Denominator:
Number of Medicare patients undergoing rectal cancer surgery for a primary tumor diagnosed in 1992-1996 in a SEER area.

Exclusion criteria: Excluded patients with cancers arising in the rectosigmoid; had tumors with a predominant squamous cell component that could have been anal in origin; HMO enrollees; with diagnoses noted exclusively on death certificates or at autopsy; where the month of diagnosis was unknown.

Numerator:
Number of above patients who died within 30 days of rectal sphincter-sparing surgery.

Patient data were case -adjusted based on age, sex, race, disease stage, comorbidity, socioeconomic status and whether surgery was emergent.

Data sources: SEER, Medicare claims

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 2,815

Stage	%
I	30
II	28
III	29
IV	8
Unstaged	5
Age	
65-69	25
70-74	27
75-79	23
80-84	16
85+	9
Male/female	54/46
Race	
White	86
Black	4
Other	10
Comorbidity	
0	67
1	25
2+	8
Nonemergent admit	91

Geographic location: U.S.

Dates: 1992-1996

Healthcare setting: All

Results:
Hospitals and surgeons were ranked by their volumes as very low, low, medium and high. There was no statistically significant association between 30-day mortality and hospital or surgeon volume.

Over the longer term, differences in surgical outcomes emerged 2 years following resection; these differences were significant and persisted after adjusting for differences in baseline patient

Comments/Quality Scoring

General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 3
  - Validity: 4
  - Adaptability: 4
  - Adequacy of risk adjustment: 4

Evidence Table 5 – Question 2b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
		characteristics. However, hospital procedure volume ceased to become a significant predictor of outcomes once surgeon procedure volume had been considered. Surgeon-specific procedure volume remained important as a predictor of outcome after adjusting for differences in hospital procedure volume.	

Hospital Procedure volume	30-day mortality (%)
Very low	3.9
Low	4.0
Medium	2.4
High	3.3
P-value	0.79
Surgeon procedure volume	
Very low	4.3
Low	3.7
Medium	3.5
High	1.7
P-value	0.20

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Schrag, Panageas, Riedel, et al., 2002

#17000

Characteristics of Quality Measure

Quality measure (QM): Abdominoperineal (APR) resection rate

Basis of QM: None

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Mortality

Intent of QM: Research (aim of the study was to compare surgeon and hospital procedure volume as predictors of outcomes for patients with rectal cancer)

Definition of denominator/numerator:
Denominator:
Number of Medicare patients undergoing rectal cancer surgery for a primary tumor diagnosed in 1992-1996 in a SEER area.

Exclusion criteria: Excluded patients with cancers arising in the rectosigmoid; had tumors with a predominant squamous cell component that could have been anal in origin; HMO enrollees; with diagnoses noted exclusively on death certificates or at autopsy; where the month of diagnosis was unknown.

Numerator:
Number of above patients for whom surgeons performed abdominoperineal surgery.

Patient data were case -adjusted based on age, sex, race, disease stage, comorbidity, socioeconomic status and whether surgery was emergent.

Data sources: SEER, Medicare claims

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 2,815

Stage	%
I	30
II	28
III	29
IV	8
Unstaged	5
Age	
65-69	25
70-74	27
75-79	23
80-84	16
85+	9
Male/female	54/46
Race	
White	86
Black	4
Other	10
Comorbidity	
0	67
1	25
2+	8
Nonemergent admit	91

Geographic location: U.S.

Dates: 1992-1996

Healthcare setting: All

Results:
APR rates were compared by providers with different case volumes. After case-mix adjusting, the association was not significant, and was further attenuated when adjusted for surgeon volume, p = 0.15.

(continued on next page)

Comments/Quality Scoring

General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 3
  - Validity: 4
  - Adaptability: 4
  - Adequacy of risk adjustment: 4

Evidence Table 5 – Question 2b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring

Hospital Procedure volume	APR rate (%)
Very low	51
Low	53
Medium	49
High	44
P-value	0.04
Surgeon procedure volume	
Very low	49
Low	54
Medium	51
High	44
P-value	0.15

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Characteristics of Quality Measure

Testing of Quality Measure

Comments/Quality Scoring

Schrag, Panageas, Riedel, et al., 2003

#34030

Quality measure (QM): 30-day mortality rate

Basis of QM: None stated

Type of QM:
(a) Outcome
(b) General

Intent of QM: Quality improvement (aim of the study was to compare surgeon and hospital procedure volume as predictors of outcomes following colon cancer resection)

Definition of denominator/numerator:
Denominator:
Number of Medicare eligible patients aged 65 or older diagnosed in SEER regions with primary colon cancer in 1991-1996.

Exclusion criteria: Excluded were patients enrolled in an HMO; operated on exclusively for intestinal bypass; diagnosis noted exclusively on death certificate or at autopsy; month of death was unknown.

Numerator:
Number of above patients who died within 30 days of operation (not clearly defined).

Adjustment was made for sex, race, age, stage of tumor, comorbidity and socioeconomic status, whether hospitalization was emergent and whether obstruction or perforation was present.

Data sources: SEER, Medicare claims from HCFA

Recommended frequency of data collection: No recommendation

Study population:
N = 24,166

Characteristic	Percent
Male/female	44.1/55.9
Age	
65-69	18.6
70-74	23.6
75-79	23.6
80+	34.2
Race	
White	87.1
Black	6.6
other	6.3
AJCC stage I	19.9
II	36.9
III	26.1
IV	14.1
Unstaged	3.0
Romano comorbidity	
0	71.3
1	23.2
2	5.6
Obstruction (Y/N)	9.0/91.0
Emergent hospitalization (Y/N)	19.8/80.2

Geographic location: U.S.

Dates: 1991-1996

Healthcare setting: All

Results:
After adjusting for surgeon procedure volume, high hospital procedure volume remained a strong predictor of low postoperative mortality. Surgeon-specific procedure volume was also an important predictor of surgical outcomes although this effect was attenuated after adjusting for hospital volume.

(continued on next page)

General comments:
2-year postoperative mortality/survival was also assessed.

Study claims that it cannot explain specific processes of care that can account for differences in mortality rates in the various hospitals.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
    - Precise specifications: 4
    - Reliability: 3
    - Validity: 4
    - Adaptability: 4
    - Adequacy of risk adjustment: 4

Evidence Table 5 – Question 2b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring

Hospital procedure volume	**30-day mortality rate%**
Very low	5.8
Low	4.6
Medium	4.1
High	3.7
P-value	< 0.0001
Surgeon procedure volume	
Very low	5.7
Low	4.6
Medium	4.2
High	3.7
P-value	< 0.0001

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Schrag, Panageas, Riedel, et al., 2003 **#34030**	**Quality measure (QM):** Ostomy rates **Basis of QM:** Clinical practice guideline (not specified) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Mortality **Intent of QM:** Quality improvement (aim of the study was to compare surgeon and hospital procedure volume as predictors of outcomes following colon cancer resection) **Definition of denominator/numerator:** Denominator: Number of Medicare eligible patients aged 65 or older diagnosed in SEER regions with primary colon cancer in 1991-1996. Exclusion criteria: Excluded were patients enrolled in an HMO; operated on exclusively for intestinal bypass; diagnosis noted exclusively on death certificate or at autopsy; month of death was unknown. Numerator: Number of above patients who had an ostomy. Adjustment was made for sex, race, age, stage of tumor, comorbidity and socioeconomic status, whether hospitalization was emergent and whether obstruction or perforation was present. **Data sources:** SEER, Medicare claims from HCFA **Recommended frequency of data collection:** No recommendation	**Study population:** N = 24,166 **Geographic location:** U.S. **Dates:** 1991-1996 **Healthcare setting:** All **Results:** Hospital volumes and surgeon volumes were each an important predictor of the ostomy rate.	**General comments:** 2-year postoperative mortality/survival was also assessed. Study claims that it cannot explain specific processes of care that can account for differences in mortality rates in the various hospitals. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 4 Adaptability: 4 Adequacy of risk adjustment: 4

Characteristic	Percent
Male/female	44.1/55.9
Age	
65-69	18.6
70-74	23.6
75-79	23.6
80+	34.2
Race	
White	87.1
Black	6.6
other	6.3
AJCC stage I	19.9
II	36.9
III	26.1
IV	14.1
Unstaged	3.0
Romano comorbidity	
0	71.3
1	23.2
2	5.6
Obstruction (Y/N)	9.0/91.0
Emergent hospitalization (Y/N)	19.8/80.2

(continued on next page)

Evidence Table 5 – Question 2b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring

Hospital procedure volume	**Ostomy rate (%)**
Very low	19.6
Low	18.5
Medium	16.4
High	15.8
P-value	< 0.0001
Surgeon procedure volume	
Very low	19.4
Low	18.4
Medium	17.2
high	15.3
P-value	< 0.0001

Evidence Table 5 – Question 2b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Simons, Ker, Groshen, et al., 1997 **#11620**	**Quality measure (QM):** Rate of sphincter-sparing procedures (SSP) **Basis of QM:** None **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Sphincter preservation **Intent of QM:** Research (aim of the study was to examine variation in the surgical treatment of rectal cancer to determine if differences exist in management and survival based on hospital type and surgical caseload) **Definition of denominator/numerator:** Denominator: Number of patients who underwent sphincter-sparing procedures (SSP) or abdominoperineal resection (APR) for rectal adenocarcinoma between 1988 and 1992. Numerator: Number of above patients who underwent SSP. **Data sources:** University of Southern California Cancer Surveillance Program (CSP), a population based cancer registry. This is part of a national SEER. The CSP provided patient age, gender, date of surgery, type of surgery, tumor stage, hospital type, status and date at last follow up. **Recommended frequency of data collection:** No recommendation	**Study population:** N: 2,006 Age: 68 median age (19-102) Race: NR Sex: 55% male Other: 125 hospitals % patients with localized disease: 52% **Geographic location:** California **Dates:** 1988-1992 **Healthcare setting:** inpatient hospital setting **Results:** Hospitals treating patients with localized disease that perform > 5 rectal cancer surgeries per year performed SSP more frequently (69% of cases) compared to hospitals performing 5 or fewer rectal cases per year (63% of cases). For regional disease, the difference was not statistically significant. Survival plots showed that a significantly higher percentage of patients (localized and regional disease) survived 5 years when operated on at a hospital performing > 5 rectal cancer surgeries a year.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 4 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 4 Adaptability: 4 Adequacy of risk adjustment: 3

Evidence Table 5 – Question 2b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Steele, 1994 **#35840**	**Quality measure:** Percentage of stage III colon cancer patients receiving surgery and chemotherapy **Basis of QM:** Clinical practice guideline It is implicit that the AHCC guidelines be followed but these are not actually cited in the article. **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** No outcome is exactly linked to the above but is said to be a marker of appropriate cancer diagnosis and treatment. No citation is provided for this statement. **Intent of QM:** Not specified (aim of the study was assess cancer patient care and outcomes on a national basis) **Definition of denominator/numerator:** Denominator: Number of patients in the National Cancer Data Base (NCDB) with a new diagnosis of colon cancer in the years 1985-1986 or 1991. Numerator: Number of the above with stage III cancer who underwent surgery and received chemotherapy. **Data sources:** National Cancer Data Base (NCDB) **Recommended frequency of data collection:** No recommendation	**Study population:** *Data given as patients (year)* N: 40,384 (85/86); 39,751 (91) Age: Median 71.3 (85/85); 72.0 (91) Race: Non-Hispanic whites 86.9% (85/85); 85.9% (91) Hispanic 1.1/1.8 African-American 6.6/8.1 Asian 0.9/1.5 Unknown 4.5/2.7 Sex: Male 48.7% (85/85), 49.6% (91) Tumor stage: 85-86/91 0 3.7/6.5 1 14.4/19.3 2 13.8/26.2 3 12.9/20.3 4 9.2/15.8 Unknown 46.0/11.9 Performance status: NR **Geographic location:** National sample; note that the sample is not probabilistic and represented different hospitals in different years **Dates:** 1991 and outcomes for 1985-86 **Healthcare setting:** 464 hospital in 1985, 474 hospitals in 1986, 937 hospitals in 1991 **Results:** Treatment trends showed effects of trial data, as a greater percentage of patients were reported as having treatment (including chemotherapy) beyond surgery in 1991 as compared to 1985/86.	**General comments:** Some “treatment” data are presented, but these are not stratified by stage or location (colon vs. rectum) and therefore do not provide sufficient information to count as a QM. Only survival would be a potential QM from this paper. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 4 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 3 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 5 – Question 2b (Published Literature) – continued

Study | **Characteristics of Quality Measure** | **Testing of Quality Measure** | **Comments/Quality Scoring**

Temple, Hsieh, Wong, et al., 2004

#29890

Quality measure (QM): 30-day postoperative mortality rate for stage IV colon cancer

Basis of QM: Clinical practice guideline (National Comprehensive Cancer Network; applicable only for stage IV and symptomatic patients)

Type of QM:
(a) Outcome
(b) General

Intent of QM: Quality improvement (aim of the study was to evaluate surgical practice patterns for patients 65 years of age and older with stage IV colorectal cancer)

Definition of denominator/numerator:
Denominator:
Number of Medicare-enrolled patients aged 65 and older, initially diagnosed with stage IV colon or rectal cancer in a SEER area during the years 1991-1999. Age, sex, race, ethnicity, comorbidity, year of diagnosis, and socioeconomic status were collected and data were risk-adjusted.

Exclusion criteria: Cohort restricted to those with a histologic diagnosis consistent with adenocarcinoma. Diagnoses exclusively on death certificates or at autopsy were excluded, as were those in which the month of diagnosis was unknown. Patients enrolled in HMOs were excluded.

Numerator:
Number of above patients who died 30 days following surgery.

Data sources: SEER, Medicare claims

Recommended frequency of data collection: No recommendation

Study population:
N: 9,011

	Pct.	Primary CDS%	No primary CDS%
Age			
65-69	21	22	18
70-74	25	26	22
75-79	23	23	24
80-84	18	17	19
≥85	13	12	18
Male/female	48/52	48/52	49/51
White	84	85	81
Black	9	9	12
Other	7	7	7
Comorbidity			
0	90	90	89
1	5	5	6
2+	5	4	5
1999	9	9	10

Geographic location: U.S.

Dates: 1991-1999

Healthcare setting: Inpatient hospital

Results:
The 30-day surgical mortality was significantly greater in the no cancer-directed surgery group among patients who underwent a surgical procedure, when compared with the primary cancer-directed surgery group (26% vs 9%; P = 0.001).

General comments:
Patient selection was accomplished in a non-randomized setting. Therefore, results are not valid. Study could not ascertain whether patients were asymptomatic at presentation (elderly patients could present with advanced stage disease.)

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  Precise specifications: 4
  Reliability: 3
  Validity: 3
  Adaptability: 2
  Adequacy of risk adjustment: 2

Evidence Table 5 – Question 2b (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td>Temple, Hsieh, Wong, et al., 2004

#29890</td>
<td>Quality measure (QM): Metastasectomy rate

Basis of QM: Clinical practice guideline (National Comprehensive Cancer Network)

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Practice patterns of patients with stage IV cancer

Intent of QM: Quality improvement (aim of the study was to evaluate surgical practice patterns for patients 65 years of age and older with stage IV colorectal cancer)

Definition of denominator/numerator:
Denominator:
Number of Medicare-enrolled patients aged 65 and older, initially diagnosed with stage IV colon or rectal cancer in a SEER area during the years 1991-1999. Age, sex, race, ethnicity, comorbidity, year of diagnosis, and socioeconomic status were collected and data were risk-adjusted.

Exclusion criteria: Cohort restricted to those with a histologic diagnosis consistent with adenocarcinoma. Diagnoses exclusively on death certificates or at autopsy were excluded, as were those in which the month of diagnosis was unknown. Patients enrolled in HMOs were excluded.

Numerator:
Number of above patients who received liver resection, pelvic exenteration and pulmonary resection between diagnosis and death.

Data sources: SEER data base, Medicare claims data

Recommended frequency of data collection: No recommendation</td>
<td>Study population:
N: 9,011

<table>
<tr><th></th><th>Pct.</th><th>Primary CDS%</th><th>No primary CDS%</th></tr>
<tr><td>Age</td><td></td><td></td><td></td></tr>
<tr><td>65-69</td><td>21</td><td>22</td><td>18</td></tr>
<tr><td>70-74</td><td>25</td><td>26</td><td>22</td></tr>
<tr><td>75-79</td><td>23</td><td>23</td><td>24</td></tr>
<tr><td>80-84</td><td>18</td><td>17</td><td>19</td></tr>
<tr><td>≥85</td><td>13</td><td>12</td><td>18</td></tr>
<tr><td>Male/female</td><td>48/52</td><td>48/52</td><td>49/51</td></tr>
<tr><td>White</td><td>84</td><td>85</td><td>81</td></tr>
<tr><td>Black</td><td>9</td><td>9</td><td>12</td></tr>
<tr><td>Other</td><td>7</td><td>7</td><td>7</td></tr>
<tr><td>Comorbidity</td><td></td><td></td><td></td></tr>
<tr><td>0</td><td>90</td><td>90</td><td>89</td></tr>
<tr><td>1</td><td>5</td><td>5</td><td>6</td></tr>
<tr><td>2+</td><td>5</td><td>4</td><td>5</td></tr>
<tr><td>1999</td><td>9</td><td>9</td><td>10</td></tr>
</table>

Geographic location: U.S.

Dates: 1991-1999

Healthcare setting: Inpatient hospital

Results:
Metastasectomy was performed in only 3.9% of the patients in the total cohort of 9,011 having received either synchronous or metachronous pulmonary resection, hepatectomy, or pelvic exenteration. Among those who underwent primary cancer-directed surgery, 5.2% had metastasectomy, the vast majority being liver resections.</td>
<td>General comments:
Patient selection was accomplished in a non-randomized setting. Therefore, results are not valid. Study could not ascertain whether patients were asymptomatic at presentation (elderly patients could present with advanced stage disease.)

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 3
- Usability: 5
- Scientific acceptability (five criteria):
Precise specifications: 4
Reliability: 3
Validity: 3
Adaptability: 2
Adequacy of risk adjustment: 2</td>
</tr>
</table>

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Temple, Hsieh, Wong, et al., 2004

#29890

Characteristics of Quality Measure

Quality measure (QM): Cancer-directed surgery (CDS) rate

Basis of QM: Basis of QM: Clinical practice guideline (National Comprehensive Cancer Network)

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Reduced mortality

Intent of QM: Quality improvement (aim of the study was to evaluate surgical practice patterns for patients 65 years of age and older with stage IV colorectal cancer)

Definition of denominator/numerator:
Denominator:
Number of Medicare-enrolled patients aged 65 and older, initially diagnosed with stage IV colon or rectal cancer in a SEER area during the years 1991-1999. Age, sex, race, ethnicity, comorbidity, year of diagnosis, and socioeconomic status were collected and data were risk-adjusted.

Exclusion criteria: Cohort restricted to those with a histologic diagnosis consistent with adenocarcinoma. Diagnoses exclusively on death certificates or at autopsy were excluded, as were those in which the month of diagnosis was unknown. Patients enrolled in HMOs were excluded.

Numerator:
Number of above patients who received CDS subsequent to diagnosis. This included patients having received bowel resection, or evidence of primary tumor resection; surgery of primary sites within the first 4 months of diagnosis.

Data sources: SEER database, Medicare claims data

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 9,011

	%	Primary CDS (%)	No primary CDS (%)
Age			
65-69	21	22	18
70-74	25	26	22
75-79	23	23	24
80-84	18	17	19
≥85	13	12	18
Male/female	48/52	48/52	49/51
White	84	85	81
Black	9	9	12
Other	7	7	7
Comorbidity			
0	90	90	89
1	5	5	6
2+	5	4	5
1999	9	9	10

Geographic location: U.S.

Dates: 1991-1999

Healthcare setting: Inpatient hospital

Results:
72% of cohort received CDS within 4 months of diagnosis. CDS rates declined with age.

Median survival of CDS patients was 10 months compared to non-CDS patients (3 months).

Comments/Quality Scoring

General comments:
Patient selection was accomplished in a non-randomized setting. Therefore, results are not valid. Study could not ascertain whether patients were asymptomatic at presentation (elderly patients could present with advanced stage disease.)

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 4
- Usability: 5
- Scientific acceptability (five criteria):
    - Precise specifications: 4
    - Reliability: 3
    - Validity: 3
    - Adaptability: 2
    - Adequacy of risk adjustment: 2

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Tropman, Hatzell, Paskett, et al., 1999

#35610

Characteristics of Quality Measure

Quality measure (QM): Percentage of patients receiving appropriate primary therapy (wide surgical resection and anastomosis) for CRC as defined by the NCI PDQ guidelines

Basis of QM: Clinical practice guideline (NCI PDQ Guidelines)

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Locoregional recurrence, overall survival.

Intent of QM: Not specified (aim of the study was to determine the degree to which colon cancer treatment in rural North and South Carolina conformed to national treatment recommendations)

Definition of denominator/numerator:
Denominator:
Number of patients treated for colon cancer in Wayne County, NC, and its six contiguous counties or in Greenwood County, SC, and its four adjacent counties during the years 1991 and 1996. Cases were identified by the North Carolina Central Cancer Registry and by local tumor registrars in SC.

Numerator:
Subset of patients above who received primary (surgery) per the NCI PDQ recommendations.

Data sources: Patient medical records and records from physician offices in the geographic regions under study

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 230

All stages	1991	1996
Male (%)	55	58
White	76	75
AA	24	25
Mean age	75	71
Tumor stage		
I	64	36
II	56	44
III	65	35

Performance status: NR

Geographic location: Wayne County, NC, and its six contiguous counties or in Greenwood County, SC, and its four adjacent counties

Dates: 1991, 1996

Healthcare setting: Rural health care facilities

Results:
A majority (80-95%) of patients received appropriate primary therapy, with the exception of SC stage I cases, who had lower rates of appropriate primary therapy (73% in 1991 and 50% in 1996).

Comments/Quality Scoring

General comments:
The article compares rates of compliance with NCI PDQ recommendations in two rural geographic regions (one in NC, one in SC) before (1991) and after (1996) an intervention to educate local physicians. The intervention took place in NC. The SC region served as a control.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 4
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 4
  - Validity: 4
  - Adaptability: 4
  - Adequacy of risk adjustment: 3

Evidence Table 5 – Question 2b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Vernon, Hughes, Heckel, et al., 1992 **#5670**	**Quality measure (QM):** Number of colorectal cancer patients that receive surgery as part of primary treatment of colorectal cancer **Basis of QM:** None stated **Type of QM:** (a) Structure (b) General **Outcome to which the QM is linked:** Presumably to improved survival **Intent of QM:** Not specified (aim of the study was to compare the quality of cre for two types of health plans – fee-for-service [FFS] with third-party coverage and HMO membership – in the diagnosis and treatment of colorectal cancer) **Definition of denominator/numerator:** Denominator: Number of patients with colorectal cancer diagnosed from 1984 through 1989 at the Kelsey-Seybold Clinic in Houston, TX, of whom 205 used a fee-for-service (FFS) plan and 125 were members of an HMO. Numerator: Number of above patients who received surgery as part of their primary treatment. **Data sources:** Medical records of patients **Recommended frequency of data collection:** No recommendation	**Study population:** FFS/HMO plans N: 205/125 Age: < 50 to ≥ 60 Race: NR Sex: 56% male/61% male Tumor stage: NR Performance status: NR **Geographic location:** Texas **Dates:** 1984-89 **Healthcare setting:** A multispecialty group practice **Results:** 82% of FFS patients had surgery compared with 81% of HMO patients. Survival was not different for the two groups.	**General comments:** The purpose of this paper was to compare "the effectiveness" of two types of health plans (FFS and HMO) offered by the same health care provider in the diagnosis and treatment of colon cancer. The two plans were compared for some measures which may be considered quality measures, but which may have other explanations for their frequency. These include: duration of symptoms before diagnosis, training of physicians who diagnosed the tumor, presence of symptoms at diagnosis, time from detection to treatment, number of treatments, Dukes stage at diagnosis, and survival. Some measures would not be quality measures. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 5 Validity: 5 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 5 – Question 2b (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Weaver, Harrison, Eskander, et al., 1991 **#6810**	**Quality measure (QM):** Percentage of patients with CRC who underwent surgical resection **Basis of QM:** None stated **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Mortality **Intent of QM:** Not specified (aim of the study was to determine if demographic observations were similar in an all-black institution with patients from all socioeconomic levels) **Definition of denominator/numerator:** Denominator: Number of patients with a diagnosis of colorectal cancer between 1971 and 1982 in the tumor registry databases at a single institution (Meharry). Numerator: Number of the above patients who underwent “surgical intervention.” **Data sources:** Hospital tumor registry, hospital medical records **Recommended frequency of data collection:** No recommendation	**Study population:** N: 118 Age: mean 68 (29-93) Race: 100% black Sex: 62% female Tumor stage: I 4 Ib 2 II 22 III 36 IV 32 Missing 22 **Geographic location:** Nashville, TN **Dates:** 1971-1982 (retrospective review) + 5 years of followup (?1987) **Healthcare setting**: Single predominantly black hospital (with University affiliation) **Results:** NA	**General comments:** Mortality was the primary endpoint of the study and the data for other potential QMs (% received surgery) are much weaker, poorly defined, and do not follow guidelines **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 4 Validity: 4 Adaptability: 3 Adequacy of risk adjustment: 3

Evidence Table 5 – Question 2b (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td>**Whittle, Steinberg, Anderson, et al., 1991**

#5450</td>
<td>**Quality measure (QM):** Perioperative mortality rate

Basis of QM: None

Type of QM:
(a) Outcome
(b) General

Intent of QM: Research (aim of the study was to estimate the perioperative mortality and 1- and 2-year survival rates of elderly Americans undergoing colon resection for colon cancer)

Definition of denominator/numerator:
Denominator:
Number of beneficiaries > 65 yr discharged during 1983-1985 with an ICD-9 code for colon cancer as primary or secondary diagnosis and ICD-9 code for colon resection listed during the same hospitalization.

Exclusion criteria: Beneficiaries who first became eligible for Medicare because of end-stage renal disease or disability, members of an HMO, beneficiaries living overseas, non participants in Part B.

Numerator:
Number of above patients who died within 30 days of admission, controlling for age, sex.

Data sources: Medicare Part A claims and enrollment records

Recommended frequency of data collection: No recommendation</td>
<td>**Study population:**
N: 5,586

<table>
<tr><td>Age</td><td>% male</td><td>% female</td></tr>
<tr><td>66-69</td><td>15</td><td>12</td></tr>
<tr><td>70-74</td><td>30</td><td>25</td></tr>
<tr><td>75-84</td><td>44</td><td>46</td></tr>
<tr><td>85+</td><td>11</td><td>17</td></tr>
</table>

Geographic location: U.S.

Dates: 1983-1985

Healthcare setting: All

Results:
Age, but not sex, was significantly associated with 1- and 2-year postoperative mortality. Decreases in survival in older age groups remained statistically significant at 1 yr (p < 0.0001) and 2 yr (p = 0.01) after adjusting for differences in life expectancy among age groups.

<table>
<tr><td>Age</td><td>% male</td><td>% female</td><td>Peri-operative mortality</td></tr>
<tr><td>66-69</td><td>15</td><td>12</td><td>3.35</td></tr>
<tr><td>70-74</td><td>30</td><td>25</td><td>3.65</td></tr>
<tr><td>75-84</td><td>44</td><td>46</td><td>6.67</td></tr>
<tr><td>85+</td><td>11</td><td>17</td><td>11.1</td></tr>
</table>
</td>
<td>**General comments:**
The observed difference between patient age and sex and postoperative outcomes can be explained by factors not considered in the analysis. Differences in age and sex and stage of disease at time of presentation, level of comorbidity, or frequency of emergency presentation, all strongly affect perioperative mortality and postoperative survival rates.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
Precise specifications: 4
Reliability: 3
Validity: 3
Adaptability: 3
Adequacy of risk adjustment: 1</td>
</tr>
</table>

Evidence Table 5 – Question 2b (Published Literature) – continued

Study

Wudel Jr., Chapman, Shyr, et al., 2002

#18640

Characteristics of Quality Measure

Quality measure (QM): Percentage of patients with colon or rectal cancer who had curative resection

Basis of QM: None stated

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Mortality

Intent of QM: Not specified (aim of the study was to determine the outcome of patients with colorectal cancer treated in the same city at 2 nearby medical centers, a university hospital and a city hospital, and to explore disparities in colorectal cancer outcomes between black and white patients)

Definition of denominator/numerator:
Denominator:
Number of patients with a diagnosis of primary colorectal cancer between 1/1/90 and 12/21/99 in the tumor registry databases at each of 2 institutions (university hospital and a city hospital). Excluded patients who were non-white and non-black.

Numerator:
Number of the above patients who received "curative surgery "defined as surgery performed in the absence of documented distant spread.

Data sources: Hospital tumor registries

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:

	University hospital	City hospital
N	565	77
Black (%)	10.6	53
Male (%)	53.3	62.7
Median age	69	74
Tumor stage		
I	31.7	29.9
II	21.9	20.8
III	23.7	16.9
IV	22.7	32.5

Performance status: NR

Geographic location: Nashville, TN

Dates: 1/1/90 and 12/21/99 (retrospective review)

Healthcare setting: University hospital, city hospital

Results:
There was no significant difference in tumor stage at the time of presentation in the two institutions studied or between racial/ethnic groups. There was no difference in the treatment modalities identified between institutions or racial/ethnic groups.

There was a significant difference in overall survival between patients treated at the university hospital (median 5.3 years) and those treated at the city hospital (median 2.1 years). Median survival was 5.7 years for white patients and 3.2 years for black patients treated at the university hospital. White patients treated at the city hospital survived 2.1 years vs. 1.4 years for black patients.

Comments/Quality Scoring

General comments:
Mortality was the primary endpoint of the study and the data for other potential QMs (% receiving "curative" surgery, chemo, or radiation therapy) are much weaker, poorly defined, and do not follow guidelines.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 4
- Scientific acceptability (five criteria):
    Precise specifications: 4
    Reliability: 5
    Validity: 4
    Adaptability: 4
    Adequacy of risk adjustment: 3

Evidence Table 6 – Question 2b (Grey Literature): *As appropriate to specific stages of colorectal cancer, what quality-of-care measures are available and what evidence is available for measures of quality of care of treatment of colorectal cancer, including surgical therapy for colon and rectal cancers?*

Study	Characteristics of Quality Measure	Comments/Quality Scoring
National Committee for Quality Assurance, 2005 **#36580**	**Quality measure (QM):** Percent of rectal cancer cases that received a sphincter preservation procedure at time of surgery **Basis of QM:** Clinical practice guideline (National Comprehensive Cancer Network [NCCN] guidelines) **Type of QM:** (a) Process (b) Technical **Outcome to which the QM is linked:** improved QoL **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of patients with rectal cancer surgery over a 12-month period. Numerator: Number of above patients who received a sphincter preservation procedure at time of surgery. **Data sources:** Cancer registry, claims data **Recommended frequency of data collection:** No recommendation	**General comments:** Not all data may be available. **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 7 – Question 2c (Published Literature): *As appropriate to specific stages of colorectal cancer, what quality-of-care measures are available and what evidence is available for measures of quality of care of treatment of colorectal cancer, including appropriate use of adjuvant chemotherapy and adjuvant radiation therapy, including for patients with metastatic but potentially curable (hepatic/pulmonary-resectable) disease?*

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Ayanian, Zaslavsky, Fuchs, et al., 2003 **#34680**	**Quality measure (QM):** Use of adjuvant chemotherapy in patients with stage III colon cancer or stage II or III rectal cancer **Basis of QM:** Other (adherence to the recommendations of the 1990 NIH Consensus Conference) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Improved survival and decreased local/regional recurrence **Intent of QM:** Not specified (aim of the study was to assess the use of adjuvant chemotherapy and radiation therapy in patients with stage III colon cancer) **Definition of denominator/numerator:** Denominator: Number of patients identified from registry records (3 regional registries within the California Cancer Registry) who were 18 years of age and older diagnosed during 1996 and 1997 with stage IIII adenocarcinoma of the colon or stage II or III adenocarcinoma of the rectum, using staging criteria of the AJCC. Patients had undergone surgery and survived for at least 30 days. Numerator: Number of above patients with colon or rectal cancer who received adjuvant chemotherapy. **Data sources:** California Cancer Registry Physician survey Office records **Recommended frequency of data collection:** No recommendation.	**Study population:** Eligible for chemo: N: 1,956 Age: 18 to > 85 Race: 72.9% white Sex: 50.2% female Tumor stage: Colon stage III 72.7%, Rectal stage III 12.8%, Rectal stage II 14.5% Performance status: 60.7% comorbidity score 0, 20.1% 1, 19.2% ≥ 2 **Geographic location:** San Francisco/Oakland, San Jose/Monterey, and Sacramento, CA areas **Dates:** 1996-97 **Healthcare setting:** Hospitals **Results:** 67% of eligible patients received adjuvant chemotherapy. Sensitivity of routinely collected registry data was 87% for chemotherapy. Only 2% of patients had registry data indicating they had received chemo but were reported by their physicians not to have received therapy. On MVA, older patients significantly less likely to receive chemo. In hierarchical models including random effects of individual hospitals, use of chemotherapy varied substantially. Relative to the 67% of patients receiving chemotherapy in the full cohort, the adjusted probability of getting chemo was 79% in hospitals, moderately (one SD) above average, and 51% in hospitals, moderately below average. Most common reasons cited for not giving adjuvant therapy: patient refusal, comorbid illness, lack of clinical indication.	**General comments:** Article attempts to estimate underreporting of adjuvant therapies in routinely collected registry data by comparing registry data with office records and physician surveys. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 4 Validity: 4 Adaptability: 4 Adequacy of risk adjustment: 4

Evidence Table 7 – Question 2c (Published Literature) – continued

Study

Beart, Steele Jr., Menck, et al., 1995

#990

Characteristics of Quality Measure

Quality measure (QM): Percentage of patients with stage III colon cancer receiving postoperative chemotherapy

Basis of QM: None mentioned; however, consistent with 1990 NIH consensus conference

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: None specified, but presumably survival

Intent of QM: Not specified (aim of the study was to identify current trends in the management of patients with carcinoma of the colon or rectum and to identify changes in patterns of care and survival)

Definition of denominator/numerator:
Denominator:
Number of stage III colon cancer patients seen in 1988 from amongst cases of colon and rectal cancer (up to 25 per program or facility) reported by over 1200 approved cancer programs and 800 other facilities on the Commission on Cancer mailing list that were invited to participate.

Numerator:
Number of above patients receiving chemotherapy.

Data sources: Hospitals sent in up to 25 consecutive cases from their medical records

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 39,502 (29,209 with colon cancer; 3599 with stage III)
Age: Median 72 years for colon cancer
Race: For entire study: African American, 9.1% for colon cancer and 6.5% for rectal cancer; Hispanic, 2.7% for colon cancer and 3.5% for rectal cancer. 1.4% of cases were Asian. The rest were Caucasian.
Sex: Male 49.3% (colon) and 57.2% (rectal)
Tumor stage: All included (4.7% stage 0, 22.1% stage I, 29.2% stage II, 22.2% stage III, 18.7% stage IV, 3.0% unknown)
Performance status: NR

Geographic location: Entire U.S.

Dates: Calendar years 1983 and 1988

Healthcare setting: Hospitals

Results:

	Colon Cancer		Rectal Cancer	
	1983	1988	1985	1988
Chemo-therapy	10.7	11.1	5.9	5.6
Radiation therapy	2.7	10.9	15.3	13.8
Combined chemo and radiation therapy	1.5	1.6	5.5	10.1

Comments/Quality Scoring

General comments: The data for this study were generated prior to 1990 so it may not reflect more modern recommendations for management.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 2
  - Reliability: 3
  - Validity: 3
  - Adaptability: 3
  - Adequacy of risk adjustment: 2

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Beart, Steele Jr., Menck, et al., 1995 **#990**	**Quality measure (QM):** Percentage of patients with stage II or III rectal cancer receiving chemoradiotherapy **Basis of QM:** None mentioned; however, consistent with 1990 NIH consensus conference **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** None specified, but presumably survival **Intent of QM:** Not specified (aim of the study was to identify current trends in the management of patients with carcinoma of the colon or rectum and to identify changes in patterns of care and survival) **Definition of denominator/numerator:** Denominator: Number of stage II or III rectal cancer patients seen in 1988 from amongst cases of colon and rectal cancer (up to 25 per program or facility) reported by over 1200 approved cancer programs and 800 other facilities on the Commission on Cancer mailing list that were invited to participate. Numerator: Number of above patients receiving chemoradiotherapy. **Data sources:** Hospitals sent in up to 25 consecutive cases from their medical records **Recommended frequency of data collection:** No recommendation	**Study population:** N: 39,502 (10,293 with rectal cancer; 2051 with stage II or III) Age: median 69.3 years for rectal cancer Race: For entire study: African American, 9.1% for colon cancer and 6.5% for rectal cancer; Hispanic 2.7% for colon cancer and 3.5% for rectal cancer. 1.4% of cases were Asian. The rest were Caucasian. Sex: Male 57.2% (rectal) Tumor stage: All included (4.7% stage 0, 22.1% stage I, 29.2% stage II, 22.2% stage III, 18.7% stage IV, 3.0% unknown) Performance status: NR **Geographic location:** Entire U.S. **Dates:** Calendar year 1983 and 1988 **Healthcare setting:** Hospitals **Results:**	**General comments:** The data for this study were generated prior to 1990 so it may not reflect more modern recommendations for management. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 2 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: 2

	Colon Cancer		Rectal Cancer	
	1983	1988	1985	1988
Chemotherapy	10.7	11.1	5.9	5.6
Radiation therapy	2.7	10.9	15.3	13.8
Combined chemo and radiation therapy	1.5	1.6	5.5	10.1

Evidence Table 7 – Question 2c (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td>**Coburn, Pricolo, and Soderberg, 1994**

#2920</td>
<td>**Quality measure (QM):** Adjuvant therapy rates

Basis of QM: None

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: None

Intent of QM: Not specified (aim of the study was to perform univariate and multivariate analyses of poor indicators in the elderly undergoing colorectal operation, and to compare clinical, pathologic, and therapeutic factors in patients younger than and older than 80 years of age)

Definition of denominator/numerator:
Denominator:
Number of subjects who had received operative treatment for colon and rectal cancer between 1961 and 1987.

Numerator:
Number of above subjects who received adjuvant therapy (chemo- or radiotherapy).

Comparisons were made between patients under and over 80 years.

Data sources: Inpatient, outpatient, and office records

Recommended frequency of data collection: No recommendation</td>
<td>**Study population:**
N: 800

<table>
<tr><th></th><th>< 80 years</th><th>> 80 years</th></tr>
<tr><td>N</td><td>177</td><td>623</td></tr>
<tr><td>Sex (%F/M)</td><td>48/52</td><td>56/44</td></tr>
<tr><td>Rectal lesions</td><td>36</td><td>23</td></tr>
<tr><td>Duke stage</td><td></td><td></td></tr>
<tr><td>A</td><td>9.0</td><td>6.0</td></tr>
<tr><td>B1</td><td>16.7</td><td>12.8</td></tr>
<tr><td>B2</td><td>31.2</td><td>42.7</td></tr>
<tr><td>C1</td><td>4.5</td><td>0</td></tr>
<tr><td>C2</td><td>21.5</td><td>21.8</td></tr>
<tr><td>D</td><td>17.1</td><td>16.7</td></tr>
</table>

Geographic location: Rhode Island, U.S.

Dates: 1961 and 1987

Healthcare setting: Academic institute

Results:
Adjuvant therapy rate was 5.1% for patients > 80 yrs and 20% for patients < 80 yrs.

Long-term survival (at 5 and 8 yr) and rate of recurrence after curative therapy were used to validate the measure.

There was a statistically significant difference in survival rates: 48% for patients < 80 vs. 32% for patients > 80.

There was no statistically significant difference between the groups with regard to recurrence after curative therapy.</td>
<td>**General comments:**
Data collected between 1961 and 1987.

Other factors that affect mortality rates in the elderly: more aggressive biologic behavior of cancer of the colon and rectum in the elderly, with aggressive local disease and less tendency towards distant dissemination, greater tendency of colon cancer to be right-sided, rarity of adjuvant therapy administered to older patients, higher complication rate in elderly patients due to comorbid conditions, and greater frequency of obstructing and perforated lesions.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
Precise specifications: 3
Reliability: 3
Validity: 3
Adaptability: 2
Adequacy of risk adjustment: 2</td>
</tr>
</table>

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Coia, Wizenberg, Hanlon, et al., 1994 **#3140**	**Quality measure (QM):** Percentage of patients receiving adjuvant radiation therapy who also received adjuvant chemotherapy (either concurrent or non-concurrent) for cancer of the sigmoid colon or rectum **Basis of QM:** Other (1990 NIH consensus guidelines) **Type of QM:** (a) Process (b) General and Technical **Outcome to which the QM is linked:** Overall survival **Intent of QM:** Not specified (aim of the study was to determine the national practice standards for the evaluation and treatment of adenocarcinoma of the rectum and sigmoid colon) **Definition of denominator/numerator:** Denominator: Number of subjects identified from data source who were treated 1998-1999 with radiation therapy for rectal/ and sigmoid adenocarcinoma. Numerator: Number of above subjects receiving chemotherapy in addition to radiation therapy for T3N+ disease. **Data sources:** Random sample of all patients in the U.S. with rectal or sigmoid colon cancer identified in a stratified two-stage cluster sampling procedure. First stage: selection of facilities from all facilities in the U.S. based on census data from a facilities survey. Second stage: select patients from sampled facilities. **Recommended frequency of data collection:** No recommendation	**Study population:** N: 408 Age: 64 (median) Race: NR Sex: 61% male Tumor stage: A-C3 (Modified Astler-Coller System); A 0.6%, B1 4.4%, B2 23.5%, B3 5.1%, C1 6.9%, C2 30.1%, C3 6.6%, unknown 22.8% Tumor location: Sigmoid 12.5%, rectum 82.8%, unknown 4.7% Performance status: 98% KPS = 80 or higher **Geographic location:** U.S. **Dates:** Patients treated 1988-89 **Healthcare setting:** 73 U.S. institutions **Results:** General results: Only 37% of patients received chemotherapy concurrent with radiation therapy. Only 55% of patients with disease through the bowel wall and/or involving lymph nodes received chemotherapy. Chemotherapy given to 44.3% of patients overall. Technical results: 95% of patients underwent simulation for radiation therapy. Port films were taken in 98% of patients.	**General comments:** This paper has many potential QMs in addition to the primary QM, which is use of chemotherapy with radiotherapy. Other QMs include: Percentage of those receiving > 40Gy radiation, percentage experiencing prolonged interruption of their radiotherapy, and percentage having chemotherapy scan as part of their evaluation. A major limitation of this paper is the fact that the data surveyed were for patients treated in the years before the NIH consensus guidelines on chemoradiotherapy. Therefore, the quality measure is using data from a group which it may be inappropriate to use. Another limitation is that it selects all patients with rectosigmoid cancers who received radiotherapy. This included some patients with stage A, B1 disease who, under usual circumstances, would have no reason to receive radiotherapy. There may have been a reason not captured by the data for these patients to receive radiotherapy. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 4 Validity: 4 Adaptability: 4 Adequacy of risk adjustment: 1

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Dominitz, Samsa, Landsman, et al., 1998 **#9380**	**Quality measure (QM):** Percentage of patients with colorectal cancer receiving chemotherapy **Basis of QM:** None **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Survival **Intent of QM:** Not specified (aim of the study was to assess the influence of race on the treatment and survival of patients with colorectal carcinoma) **Definition of denominator/numerator:** Denominator: Number of white/black patients with colorectal cancer identified from the VA Patient Treatment File (PTF) who were discharged from VA hospitals with a diagnosis of CRC (ICD-9-CM codes 153.0-153.4, 153.6-154.1) during fiscal year 1989. To exclude prevalent cases, any patient with a diagnosis of CRC (ICD-9-CM codes 153.0-153.4, 153.6-154.1, V10.05-V10.06) for hospitalization during FY 1984-1988, or a personal history of CRC (ICD-9-CM codes V10.05-V10.06) during the index hospitalization, was excluded. Male veterans only. No ulcerative colitis or Crohn's disease. Numerator: Number of above white/black patients treated with chemotherapy, as indicated by specific ICD-9-CM codes in the PTF. **Data sources:** VA PTF **Recommended frequency of data collection:** No recommendation	**Study population:** N: 2,607 whites + 569 blacks Age: 67.1 ± 9.1 (whites); 66.4 ± 9.9 (blacks) Race: See above Sex: 100% male Tumor stage: All stages Performance status: NR **Geographic location:** VA Medical Centers **Dates:** 1989 **Healthcare setting:** VA Hospitals **Results:** No statistically significant differences in rates of chemotherapy in blacks vs. whites. No difference in 5-year relative survival or overall survival in blacks vs. whites.	**General comments:** The article compares rates of surgery, radiotherapy, and chemotherapy among blacks and whites. No attempt is made to compare to a gold standard (e.g., a guideline) to determine whether the rates in blacks or whites are optimal. The study is limited because of its use of an administrative database that lacked clinical details and did not allow for adjustment to disease severity. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 3 Reliability: 3 Validity: 1 Adaptability: 1 Adequacy of risk adjustment: 1

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Govindarajan, Shah, Erkman, et al., 2003 **#35310**	**Quality measure (QM):** Percentage of patients with stage II, III colorectal cancer receiving chemotherapy **Basis of QM:** None **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Not firmly linked to any outcome, but presumably to survival, quality of life, or rates of local recurrence **Intent of QM:** Not specified (aim of the study was to analyze disease stage, treatment received, and socioeconomic factors to better understand the factors influencing survival differences between African-Americans and Caucasians with colorectal cancer) **Definition of denominator/numerator:** Denominator: Number of African-Americans (AAs)/Caucasians, aged 18 older, with CRC treated between 1984 and 1997 at a state-funded University hospital located in Arkansas, identified through the hospital tumor registry using appropriate tumor registry codes. Numerator: Number of above AAs/Caucasians treated with chemotherapy. **Data sources:** Tumor registry at Univ. of Arkansas. **Recommended frequency of data collection:** No recommendation	**Study population:** N: 617 All figures below for Caucasians/AAs Age: 60.0/61.5 Race: 427 Caucasians/190 AAs Sex: 47.1% male/39.5% male Tumor stage: Stages 0-IV Performance status: NR Other: - Not high school grad: 45%/60% - Low income: 45%/64% - High poverty: 41%/68% **Geographic location:** Arkansas **Dates:** 1984-1997 **Healthcare setting:** University hospital **Results:** Authors show that significantly higher percentages of Caucasians received chemotherapy, compared with AAs, for patients with all stages of CRC, and for patients with only stages II and III disease. Cancer-specific mortality was higher in African-Americans than in Caucasians for all stages.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 3 Reliability: 3 Validity: 1 Adaptability: 1 Adequacy of risk adjustment: 1

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Hyman, Labow, and Vermont Chapter of the American College of Surgeons, 2002 **#18980**	**Quality measure (QM):** Adjuvant therapy rate **Basis of QM:** NIH consensus conference guidelines **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Mortality? **Intent of QM:** Not specified (aim of the study was to assess the feasibility of performing a quality study of the surgical management of colorectal cancer using a voluntary registry) **Definition of denominator/numerator:** Denominator: Number of colorectal cancer patients reported to registry by 33 surgeons in Vermont Numerator: Number of patients offered adjuvant therapy **Data sources:** Prospective statewide voluntary registry created by the Vermont chapter of ACS with the Vermont Program for Quality Health Care **Recommended frequency of data collection:** No recommendation	**Study population:** N: 364 (33 surgeons) Age: Mean 68.7 Stage of tumor: Stage I = 24%, stage II = 32%, stage II = 28%, stage IV = 16% **Geographic location:** Vermont **Dates:** April 1, 1999 to March 31, 2001 **Healthcare setting:** Mixed **Results:** All patients with stage III colon cancer and stages II or III rectal cancer were offered adjuvant therapy.	**General comments:** The study was not designed with an explicit intention to compare quality of care among participating surgeons (although it could potentially do so), but for comparison with national benchmarks. A voluntary registry was used as the source of data. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 3 Reliability: 2 Validity: 4 Adaptability: 3 Adequacy of risk adjustment: 3

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Jessup, McGinnis, Steele Jr., et al., 1996 **#35360**	**Quality measure (QM):** Percentage of patients with stage III colon cancer receiving adjuvant chemotherapy **Basis of QM:** Clinical practice guideline (NCI-NIH Consensus Development conference) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Survival **Intent of QM:** Not specified (aim of the study was to report time trends in stage of disease, treatment patterns, and survival for patients with selected cancers [including colon cancer]) **Definition of denominator/numerator:** Denominator: Number of Cases of stage III colon cancer reported to the National Cancer Database in 1988 and 1993 Numerator: Number of patients who received adjuvant chemotherapy **Data sources:** National Cancer Database **Recommended frequency of data collection:** No recommendation	**Study population:** N: 9,509 with stage III colon cancer Age: All ages included Race: All races Sex: Both sexes Tumor stage: All stages Performance status: NR **Geographic location:** United States **Dates:** 1985-1993 **Healthcare setting:** Hospitals **Results:** 43% of stage III patients received chemotherapy. Overall (not cancer-specific) survival was reported. Those stage II and III patients who received surgery and chemotherapy had a 49% survival rate compared to 44% for those who received surgery alone.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 2 Adaptability: 4 Adequacy of risk adjustment: 2

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Keating, Landrum, Meara, et al., 2005 **#36080**	**Quality measure (QM):** Rate of adjuvant chemotherapy for patients with stage III colon cancer **Basis of QM:** Clinical practice guideline (not specified, but likely 1990 NCI Consensus Statement) **Type of QM:** (a) Structure (b) General **Outcome to which the QM is linked:** Improved survival is implied **Intent of QM:** To assess quality of care (aim of the study was to examine associations between increases in managed care market share and changes in the quality of care delivered to cancer patients in the fee-for-service sector) **Definition of denominator/numerator:** Denominator: Number of patients with a first diagnosis of stage III CRC 1993-1999 in a given SEER county who had undergone surgery, were alive and enrolled in fee-for-service Medicare (parts A and B) through month 4. Numerator: Number of patients with stage III CRC in a given county who received adjuvant chemotherapy (The specific CPT, ICD-9, HCPCS, and Revenue Center codes used to identify chemotherapy administration are listed in the manuscript). **Data sources:** SEER –Medicare dataset 1990 U.S. Census **Recommended frequency of data collection:** No recommendation	**Study population:** N: 48,027 Age: 66-85+ Race: 88 white Sex: 46% male Other: Income, % high school graduates in census tract of residence, comorbidity score, market share of managed care **Geographic location:** SEER geographic regions **Dates:** 1993-1999 **Healthcare setting:** Not stated **Results:** Increased market share of managed care in a given county resulted in no significant change in rates of adjuvant chemotherapy for stage III colon cancer.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 3 Validity: 3 Adaptability: 4 Adequacy of risk adjustment: 4

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Keating, Landrum, Meara, et al., 2005 **#36080**	**Quality measure (QM):** Rate of adjuvant chemotherapy and radiation therapy for patients with stage II or III rectal cancer **Basis of QM:** Clinical practice guideline (not specified, but likely 1990 NCI Consensus Statement) **Type of QM:** (a) Structure (b) General **Outcome to which the QM is linked:** Generally, improved survival. **Intent of QM:** To assess quality of care (aim of the study was to examine associations between increases in managed care market share and changes in the quality of care delivered to cancer patients in the fee-for-service sector) **Definition of denominator/numerator:** Denominator: Number of patients with a first diagnosis of stage II, III rectal cancer in 1993-1999 in a given SEER county who had undergone surgery, were alive and enrolled in fee-for-service Medicare (parts A and B) through month 4. Numerator: Number of patients with stage II, III rectal cancer in a given county who received adjuvant chemotherapy and radiation therapy. **Data sources:** SEER-Medicare dataset; 1990 U.S. Census **Recommended frequency of data collection:** No recommendation	**Study population:** N: 48,027 Age: 66-85+ Race: 88% white Sex: 46% male Other: Income, % high school graduates in census tract of residence, comorbidity score, market share of managed care **Geographic location:** SEER geographic regions **Dates:** 1993-1999 **Healthcare setting:** Not stated **Results:** Increased market share of managed care in a given county resulted in significant decrease in % of patients with stage II or III rectal cancer receiving adjuvant chemotherapy and radiotherapy.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 4 Adequacy of risk adjustment: 1

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Mahoney, Kuo, Topilow, et al., 2000 **#26120**	**Quality measure (QM):** Percentage of patients with stage III colon cancer receiving adjuvant chemotherapy **Basis of QM:** Clinical practice guideline (NCI-NIH Consensus Development Conference) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Survival **Intent of QM:** Not specified (aim of the study was to assess the use of adjuvant chemotherapy in an aging population from the time when the initial recommendation for chemotherapy was made) **Definition of denominator/numerator:** Denominator: Number of patients with stage III colon cancer in the Tumor Registry of Jersey Shore Medical Center. Numerator: Number of patients receiving postoperative chemotherapy. **Data sources:** Tumor registry **Recommended frequency of data collection:** No recommendation	**Study population:** N: 69 Age: 40-97 Race: Not reported Sex: 28 men, 41 women Tumor stage: III Performance status: NR **Geographic location:** New Jersey **Dates:** January 1, 1989-December 30, 1996 **Healthcare setting:** Jersey Shore Medical Center **Results:** 49% of patients received chemotherapy; men had a 5.8 times greater chance of receiving chemotherapy than women.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 4 Validity: 2 Adaptability: 2 Adequacy of risk adjustment: 2

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Neugut, Fleischauer, Sundararajan, et al., 2002 **#18450**	**Quality measure (QM):** Use of chemotherapy of combined chemoradiotherapy in stage II and III rectal cancer patients among the elderly **Basis of QM:** Clinical practice guideline (NIH and NCCN) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Survival **Intent of QM:** Not specified (aim of the study was to investigate the use of treatment with adjuvant 5-FU-based chemotherapy and radiation therapy among patients over 65 years of age with surgically resected stage II or III rectal cancer) **Definition of denominator/numerator:** Denominator: Number of patients with histologically confirmed primary rectal cancer, diagnosed 1992-1996, stage II-III, age ≥ 65, s/p surgical tumor resection, eligible for Medicare Parts A and B in the 12 mo before diagnosis and 120 days after diagnosis, and had survived more than 4 mo after diagnosis. Excluded members of HMO in the 12 mo before and 4 mo after their diagnosis. Numerator: Number of patients who received both chemotherapy and radiotherapy. **Data sources:** SEER-Medicare database **Recommended frequency of data collection:** No recommendation	**Study population:** N: 1,807 Age: 65-85+ Race: 1592 non-Hispanic white Sex: 964 female Tumor stage: II (983). III (824) Performance status: NR Charlson-Deyo comorbidity score: 0 (1098), 1 (299), > 1 (410) **Geographic location:** SEER geographic regions **Dates:** 1992-96 **Healthcare setting:** U.S. facilities **Results:** 51% received adjuvant chemotherapy and 48% received radiotherapy overall. 38% received surgery alone; 11% received surgery plus radiation therapy, 14% received surgery plus adjuvant chemotherapy and 37% received surgery with radiation plus adjuvant chemotherapy. Patients with stage III disease were significantly more likely than patients with stage II disease to receive combined 5-FU chemotherapy and radiotherapy. Age inversely associates with receiving combined chemo-radiotherapy. Among cases with stage III cancer, number of nodes and comorbidity score were also significant predictors of receiving combined therapy.	**General comments:** Impossible from this dataset to ascertain if the frequency of adjuvant chemotherapy or radiotherapy use was “optimal” in the population under study. For example, omission of chemotherapy in an elderly patient with stage III rectal cancer may be a medically sound decision if the patient has significant comorbidities. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 4 Adequacy of risk adjustment: 1

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Newcomb and Carbone, 1993 **#3760**	**Quality measure (QM):** Rate of adjuvant chemotherapy for colorectal cancer **Basis of QM:** None mentioned, but presumably practice guideline **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Not specified, but presumably survival **Intent of QM:** Not specified (aim of the study was to evaluate the selection of cancer treatment among the elderly) **Definition of denominator/numerator:** Denominator: Number of women residents of Wisconsin aged 20-74 at the time of diagnosis with a new diagnosis of carcinoma of the large bowel during 1989-1991, and who had a listed telephone number and spoke English, and whose physician consented to their participation, and who agreed to a telephone interview, and were among the 628 consecutive participants interviewed September 1, 1990 through November 30, 1990. Numerator: Number of subjects receiving chemotherapy. **Data sources:** Registry for staging information and patient interviews (for the treatment information) **Recommended frequency of data collection:** No recommendation	**Study population:** N: 121 with colorectal Age: 20-74 Race: NR Sex: Female Tumor stage: All stages Performance status: NR **Geographic location:** Wisconsin **Dates:** Sep 1 through Nov 30, 1990 **Healthcare setting:** None (all participants were outpatients contacted by phone) **Results:** 41% of patients less than 65 and 26% ≥ 65 received chemotherapy. Older women were less likely to be referred to medical or radiation oncologists; they were also less likely to be presented with more than one treatment option.	**General comments:** Relying on recall of patients for whether they received a treatment is open to bias. For some of the patients, chemotherapy would not have been appropriate, and these patients should not be included in the denominator. Therefore, the result may not be conclusive. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 3 - Scientific acceptability (five criteria): Precise specifications: 3 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Oliveria, Yood, Campbell, et al., 2004 **#29680**	**Quality measure (QM):** Referral to medical oncologist for consideration of adjuvant chemotherapy **Basis of QM:** Clinical practice guideline (1990 NCI guidelines for stage III and IV disease [refs 9, 18, 19]) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Survival, quality of life **Intent of QM:** Not specified (aim of the study was to describe treatment patterns for patients with colorectal cancer and to examine reasons why patients do not receive chemotherapy) **Definition of denominator/numerator:** Denominator: Number of members of a Massachusetts HMO who were newly diagnosed with CRC from 1/1/97 to 6/30/99 based on ICD-9 codes for CRC and related CPT-4 procedure codes for resection from the HMO's computerized research database. Numerator: Number of patients above who were referred to a medical oncologist. **Data sources:** Computerized database of Massachusetts HMO **Recommended frequency of data collection:** No recommendation	**Study population:** N: 217 Age: Median age 72.0 years; range, 38 to > 80 Race: NR Sex: 48% male Tumor stage: I-IV Performance status: NR **Geographic location:** Massachusetts **Dates:** 1997-99 **Healthcare setting:** HMO **Results:** 66% of patients had a referral to an oncologist or evidence of chemotherapy within 4 months of the index date. Stratified by stage at diagnosis, authors report percentage of patients who were referred to a medical oncologist and whether they subsequently received chemotherapy. Among patients who did not get referred to a medical oncologist, authors report the reasons for no referral (patient refusal, not recommended by MD, comorbidities/death, or unknown). Multivariable analysis revealed patient age (< 70 vs. ≥ 70) and tumor stage (III vs. I) to be significant predictors of referral.	**General comments:** Authors conclude that both patient and physician factors influence the rate of referral to a medical oncologist. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 4 Validity: 4 Adaptability: 3 Adequacy of risk adjustment: 3

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Potosky, Harlan, Kaplan, et al., 2002 **#19420**	**Quality measure (QM):** Percentage of patients with stage II, III rectal cancer receiving adjuvant chemotherapy (with or without radiotherapy) **Basis of QM:** Clinical practice guideline (NCI-NIH Consensus Development conference) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Survival **Intent of QM:** Not specified (aim of the study was to assess the dissemination of adjuvant therapies for stages II and III colorectal cancer, and multiple clinical and non-clinical characteristics associated with the use of minimally acceptable adjuvant therapy as a standard of care) **Definition of denominator/numerator:** Denominator: Number of patients with stage II, III rectal cancer diagnosed in 1990-1991 or 1995 for whom the offer of the receipt of chemotherapy was known. Numerator: Number of patients receiving postoperative chemotherapy with or without radiotherapy. **Data sources:** SEER program **Recommended frequency of data collection:** No recommendation	**Study population:** N: 1,366 stage II, III rectal cancer Age: All Race: 86% white, 7% African American, 5% Hispanic Sex: 59% male Tumor stage: II, III Performance status: NR **Geographic location:** Several cities across U.S. **Dates:** 1990-1991 or 1995 **Healthcare setting:** Hospitals **Results:** Because the data are presented by year and by other demographics, it is difficult to determine the overall % of patients who received chemotherapy.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 4 Adequacy of risk adjustment: 4

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Potosky, Harlan, Kaplan, et al., 2002 **#19420**	**Quality measure (QM):** Percentage of patients with stage III colon cancer receiving adjuvant chemotherapy **Basis of QM:** Clinical practice guideline (NCI-NIH Consensus Development conference) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Survival **Intent of QM:** Not specified (aim of the study was to assess the dissemination of adjuvant therapies for stages II and III colorectal cancer, and multiple clinical and non-clinical characteristics associated with the use of minimally acceptable adjuvant therapy as a standard of care) **Definition of denominator/numerator:** Denominator: Number of patients with stage III colon cancer diagnosed in 1990-1991 or 1995 for whom the offer of the receipt of chemotherapy was known. Numerator: Number of patients receiving postoperative chemotherapy. **Data sources:** SEER program **Recommended frequency of data collection:** No recommendation	**Study population:** N: 779 stage III colon cancer Age: All Race: 85% white, 9% African American, 4% hispanic Sex: 47% male Tumor stage: Stage III Performance status: NR **Geographic location:** Several cities across U.S. **Dates:** 1990-1991 or 1995 **Healthcare setting:** Hospitals **Results:** Because the data are presented by year and by other demographics, it is difficult to determine the overall % of patients who received chemotherapy.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 4 Adequacy of risk adjustment: 4

Evidence Table 7 – Question 2c (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td>**Retchin and Brown, 1990**

#7970</td>
<td>**Quality measure (QM):** Palliative chemotherapy rates

Basis of QM: Clinical practice guideline (not cited, but likely standard of care)

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Appropriate pre- and postoperative care

Intent of QM: Quality improvement (aim of the study was to compare the processes of care for colorectal cancer patients in HMOs with those in fee-for-service [FFS] settings)

Definition of denominator/numerator:
Denominator:
Number of Medicare patients enrolled in HMO or FFS health plans who were hospitalized for colorectal cancer (based on discharge diagnosis or equivalent symptoms, e.g., cancer or mass or tumor of the rectum, sigmoid, cecum or colon; admission for colectomy, hemicolectomy, polypectomy; rectal or gastrointestinal bleeding and abdominal pain, vomiting, obstruction, dehydration, obstipation or severe constipation). FFS patients included in the study were hospitalized and had discharge diagnoses including malignant neoplasms of the colon, rectum, rectosigmoid junction or anus. Patients with carcinoma in situ of either the colon or rectum were also eligible. FFS patients were selected according to number of patients discharged from 7/83 to 3/31/86. HMO patients with an enrollment date of (1/83 to 5/84) to 3/31/86 were included.

Exclusion criteria: Individuals enrolled in HMOs with fewer than 2000 enrollees were eliminated.

Numerator:
Number of patients with advanced disease who received palliative chemotherapy.</td>
<td>**Study population:**

<table>
<tr><th></th><th>FFS n = 180</th><th>HMO n = 150</th></tr>
<tr><td>Mean age</td><td>70.1</td><td>72.3</td></tr>
<tr><td>% male</td><td>49.4</td><td>58.7</td></tr>
<tr><td>% white</td><td>86.7</td><td>95.2</td></tr>
</table>

Geographic location: U.S. HMOs were geographically represented

Dates: 1983-1986

Healthcare setting: Inpatient and outpatient

Results:
36% of HMO patients with advanced disease received palliative chemotherapy compared to 18% of FFS patients. These differences were not statistically significant.</td>
<td>**General comments:**
Confounding variables were not controlled for, FFS patients may have been sicker. Stage of disease could be another possible confounder.

Pre- or postoperative should be added to analysis.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
Precise specifications: 4
Reliability: 3
Validity: 3
Adaptability: 1
Adequacy of risk adjustment: 1</td>
</tr>
</table>

Evidence Table 7 – Question 2c (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr><td></td><td>Data sources: Medical records, Medicare claims from Medicare Automated Data Retrieval System

Recommended frequency of data collection: No recommendation</td><td></td><td></td></tr>
<tr><td>Roetzheim, Pal, Gonzalez, et al., 2000

#23910</td>
<td>Quality measure (QM): Percentage of patients with a colon or rectal cancer diagnosis who received chemotherapy

Basis of QM: None stated (see General comments)

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Mortality

Intent of QM: Not specified (aim of the study was to explore the influence of race/ethnicity and insurance payer on the treatment of and outcomes for colorectal cancer patients in Florida)

Definition of denominator/numerator:
Denominator:
Number of incident cases of colon or rectal cancer occurring in Florida in 1994 as listed in the state tumor registry.

Numerator:
Number of the above patients who also received chemotherapy within 4 months of initiation of therapy.

Data sources: Florida state cancer registry (Florida Cancer Data System = FCDS); Florida Agency for Health Care Administration AHCA discharge abstracts (admissions to all nonfederal acute care hospitals and patient visits to ambulatory surgical centers, freestanding radiation therapy centers and diagnostic imaging centers)

Recommended frequency of data collection: No recommendation</td>
<td>Study population:
N: 9,548

<table>
<tr><th>Patient characteristic</th><th>Percent</th></tr>
<tr><td>Male</td><td>51</td></tr>
<tr><td>Race</td><td></td></tr>
<tr><td>White</td><td>85</td></tr>
<tr><td>Black</td><td>6</td></tr>
<tr><td>Hispanic</td><td>8</td></tr>
<tr><td>Diagnosis stage</td><td></td></tr>
<tr><td>In situ</td><td>6</td></tr>
<tr><td>Local</td><td>30</td></tr>
<tr><td>Regional</td><td>42</td></tr>
<tr><td>Distant</td><td>16</td></tr>
<tr><td>Unstaged</td><td>6</td></tr>
<tr><td>Anatomic site</td><td></td></tr>
<tr><td>Colon</td><td>84</td></tr>
<tr><td>Rectal</td><td>16</td></tr>
<tr><td>Comorbidity index</td><td></td></tr>
<tr><td>0</td><td>71</td></tr>
<tr><td>1</td><td>21</td></tr>
<tr><td>≥ 2</td><td>8</td></tr>
</table>

Geographic location: Florida

Dates: 1994

Healthcare setting: Multiple

Results:
21% of the patients in the study received chemotherapy, but no validity testing was done for chemotherapy.

Hispanics were less likely than non-Hispanic whites to receive chemotherapy among non-Medicare patients. Persons with commercial HMO insurance were less</td>
<td>General comments:
Existing guidelines are for stage III colon cancer and stage II or III rectal cancer only, so measuring and reporting data on all chemotherapy for all stages of colon or rectal cancer is not guideline- or evidence-driven.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 4
- Scientific acceptability (five criteria):
Precise specifications: 2
Reliability: 2
Validity: 2
Adaptability: 2
Adequacy of risk adjustment: 1</td></tr>
</table>

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
		likely than those with commercial FFS insurance to receive chemotherapy. Other factors predictive of receiving chemotherapy were younger age, higher education, being married, having rectal cancer, advanced tumor stage, and lower level of comorbid illness. Among non-Medicare patients, mortality rates were higher in all models for patients with commercial HMOs compared with patients with commercial FFS insurance.	
Rogers, Ray, and Smalley, 2004 **#30130**	**Quality measure (QM):** Percentage of patients with a diagnosis of stage III colorectal cancer receiving chemotherapy **Basis of QM:** Not stated **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Not stated, but presumably survival or recurrence of CRC cancer **Intent of QM:** Not specified (aim of the study was to examine the effect of race on CRC outcomes in patients who had identical health care coverage) **Definition of denominator/numerator:** Denominator: Number of patients enrolled in both Tennessee Medicaid and Medicare and hospitalized with a diagnosis of colorectal cancer. Numerator: Number of above patients who received chemotherapy within 120 days of diagnosis. **Data sources:** Medical records, administrative files from the Tennessee Medicaid program, Tennessee death certificates, and the National Death Index **Recommended frequency of data collection:** No recommendation	**Study population:** N: 969 total Age: 78.9 ± 7.5 years Race: 272 black (28%), 697 white (72%) Sex: 73.9% female (whites), 72.4% female (Blacks) Tumor stage: 75.6% (whites) and 72.1% (blacks) had stage III disease Performance status: Charlson Deyo score of 0 in 64% (whites) and 69% in Blacks **Geographic location:** Tennessee **Dates:** 1984-1994 **Healthcare setting:** Patients identified from hospitalizations **Results:** 7.8% of whites and 9.4% of blacks had chemotherapy within 120 days of diagnosis. There was no difference in survival between whites and blacks.	**General comments:** Study concluded that when there was equal access to care, outcomes were equal in whites and blacks. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 4 Validity: 4 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Schrag, Cramer, Bach, et al., 2000 **#23710**	**Quality measure (QM):** Postoperative chemotherapy rates **Basis of QM:** Not stated **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Mortality **Intent of QM:** Quality improvement (aim of the study was to determine whether hospital procedure volume predicts short- and long-term survival following primary colon cancer surgery) **Definition of denominator/numerator:** Denominator: Number of patients with stage III tumors who survived 3 months postoperatively, were enrolled in Medicare Part B, were 65 years and older, were diagnosed as having primary adenocarcinoma of the colon in a SEER area, and underwent surgery followed by at least one claim for chemotherapy. Exclusion criteria: Patients were excluded if diagnoses were exclusively noted on death certificates or at autopsy; month of diagnosis was unknown; or patient was enrolled in an HMO. Also, patients who were operated on exclusively for local resection or creation of an ostomy were excluded. Numerator: Number of patients who received postoperative chemotherapy within 3 months of surgery. **Data sources:** SEER for patients 65 and older Medicare Claims Part B **Recommended frequency of data collection:** No recommendation	**Study population:** **N:** 6,423 **Geographic location:** U.S. **Dates:** 1991-1996 **Healthcare setting:** All U.S. **Results:** Overall postoperative chemotherapy rate within 3 months of surgery was 54.8%. Differences were marginally significant for hospitals with low (51.2%), medium (56.6%), high (55.6%), and very high (55.5%) volume. The difference in 5-year mortality for patients operated on at very high- vs. low-volume hospitals was 4.4%.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: 4

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Schrag, Cramer, Bach, et al., 2001 **#21910**	**Quality measure (QM):** Percentage of patients with stage III colon cancer receiving adjuvant chemotherapy **Basis of QM:** Clinical practice guideline (NCI-NIH Consensus Development Conference) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Survival **Intent of QM:** Not specified (aim of the study was to assess the extent to which adjuvant therapy is used among the elderly) **Definition of denominator/numerator:** Denominator: Number of patients aged 65 years and older enrolled in Medicare A and B, diagnosed with primary colon adenocarcinoma stage III, in a SEER area during the years 1991-1996 and not part of an HMO, and who had colon cancer surgery performed within 3 months of primary diagnosis. Numerator: Number of patients who received radiotherapy (and chemotherapy) within 6 months of surgery. **Data sources:** Linkage of SEER population-based cancer registries with Medicare database of HCFA **Recommended frequency of data collection:** No recommendation	**Study population:** N: 6,262 patients with stage III colon cancer Age: > 65 Race: All races Sex: Both sexes Tumor stage: Stage III Performance status: NR **Geographic location:** 5 states and 6 U.S. metropolitan areas **Dates:** 1991-1996 **Healthcare setting:** Hospitals **Results:** 55% of stage III patients received chemotherapy. Age at diagnosis was highly associated with receipt of adjuvant treatment.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 4 Adequacy of risk adjustment: 4

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Schrag, Gelfand, Bach, et al., 2001 **#21280**	**Quality measure (QM):** Percentage of patients with stage II or III rectal cancer receiving chemoradiotherapy **Basis of QM:** NIH consensus statement **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** None is specified, but presumably it would be pelvic recurrence **Intent of QM:** Not specified (aim of the study was to examine the relationship between patient characteristics and the use of adjuvant radiotherapy with and without chemotherapy among patients 65 years of age and older with stage II and II rectal cancer) **Definition of denominator/numerator:** Denominator: Number of patients aged 65 years and older enrolled in Medicare A and B, diagnosed with primary rectal adenocarcinoma stage II or III, in a SEER area during the years 1991-1996 and not part of an HMO, and who had rectal cancer surgery performed within 6 months of primary diagnosis and who survived more than 6 months and who did not have a secondary cancer within 6 months. Numerator: Number of patients who received radiotherapy (and chemotherapy) within 6 months of surgery. **Data sources:** Linkage of SEER population-based cancer registries with Medicare database of HCFA **Recommended frequency of data collection:** No recommendation	**Study population:** N: 1,411 Age: > 65 Race: 88% white, 4% black, 8% other Sex: Male 54% Tumor stage: Stage II, III Performance status: NR **Geographic location:** 5 states and 6 U.S. metropolitan areas **Dates:** 1992-1996 **Healthcare setting:** Hospitals **Results:** 57% of patients received radiotherapy (42% with chemotherapy and 15% radiation alone).	**General comments:** The data for this study were generated prior to 1990 so it may not reflect more modern recommendations for management. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 4 Adequacy of risk adjustment: 3

Evidence Table 7 – Question 2c (Published Literature) – continued

Study

Schrag, Panageas, Riedel, et al., 2003

#34030

Characteristics of Quality Measure

Quality measure (QM): Adjuvant chemotherapy rate

Basis of QM: Clinical practice guideline (not specified)

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Mortality

Intent of QM: Quality improvement (aim of the study was to compare surgeon and hospital procedure volume as predictors of outcomes following colon cancer resection)

Definition of denominator/numerator:
Denominator:
Number of Medicare eligible patients aged 65 or older diagnosed in SEER regions with primary colon cancer in 1991-1996.

Exclusion criteria: Excluded were patients enrolled in an HMO; operated on exclusively for intestinal bypass; diagnosis noted exclusively on death certificate or at autopsy; month of death was unknown.

Numerator:
Number of patients who received adjuvant chemotherapy.

Adjustment was made for sex, race, age, stage of tumor, comorbidity and socioeconomic status, whether hospitalization was emergent and whether obstruction or perforation was present.

Data sources: SEER, Medicare claims from HCFA

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N = 24,166

Characteristic	Percent
Male/female	44.1/55.9
Age	
65-69	18.6
70-74	23.6
75-79	23.6
80+	34.2
Race	
White	87.1
Black	6.6
other	6.3
AJCC stage I	19.9
II	36.9
III	26.1
IV	14.1
Unstaged	3.0
Romano comorbidity	
0	71.3
1	23.2
2	5.6
Obstruction (Y/N)	9.0/91.0
Emergent hospitalization (Y/N)	19.8/80.2

Geographic location: U.S.

Dates: 1991-1996

Healthcare setting: All

Results:
Adjuvant chemotherapy rate differences were statistically insignificant.

(continued on next page)

Comments/Quality Scoring

General comments:
2-year postoperative mortality/survival was also assessed.

Study claims that it cannot explain specific processes of care that can account for differences in mortality rates in the various hospitals.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 3
  - Validity: 3
  - Adaptability: 4
  - Adequacy of risk adjustment: 4

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring

Hospital procedure volume	**Adjuvant chemo%**
Very low	51
Low	56
Medium	57
High	56
P value	NS
Surgeon procedure volume	
Very low	52
Low	55
Medium	54
High	56
P value	NS

After adjusting for surgeon procedure volume, high hospital procedure volume remained a strong predictor of low postoperative mortality rates.

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Steele, 1994 **#35840**	**Quality measure:** Percentage of stage III colon cancer patients receiving surgery and chemotherapy **Basis of QM:** Clinical practice guideline It is implicit that the AHCC guidelines be followed but these are not actually cited in the article. There are also guidelines for chemotherapy in stage III colon cancer and chemo/radiation therapy for stage II and III rectal cancer (NCC), but these are not cited by the authors. **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** No outcome is exactly linked to the above but is said to be a marker of appropriate cancer diagnosis and treatment. No citation is provided for this statement. **Intent of QM:** Not specified (aim of the study was to assess cancer patient care and outcomes on a national basis) **Definition of denominator/numerator:** Denominator: Number of patients in the National Cancer Data Base (NCDB) with a new diagnosis of colon cancer in the years 1985-1986 or 1991. Numerator: Number of the above with stage III cancer who underwent surgery and received chemotherapy. **Data sources:** National Cancer Data Base (NCDB) **Recommended frequency of data collection:** No recommendation	**Study population:** *Data given as patients (year)* N: 40,384 (85/86); 39,751 (91) Age: Median 71.3 (85/85); 72.0 (91) Race: Non-Hispanic whites 86.9% (85/85); 85.9% (91) Hispanic 1.1/1.8 African-American 6.6/8.1 Asian 0.9/1.5 Unknown 4.5/2.7 Sex: Male 48.7% (85/85), 49.6% (91) Tumor stage: 85-86/91 0 3.7/6.5 1 14.4/19.3 2 13.8/26.2 3 12.9/20.3 4 9.2/15.8 Unknown 46.0/11.9 Performance status: NR **Geographic location:** National sample; note that the sample is not probabilistic and represented different hospitals in different years **Dates:** 1991 and outcomes for 1985-86 **Healthcare setting:** 464 hospital in 1985, 474 hospitals in 1986, 937 hospitals in 1991 **Results:** Treatment trends showed effects of trial data, as a greater percentage of patients were reported as having treatment (including chemotherapy) beyond surgery in 1991 as compared to 1985/86.	**General comments:** Some “treatment” data are presented, but these are not stratified by stage or location (colon vs. rectum) and therefore do not provide sufficient information to count as a QM. Only survival would be a potential QM from this paper. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 4 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 3 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Steele Jr., 1994 **#35390**	**Quality measure (QM):** Percentage of patients with stage III colon cancer receiving postoperative chemotherapy **Basis of QM:** None **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** None specified, but presumably it would be survival **Intent of QM:** Not specified (aim of the study was assess cancer patient care and outcomes on a national basis) **Definition of denominator/numerator:** Denominator: Number of stage III colon cancer patients in 1990 reported to the National Cancer Data Base (NCDB). Numerator: Number of above patients receiving chemotherapy (with or without radiation). **Data sources:** Registry information reported to National Cancer Data Base **Recommended frequency of data collection:** No recommendation	**Study population:** N: 6,299 patients Age: All Race: All Performance status: NR **Geographic location:** Entire U.S. **Dates:** 1985, 1988, 1990 **Healthcare setting:** Hospitals **Results:** 38.9% received chemotherapy and surgery (with or without radiation therapy).	**General comments:** This paper addresses similar issues as in Beart et al. (1995; #990). **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 3 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Steele Jr., 1994 **#35390**	**Quality measure (QM):** Percentage of patients with stage II or III rectal cancer receiving chemoradiotherapy **Basis of QM:** None **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** None specified, but presumably it would be survival **Intent of QM:** Not specified (aim of the study was assess cancer patient care and outcomes on a national basis) **Definition of denominator/numerator:** Denominator: Number of patients with stage II, III rectal cancer in 1990 reported to the National Cancer Data Base (NCDB). Numerator: Number of above patients receiving chemoradiotherapy. **Data sources:** Registry information reported to National Cancer Data Base (NCDB) **Recommended frequency of data collection:** No recommendation	**Study population:** N: 5,495 Age: Median 69.3 years for rectal cancer Race: For entire study: African American, 9.1% for colon cancer and 6.5% for rectal cancer; Hispanic, 2.7% for colon cancer and 3.5% for rectal cancer. 1.4% of cases were Asian. The rest were Caucasian. Sex: Male 57.2% (rectal). Tumor stage: All included (4.7% stage 0, 22.1% stage I, 29.2% stage II, 22.2% stage III, 18.7% stage IV, 3.0% unknown Performance status: NR **Geographic location:** Entire U.S. **Dates:** Calendar years 1983 and 1988 **Healthcare setting:** Hospitals **Results:** Not specifically stated, but can be calculated form Table 19. 43% of stage II or III patients received surgery and radiation (with or without chemotherapy).	**General comments:** This paper addresses similar issues as in Beart et al. (1995; #990). **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 3 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Steele and Jessup, 1995 **#35850**	**Quality measure (QM):** Percentage of patients with stage III colon cancer receiving postoperative chemotherapy **Basis of QM:** None **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** None specified, but presumably it would be survival **Intent of QM:** Not specified (aim of the study was assess cancer patient care and outcomes on a national basis) **Definition of denominator/numerator:** Denominator: Number of stage III colon cancer patients in 1992 reported to the National Cancer Data Base (NCDB). Numerator: Number of above patients receiving chemotherapy (with or without radiation). **Data sources:** Registry information reported to National Cancer Data Base (NCDB) **Recommended frequency of data collection:** No recommendation	**Study population:** N: 9,465 Age: All Race: All Performance status: Not stated **Geographic location:** Entire U.S. **Dates:** Calendar year 1986/7 and 1992 **Healthcare setting:** Hospitals **Results:** 44.6% received chemotherapy and surgery (with or without radiation therapy).	**General comments:** This paper addresses similar issues as Beart et al. (1995; #990), and Steele Jr. (1994; #35390) except that it includes data from 1992, whereas the others have data ending in 1988 and 1990. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 2 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Steele and Jessup, 1995 **#35850**	**Quality measure (QM):** Percentage of patients with stage II or III rectal cancer receiving chemoradiotherapy **Basis of QM:** None **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** None specified, but presumably it would be survival **Intent of QM:** Not specified (aim of the study was assess cancer patient care and outcomes on a national basis) **Definition of denominator/numerator:** Denominator: Number of stage II, III rectal cancer patients in 1992 reported to the National Cancer Data Base (NCDB). Numerator: Number of above patients receiving chemoradiotherapy. **Data sources:** Registry information reported to National Cancer Data Base (NCDB) **Recommended frequency of data collection:** No recommendation	**Study population:** N: 9,465 Age: All Race: All Performance status: Not stated Other: Not stated **Geographic location:** Entire U.S. **Dates:** Calendar year 1986/7 and 1992 **Healthcare setting:** Hospitals **Results:** Not specifically stated, but can be calculated form Tables 5-13 that 46% of stage II or III patients received surgery and radiation (with or without chemotherapy).	**General comments:** This paper addresses similar issues as Beart et al. (1995; #990), and Steele Jr. (1994; #35390) except that it includes data from 1992, whereas the others have data ending in 1988 and 1990. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 2 Reliability: 2 Validity: 3 Adaptability: 5 Adequacy of risk adjustment: 1

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Sundararajan, Grann, Jacobson, et al., 2001 **#21760**	**Quality measure (QM):** Percentage of patients with stage III colon cancer receiving adjuvant chemotherapy **Basis of QM:** Clinical practice guideline (NCI-NIH Consensus Development Conference) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Survival **Intent of QM:** Not specified (aim of the study was to assess the distribution of adjuvant chemotherapy in the elderly) **Definition of denominator/numerator:** Denominator: Number of patients aged 65 years and older enrolled in Medicare A and B, diagnosed with primary colon adenocarcinoma stage III, in a SEER area during the years 1992-1996 and not part of an HMO, and who had colon cancer surgery performed within 120 days of primary diagnosis. Numerator: Number of patients who received chemotherapy within 4 months of surgery. **Data sources:** Linkage of SEER population-based cancer registries with Medicare database of HCFA **Recommended frequency of data collection:** No recommendation	**Study population:** N: 4,998 patients with stage III colon cancer Age: > 65 Race: All races Sex: Both sexes Tumor stage: Stage III Performance status: NR **Geographic location:** 5 states and 6 U.S. metropolitan areas **Dates:** 1992-1996 **Healthcare setting:** Hospitals **Results:** 50% of stage III patients received chemotherapy.	**General comments:** This paper is very similar to Schrag et al. (2001; #21910), which looked at patients from 1991-1990. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 4 Adequacy of risk adjustment: 3

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Temple, Hsieh, Wong, et al., 2004 **#29890**	**Quality measure (QM):** Chemotherapy rate for stage IV colon or rectal cancer **Basis of QM:** Clinical practice guideline (National Comprehensive Cancer Network Guideline) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Practice patterns of patients with stage IV cancer **Intent of QM:** Quality improvement (aim of the study was to evaluate surgical practice patterns for patients 65 years of age and older with stage IV colorectal cancer) **Definition of denominator/numerator:** Denominator: Number of Medicare-enrolled patients aged 65 and older, initially diagnosed with stage IV colon or rectal cancer in a SEER area during the years 1991-1999. Age, sex, race, ethnicity, comorbidity, year of diagnosis, and socioeconomic status were collected and data were risk-adjusted. Exclusion criteria: Cohort restricted to those with a histologic diagnosis consistent with adenocarcinoma. Diagnoses exclusively on death certificates or at autopsy were excluded, as were those in which the month of diagnosis was unknown. Patients enrolled in HMOs were excluded. Numerator: Number of above patients who received chemotherapy within 4 months of diagnosis. **Data sources:** SEER, Medicare claims **Recommended frequency of data collection:** No recommendation	**Study population:** N: 9,011 Age: 21% 65-69; 25% 70-74; 23% 75-79; 18% 80-84; 13% ≥ 85 Sex: 48% male, 52% female Race: 84% white, 9% black, 7% other Comorbidities: 90% had 0; 5% had 1; 5% had 2+ **Geographic location:** U.S. **Dates:** 1991-1999 **Healthcare setting:** inpatient hospital **Results:** Only 44% of the cohort received chemotherapy within 4 months of diagnosis. Palliative radiotherapy was administered to only 12% of cohort members within the first 4 months of treatment; these were primarily patients with rectal cancer.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 2 Adequacy of risk adjustment: 2

Evidence Table 7 – Question 2c (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Tropman, Hatzell, Paskett, et al., 1999 **#35610**	**Quality measure (QM):** Percentage of patients receiving appropriate adjuvant chemotherapy for CRC as defined by the NCI PDQ guidelines **Basis of QM:** Clinical practice guideline (NCI PDQ Guidelines) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Locoregional recurrence, overall survival. **Intent of QM:** Not specified (aim of the study was to determine the degree to which colon cancer treatment in rural North and South Carolina conformed to national treatment recommendations) **Definition of denominator/numerator:** Denominator: Number of patients treated for colon cancer in Wayne County, NC, and its six contiguous counties or in Greenwood County, SC, and its four adjacent counties during the years 1991 and 1996. Cases were identified by the North Carolina Central Cancer Registry and by local tumor registrars in SC. Numerator: Number of patients above who received primary and adjuvant therapy per the NCI PDQ recommendations. **Data sources:** Patient medical records and records from physician offices in the geographic regions under study **Recommended frequency of data collection:** No recommendation	**Study population:** N: 230 *1991/1996 data* Age: Mean 75/71 Race: 76% white/75% white Sex: 55% male/58% male Tumor stage: I-III Performance status: NR **Geographic location:** Wayne County, NC, and its six contiguous counties or in Greenwood County, SC, and its four adjacent counties **Dates:** 1991, 1996 **Healthcare setting:** Rural health care facilities **Results:** A higher % of patients with stage III cancers received adjuvant chemotherapy compared to patients with stage II disease, a finding in keeping with the stronger PDQ support for adjuvant therapy for stage III disease. 44% of patients in NC with stage III colon cancer received chemotherapy in 1996 compared with 16% of patients with stage II disease.	**General comments:** The article compares rates of compliance with NCI PDQ recommendations in two rural geographic regions (one in NC, one in SC) before (1991) and after (1996) an intervention to educate local physicians. The intervention took place in NC. The SC region served as a control. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 4 Validity: 4 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 7 – Question 2c (Published Literature) – continued

Study

Wudel Jr., Chapman, Shyr, et al., 2002

#18640

Characteristics of Quality Measure

Quality measure (QM): Percentage of patients with colon or rectal cancer who had chemotherapy

Basis of QM: None stated

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Mortality

Intent of QM: Not specified (aim of the study was to determine the outcome of patients with colorectal cancer treated in the same city at 2 nearby medical centers, a university hospital and a city hospital, and to explore disparities in colorectal cancer outcomes between black and white patients)

Definition of denominator/numerator:
Denominator:
Number of patients with a diagnosis of primary colorectal cancer between 1/1/90 and 12/21/99 in the tumor registry databases at each of 2 institutions (university hospital and a city hospital). Excluded patients who were non-white and non-black.

Numerator:
Number of the above patients who received chemotherapy.

Data sources: Hospital tumor registries

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population (university hospital = UH, city hospital = CH)
N: 565 UH; 77 CH
Age: Median 69 UH, 74 CH
Race: 10.6% black UH; 53% black CH
Sex: 53.3% male UH; 62.7% male CH

Tumor Stage	UH	CH
I	31.7	29.9
II	21.9	20.8
III	23.7	16.9
IV	22.7	32.5

Performance status: NR

Geographic location: Nashville, TN

Dates: 1/1/90 and 12/21/99 (retrospective review)

Healthcare setting: University hospital, city hospital

Results:
There was no significant difference in tumor stage at the time of presentation in the two institutions studied or between racial/ethnic groups. There was no difference in the treatment modalities identified between institutions or racial/ethnic groups.

There was a significant difference in overall survival between patients treated at the university hospital (median 5.3 years) and those treated at the city hospital (median 2.1 years). Median survival was 5.7 years for white patients and 3.2 years for black patients treated at the university hospital. White patients treated at the city hospital survived 2.1 years vs. 1.4 years for black patients.

There was no survival advantage for patients receiving chemotherapy or radiotherapy.

Comments/Quality Scoring

General comments:
Mortality was the primary endpoint of the study and the data for other potential QMs (% receiving "curative" surgery, chemo, or radiation therapy) are much weaker, poorly defined, and do not follow guidelines.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 3
- Scientific acceptability (five criteria):
    Precise specifications: 3
    Reliability: 2
    Validity: 2
    Adaptability: 3
    Adequacy of risk adjustment: 1

Evidence Table 8 – Question 2c (Grey Literature): *As appropriate to specific stages of colorectal cancer, what quality-of-care measures are available and what evidence is available for measures of quality of care of treatment of colorectal cancer, including appropriate use of adjuvant chemotherapy and adjuvant radiation therapy, including for patients with metastatic but potentially curable (hepatic/pulmonary-resectable) disease?*

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Colon Cancer Workgroup, 2003 **#36650**	**Quality measure (QM):** Adjuvant chemotherapy is administered to patients with lymph node positive colon cancer **Basis of QM:** Clinical practice guideline (National Comprehensive Cancer Network [NCCN] guidelines) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Improved health status **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of patients having colon cancer resection. Numerator: Number of above patients receiving combination chemotherapy. **Data sources:** Medical records **Recommended frequency of data collection:** No recommendation	**General comments:** Older patients or those with comorbidities may not receive chemotherapy. **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 8 – Question 2c (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Institute of Medicine report, 2005 **#36680**	**Quality measure (QM):** Adjuvant chemotherapy after surgery for Stage III colon cancer **Basis of QM:** Clinical practice guideline (National Comprehensive Cancer Network [NCCN] guidelines) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of patients with Stage III colon cancer who undergo surgery. Numerator: Number of above patients who receive a full course of adjuvant chemotherapy after surgery. **Data sources:** Surveillance, Epidemiology and End Results Program (SEER)-Medicare dataset, medical records **Recommended frequency of data collection:** No recommendation	**General comments:** Stage III colon cancer refers to tumors that have spread through the wall of the colon or rectum into 1 to 4 regional lymph nodes and nearby tissues or organs. The current standard for chemotherapy is a 6-month course. Older patients are less likely to receive recommended adjuvant chemotherapy, despite evidence that they tolerate it well. Race, marital status, hospital volume and individual hospitals are also associated with receipt of adjuvant chemotherapy. Key references cited: Ayanian et al., 2003 Moore and Haller, 1999 NCCN, 2004 Neugut et al., 2002 **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 8 – Question 2c (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
National Committee for Quality Assurance, 2005 **#36580**	**Quality measure (QM):** Percent of late-stage CRC cancer cases (stage ≥ III) that received one or more courses of adjuvant chemotherapy within 1 year of initial cancer surgery **Basis of QM:** Clinical practice guideline (National Comprehensive Cancer Network [NCCN] guidelines) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Improved health status **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of newly diagnosed colon cancer cases (stage ≥ III) that received surgical treatment in a 12-month period. Numerator: Number of above who received one or more courses of adjuvant chemotherapy within 1 year of surgery. **Data sources:** Cancer registry, claims data **Recommended frequency of data collection:** No recommendation	**General comments:** None **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 9 – Question 2d (Published Literature): *As appropriate to specific stages of colorectal cancer, what quality-of-care measures are available and what evidence is available for measures of quality of care of treatment of colorectal cancer, including appropriate use of radiation therapy for either curative or palliative therapy, specifically for rectal cancers?*

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Ayanian, Zaslavsky, Fuchs, et al., 2003 **#34680**	**Quality measure (QM):** Use of adjuvant radiation therapy in patients with stage II or III rectal cancer **Basis of QM:** Other (1990 NIH Consensus Conference) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Decreased local/regional recurrence. **Intent of QM:** Not specified (aim of the study was to estimate underreporting of adjuvant therapies in routinely collected registry data, assess rates of adjuvant therapies and factors associated with use, and ascertain reasons why eligible patients were not treated) **Definition of denominator/numerator:** Denominator: Number of subjects identified from registry records (3 regional registries within the California Cancer Registry) who were 18 years of age and older and diagnosed during 1996 and 1997 with stage II or III adenocarcinoma of the rectum, using staging criteria of the AJCC. Patients had undergone surgery and survived for at least 30 days. Numerator: Number of above subjects with rectal cancer who received adjuvant radiotherapy. **Data sources:** California Cancer Registry Physician survey Office records **Recommended frequency of data collection:** No recommendation	**Study population:** Eligible for radiation therapy: N: 534 Age: 18 to > 85 Race: 73.4% white Sex: 45.9% female Tumor stage: Rectal stage III 46.8%, rectal stage II 53.2% Performance status: 64.8% comorbidity score 0, 19.3% 1, 15.9% ≥ 2 **Geographic location:** San Francisco/Oakland, San Jose/Monterey, and Sacramento, CA areas **Dates:** 1996-97 **Healthcare setting:** Hospitals **Results:** 64% of eligible patients received radiation. Sensitivity of routinely collected registry data was 93% for radiation therapy. Only 2% of patients had registry data indicating they had received radiation therapy but were reported by their physicians not to have received the therapy. Adjusted rates for radiation therapy for rectal cancer were most strongly associated with age. Older patients were less likely ($p< .001$) to receive radiation therapy than younger patients. Most common reasons cited for not giving adjuvant therapy: patient refusal, comorbid illness, lack of clinical indication.	**General comments:** Article attempts to estimate underreporting of adjuvant therapies in routinely collected registry data by comparing registry data with office records and physician surveys. Because the standard of care is chemo-radiotherapy, this QM would have been more important if it had been modified to the use of adjuvant chemo/radiotherapy after resection of stage II and III rectal cancer. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 4 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 5 Validity: 5 Adaptability: 5 Adequacy of risk adjustment: 1

Evidence Table 9 – Question 2d (Published Literature) – continued

Study

Baxter, Rothenberger, Morris, et al., 2005

#44990

Characteristics of Quality Measure

Quality measure (QM): Use of adjuvant radiation therapy in patients with AJCC stage II or III rectal cancer

Basis of QM: National Institutes of Health (NIH) Consensus Conference

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Decreased local/regional recurrence in patients with rectal cancer.

Intent of QM: To evaluate U.S. trends in adjuvant radiation therapy use over a 25-year period, timing of radiation therapy (pre- vs. postoperative) and factors affecting radiation delivery.

Definition of denominator/numerator:
Denominator:
Number of patients ≥ 18 yrs. of age diagnosed with adenocarcinoma of the rectum between January 1976 through December 2000.

Exclusion criteria: patients who had in situ or metastatic disease, patients with malignancies other than adenocarcinoma and patients who did not undergo some form of surgical therapy.

Numerator:
Number of above patients with stage II or III rectal cancer who received adjuvant radiotherapy.

Data sources:
Surveillance Epidemiology and End Results (SEER) cancer registry

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 45,627

	RT Use	No RT Use
N	14,571	30,429
Median age	65	70
% male	61	55
% Non AA	94	95
Seer Stage (%)		
Localized	29	67
Regional	64	29
Unknown	7	4
Grade (%)		
Well diff.	8	15
Moderate diff.	62	54
Poor diff.	19	10
unknown	11	21

Geographic location: 14 SEER cancer registry sites across the U.S.

Dates: 1976-2000

Healthcare setting: Hospitals

Results:

	RT Use	No RT Use
N	14,571	30,429
Year of Diagnosis	%	%
1976-1980	15	85
1981-1985	25	75
1986-1990	33	67
1991-1995	38	62
1996-2000	42	58

Frequency of radiation therapy use for patients with rectal cancer increased substantially over study period: 12 percent underwent RT in 1976 compared to 42 percent in 2000 (p < 0.0001). For patients with regional spread, the percent receiving RT increased from 17% to 65%. Of those with regional spread who

Comments/Quality Scoring

General comments:

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
    - Precise specifications: 4
    - Reliability: 3
    - Validity: 3
    - Adaptability: 5
    - Adequacy of risk adjustment: 1

Evidence Table 9 – Question 2d (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr><td></td><td></td><td>
<p>also underwent radical excision, 41% received RT in 1983 compared to 65% in 2000 (p < 0.0001).</p>
<p>By 2000, RT use for Stage II patients was 59%; for stage III, 68%. Increased use was almost entirely due to post operative RT use until 1996. Since then, postoperative use rate has declined while preoperative RT use has increased substantially (p < 0.0001).</p>
<p>Demographic differences in RT use exist. Patients who underwent RT tended to be younger (65 yrs) compared to those not undergoing RT use (70 yrs; p < 0.0001). They were more likely to be male (61% vs. 55%; p < 0.0001); they were also more likely to have regional spread (64%) than those who did not undergo RT (29%).</p>
<p>AAs were more likely to have received RT (35%) than non-AA (32%), p< .0003. AAs were also more likely to have regional disease (47 vs. 42%) than non-AAs, p < 0.00001.</p>
<table>
<tr><td>Patients since 1988</td><td>Odds ratio for RT use</td></tr>
<tr><td>Age at diagnosis</td><td></td></tr>
<tr><td>> 70</td><td>1</td></tr>
<tr><td>< 65 - ≤ 70</td><td>3.03</td></tr>
<tr><td>≤ 60</td><td>4.95</td></tr>
<tr><td>Male</td><td>1</td></tr>
<tr><td>Female</td><td>.81</td></tr>
<tr><td>Non AA</td><td>1</td></tr>
<tr><td>AA</td><td>.77</td></tr>
<tr><td>AJCC tumor stage</td><td></td></tr>
<tr><td>II</td><td>1</td></tr>
<tr><td>III</td><td>1.76</td></tr>
<tr><td>Grade</td><td></td></tr>
<tr><td>Poorly differentiated</td><td>1</td></tr>
<tr><td>Moderate</td><td>.79</td></tr>
<tr><td>Well</td><td>.71</td></tr>
<tr><td>Type of surgery</td><td></td></tr>
<tr><td>Local</td><td>1</td></tr>
<tr><td>Radical</td><td>1.34</td></tr>
</table>
</td><td></td></tr>
</table>

Evidence Table 9 – Question 2d (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr><td></td><td></td><td>Male sex and younger age were predictors of RT use (p < 0.0001). AAs were less likely to undergo RT (p < 0.003) than non-AAs. Patients with poorly differentiated rectal cancer and those with AJCC stage II were significantly more likely to undergo RT use than those with well- or moderately differentiated rectal cancer or with AJCC stage II cancer (p < 0.0001). The year of diagnosis and geographic location by registry remained important predictors of RT use (p < 0.0001).</td><td></td></tr>
<tr><td>Beart, Steele Jr., Menck, et al., 1995

#990</td>
<td>Quality measure (QM): Percentage of patients with rectal cancer receiving radiotherapy

Basis of QM: None

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: None is specified, but presumably it would be survival

Intent of QM: Not specified (aim of the study was to identify current trends in the management of patients with carcinoma of the colon or rectum and to identify changes in patterns of care and survival)

Definition of denominator/numerator:
Denominator:
Number of subjects with stage II or III rectal cancer seen in 1988 from amongst cases of colon and rectal cancer (up to 25 per program or facility) reported by over 1200 approved cancer programs and 800 other facilities on the Commission on Cancer mailing list that were invited to participate.

Numerator:
Number of above subjects receiving chemoradiotherapy.

Data sources: Hospitals sent in up to 25 consecutive cases from their medical records

Recommended frequency of data collection: No</td>
<td>Study population:
N: 39,502 (10,293 with rectal cancer; 2051 with stage II or III)
Age: Median 69.3 years for rectal cancer
Race: For entire study: African American, 9.1% for colon cancer and 6.5% for rectal cancer; Hispanic, 2.7% for colon cancer and 3.5% for rectal cancer. 1.4% of cases were Asian. The rest were Caucasian.
Sex: Male 57.2% (rectal)
Tumor stage: All included (4.7% stage 0, 22.1% stage I, 29.2% stage II, 22.2% stage III, 18.7% stage IV, 3.0% unknown)
Performance status: NR

Geographic location: Entire U.S.

Dates: Calendar years 1983 and 1988

Healthcare setting: Hospitals

Results:

<table>
<tr><th></th><th colspan="2">Colon Cancer</th><th colspan="2">Rectal Cancer</th></tr>
<tr><th></th><th>1983</th><th>1988</th><th>1985</th><th>1988</th></tr>
<tr><td>Chemo-therapy</td><td>10.7</td><td>11.1</td><td>5.9</td><td>5.6</td></tr>
<tr><td>Radiation therapy</td><td>2.7</td><td>10.9</td><td>15.3</td><td>13.8</td></tr>
<tr><td>Combined chemo and RT</td><td>1.5</td><td>1.6</td><td>5.5</td><td>10.1</td></tr>
</table>
.</td>
<td>General comments:
The data for this study were generated prior to 1990 so it may not reflect more modern recommendations for management.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
Precise specifications: 2
Reliability: 3
Validity: 3
Adaptability: 5
Adequacy of risk adjustment: 2</td></tr>
</table>

Evidence Table 9 – Question 2d (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr><td></td><td>recommendation</td><td></td><td></td></tr>
<tr>
<td>Coburn, Pricolo, and Soderberg, 1994

#2920</td>
<td>Quality measure (QM): Adjuvant therapy rates

Basis of QM: None

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: None

Intent of QM: Not specified (aim of the study was to perform univariate and multivariate analyses of poor indicators in the elderly undergoing colorectal operation, and to compare clinical, pathologic, and therapeutic factors in patients younger than and older than 80 years of age)

Definition of denominator/numerator:
Denominator:
Number of subjects who had received operative treatment for colon and rectal cancer between 1961 and 1987.

Numerator:
Number of above subjects who received adjuvant therapy (chemo- or radiotherapy).

Comparisons were made between patients under and over 80 years.

Data sources: Inpatient, outpatient, and office records

Recommended frequency of data collection: No recommendation</td>
<td>Study population:
N: 800

<table>
<tr><th></th><th>< 80 years</th><th>> 80 years</th></tr>
<tr><td>N</td><td>177</td><td>623</td></tr>
<tr><td>Sex (F%/M%)</td><td>48/52</td><td>56/44</td></tr>
<tr><td>Rectal lesions</td><td>36</td><td>23</td></tr>
<tr><td>Duke stage</td><td></td><td></td></tr>
<tr><td>A</td><td>9.0</td><td>6.0</td></tr>
<tr><td>B1</td><td>16.7</td><td>12.8</td></tr>
<tr><td>B2</td><td>31.2</td><td>42.7</td></tr>
<tr><td>C1</td><td>4.5</td><td>0</td></tr>
<tr><td>C2</td><td>21.5</td><td>21.8</td></tr>
<tr><td>D</td><td>17.1</td><td>16.7</td></tr>
</table>

Geographic location: Rhode Island, U.S.

Dates: 1961 and 1987

Healthcare setting: Academic institute

Results:
Adjuvant therapy rate was 5.1% for patients > 80 yrs and 20% for patients < 80 yrs.

Long-term survival (at 5 and 8 yr) and rate of recurrence after curative therapy were used to validate the measure.

There was a statistically significant difference in survival rates: 48% for patients < 80 vs. 32% for patients > 80.

There was no statistically significant difference between the groups with regard to recurrence after curative therapy.</td>
<td>General comments:
Data collected between 1961 and 1987.

Other factors that affect mortality rates in the elderly: more aggressive biologic behavior of cancer of the colon and rectum in the elderly, with aggressive local disease and less tendency towards distant dissemination, greater tendency of colon cancer to be right-sided, rarity of adjuvant therapy administered to older patients, higher complication rate in elderly patients due to comorbid conditions, and greater frequency of obstructing and perforated lesions.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
Precise specifications: 4
Reliability: 3
Validity: 3
Adaptability: 2
Adequacy of risk adjustment: 2</td>
</tr>
</table>

Evidence Table 9 – Question 2d (Published Literature) – continued

Study

Demissie, Oluwole, Balasubramanian, et al., 2004

#31380

Characteristics of Quality Measure

Quality measure (QM): Non-receipt of standard radiation treatment

Basis of QM: Clinical practice guideline (NIH guidelines)

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked:

Intent of QM: Not specified (aim of the study was to examine colorectal cancer treatment differences between races with comparable disease at presentation)

Definition of denominator/numerator:
Denominator:
Number of white or black subjects diagnosed with rectal cancer between Jan 1, 1988 and Dec 31, 1997.

Exclusion criteria: Subjects neither white nor black, unknown treatment history, cancer diagnosed at autopsy, in-situ tumor or carcinoid tumor, rare histological types.

Numerator:
Number of above subjects not receiving radiation therapy (defined as beam radiation, radioactive implants, radioisotopes, or a combination of these).

Comparisons were made between blacks and whites.

Data sources: SEER database

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:

Characteristic	Male		Female	
	White	Black	White	Black
n	49,359	4383	47,803	4832
< 84 yr	92.5	95.3	84	92
AJJCC Tumor Stage				
II	26.84	23.07	24.18	20.99
II	29.54	26.44	32.49	28.04
III	22.66	23.02	23.77	24.71
IV	16.76	22.36	15.70	20.88
Unknown	4.2	5.11	3.87	5.38

Geographic location: SEER geographic regions

Dates: 1988-1997

Healthcare setting: Mixed

Results:
While there is no significant racial difference in radiation therapy for stages II and IV rectal cancer, notable differences exist for stage I and stage III rectal cancer. For stage III rectal cancer, blacks had a higher risk of non-receipt of radiation therapy. For stage I, black males had a lower likelihood of non-receipt of radiation therapy.

Odds of non-receipt of radiation therapy for rectal cancer for blacks as compared with whites by sex (whites formed the reference group):

(continued on next page)

Comments/Quality Scoring

General comments:
The intent-to treat and treatment received analyses are compared, and the former is stated to be a more valid comparison.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 3
  - Validity: 3
  - Adaptability: 4
  - Adequacy of risk adjustment: 4

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring

Radiation therapy	Male		Female	
	unadjusted	adjusted	unadjusted	adjusted
AJCC stage I	0.5	0.51	0.93	0.96
AJCC stage II	0.67	0.81	1.22	1.37
AJCC stage III	1.67	2.04	1.14	1.54
AJCC stage IV	0.92	1.03	1.23	1.43
unstaged	0.81	1.00	0.86	1.04

(adjusted for age, tumor grade and histology)

Black-to-white disparity in non-receipt of radiation therapy was more prominent when actual treatment received rather than intent-to-treat was considered.
Number of patients who refused treatment:
Stage I: 32.8% black and 9.2% white males and 19.4% black and 12.8% white females.

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Dominitz, Samsa, Landsman, et al., 1998 **#9380**	**Quality measure (QM):** Percentage of patients with colorectal cancer receiving radiation therapy **Basis of QM:** None **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Survival **Intent of QM:** Not specified (aim of the study was to assess the influence of race on the treatment and survival of patients with colorectal carcinoma) **Definition of denominator/numerator:** Denominator: Number of white/black patients with colorectal cancer identified from the VA Patient Treatment File (PTF) who were discharged from VA hospitals with a diagnosis of CRC (ICD-9-CM codes 153.0-153.4, 153.6-154.1) during fiscal year 1989. To exclude prevalent cases, any patient with a diagnosis of CRC (ICD-9-CM codes 153.0-153.4, 153.6-154.1, V10.05-V10.06) for hospitalization during FY 1984-1988, or a personal history of CRC (ICD-9-CM codes V10.05-V10.06) during the index hospitalization, was excluded. Male veterans only. No ulcerative colitis or Crohn's disease. Numerator: Number of above white/black patients treated with radiation therapy, as indicated by specific ICD-9-CM codes in the PTF. **Data sources:** VA PTF **Recommended frequency of data collection:** No recommendation	**Study population:** N: 2,607 whites + 569 blacks Age: 67.1 ± 9.1 (whites); 66.4 ± 9.9 (blacks) Race: See above Sex: 100% male Tumor stage: All stages Performance status: NR **Geographic location:** VA Medical Centers **Dates:** 1989 **Healthcare setting:** VA Hospitals **Results:** No statistically significant differences in rates of radiation therapy in blacks vs. whites. No difference in 5-year relative survival or overall survival in blacks vs. whites.	**General comments:** The article compares rates of surgery, radiotherapy, and chemotherapy among blacks and whites. No attempt is made to compare to a gold standard (e.g., a guideline) to determine whether the rates in blacks or whites are optimal. The study is limited because of its use of an administrative database that lacked clinical details and did not allow for adjustment to disease severity. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 3 Reliability: 3 Validity: 1 Adaptability: 1 Adequacy of risk adjustment: 1

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Govindarajan, Shah, Erkman, et al., 2003 **#35310**	**Quality measure (QM):** Percentage of patients with stage II, III colorectal cancer receiving radiation therapy **Basis of QM:** None **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Not firmly linked to any outcome, but presumably to survival, quality of life, or rates of local recurrence **Intent of QM:** Not specified (aim of the study was to analyze disease stage, treatment received, and socioeconomic factors to better understand the factors influencing survival differences between African-Americans and Caucasians with colorectal cancer) **Definition of denominator/numerator:** Denominator: Number of African-Americans (AAs)/Caucasians, aged 18 older, with CRC treated between 1984 and 1997 at a state-funded University hospital located in Arkansas, identified through the hospital tumor registry using appropriate tumor registry codes. Numerator: Number of above AAs/Caucasians treated with radiation therapy. **Data sources:** Tumor registry at Univ. of Arkansas **Recommended frequency of data collection:** No recommendation	**Study population:** N: 617 All figures below for Caucasians/AAs Age: 60.0/61.5 Race: 427 Caucasians/190 AAs Sex: 47.1% male/39.5% male Tumor stage: Stages 0-IV Performance status: NR Other: - Not high school grad: 45%/60% - Low income: 45%/64% - High poverty: 41%/68% **Geographic location:** Arkansas **Dates:** 1984-1997 **Healthcare setting:** University hospital **Results:** Authors show that significantly higher percentages of Caucasians received radiation therapy, compared with AAs, for patients with all stages of CRC, and for patients with only stages II and III disease. Cancer-specific mortality was higher in African-Americans than in Caucasians for all stages.	**General comments:** It is not possible to use the QM “rates of use of radiation” because they grouped colon and rectal cancer together, but radiotherapy is only indicated for rectal cancer. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 3 Reliability: 3 Validity: 1 Adaptability: 1 Adequacy of risk adjustment: 1

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Kline, Smith, Coia, et al., 1997 **#12070**	**Quality measure (QM):** Adherence to radiotherapy management treatment guidelines for patients with adenocarcinoma of the rectum and sigmoid colon **Basis of QM:** Clinical practice guideline (Patterns of Care Study Treatment-Planning Committee consensus guidelines) **Type of QM:** (a) Process (b) Technical **Outcome to which the QM is linked:** Not specifically stated, but presumably reduction in complications due to radiation therapy, reduction in local-regional recurrence, or improved survival **Intent of QM:** Not specified (aim of the study was to conduct a study of the process of treatment planning and treatment of adenocarcinoma of the rectum and sigmoid in the U.S., and to compare survey results to consensus guidelines) **Definition of denominator/numerator:** Denominator: Number of cases of cancer of rectum or sigmoid colon treated 1989-90 at one of 75 facilities selected from among a random sample of all U.S. facilities administering megavoltage radiation therapy. Numerator: Number of above patients receiving radiotherapy according to treatment guidelines. **Data sources:** 1989-90 PCS Survey **Recommended frequency of data collection:** No recommendation	**Study population:** N: NR Age: NR Race: NR Sex: NR Tumor stage: NR Performance status: NR **Geographic location:** U.S. **Dates:** 1989-90 **Healthcare setting:** Academic, hospital-based, and free-standing radiation therapy centers **Results:** Adherence to a variety of guideline measures reported in the study. For example: Guideline: “Information from a pelvic CT may be useful in determining field borders.” Result of survey: CT used for radiation therapy planning in only 17-21% of cases. Other radiation therapy quality indicators assessed include: 1. Placement of clips by surgeon when tumor adherent to other pelvic structures. 2. Isodose distribution generated for dose prescription. 3. Beam energy used should be ≥ 4 MV. 4. At least 3 radiation therapy fields should be used. 5. Fields should be shaped with custom blocks. 6. Wedges or compensators should be used as needed. 7. Port films should be taken. 8. Patients should be simulated with contrast in rectum. 9. A small bowel series should be done if the total dose will exceed 50 Gy. 10. Prone setup used.	**General comments:** This paper describes a number of very technical measures of quality relevant to radiation therapy rather than a more general measure of whether the radiation was performed at all for a particular indication. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 5 Validity: 5 Adaptability: 5 Adequacy of risk adjustment: 1

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Merrill, Brown, Potosky, et al., 1999 **#27110**	**Quality measure (QM):** Percentage of CRC patients who had radiotherapy **Basis of QM:** None **Type of QM:** (a) Structure (b) General **Outcome to which the QM is linked:** Presumably survival **Intent of QM:** Not specified (aim of the study was to compare treatment utilization and long-term survival in HMO and fee-for-service [FFS] settings for Medicare colorectal cancer cases) **Definition of denominator/numerator:** Denominator: Number of CRC patients in each subgroup of the dataset (see Data sources, below). Numerator: Number of above patients who had adjuvant radiotherapy. **Data sources:** 1. Two tumor registries on colon and rectum cancer patients diagnosed 1985-92 and followed up through 31 December 1994. Both registries are part of SEER. 2. Medicare inpatient claims data. 3. Databases of two HMO plans, Kaiser Permanente of Northern California and Group Health Cooperative of Puget Sound. 4. 1990 U.S. Census **Recommended frequency of data collection:** No recommendation	**Study population:** N: 15,352 total Age: ≥ 65 Race: 81.2 to 95.3% white depending on subgroup Sex: 46.8 to 54.3% male, depending on subgroup Tumor stage: 0-IV Performance status: NR Comorbidity Index: 0-2+ **Geographic location:** San-Francisco-Oakland area, Seattle-Puget Sound area **Dates:** 1985-1992 **Healthcare setting:** 2 tumor registries participating in the SEER Program augmented with Medicare data along with HMOs KPNC and GHC. **Results:** The standardized rate of adjuvant radiotherapy use following surgery was significantly higher among HMO cases (44%, 95% CI 37%-50%) than among FFS cases (35%, 95% CI 33-38%). Cancer-specific mortality rates were similar in both settings.	**General comments:** A very high-quality study by experienced researchers. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: 5

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Minsky, Coia, Haller, et al., 1998 **#9280**	**Quality measure (QM):** Use of modern radiation therapy techniques; adherence to recommendations of NCI-sponsored RCT in rectal cancer patients. **Basis of QM:** Other: (use of modern radiation therapy techniques as defined by consensus of experts [Patterns of Care Rectal Cancer Committee]; adherence to RCT recommendations described as above) **Type of QM:** (a) Process (b) General/Technical **Outcome to which the QM is linked:** Presumably locoregional recurrence, survival, and reduction in radiation therapy-related complications **Intent of QM:** Not specified (aim of the study was to determine the U.S. national practice standards for patients with adenocarcinoma of the rectum treated in radiation oncology facilities) **Definition of denominator/numerator:** Denominator: Number of patients with rectal cancer treated with curative intent from 1992-1994, with no evidence of extrapelvic disease, micro or gross residual disease after surgery, or prior or concurrent malignancies or treatment for rectal cancer, who received radiation therapy as a component of their definitive or adjuvant management, and who were identified from a facilities survey conducted by the PCS. Numerator: Number of above patients whose radiation therapy conformed to recommendations of the expert panel (on various technical dimensions); subset of above patients whose treatment adhered to specific recommendations of the NCI RCTs. **Data sources:** PCS national survey **Recommended frequency of data collection:** No recommendation	**Study population:** N: 507 Age: 64 Race: NS Sex: 64% male Tumor stage: Tis-3, N0-N3 Performance status: 83% KPS 90-100 Differentiation: 65% moderate Resection margins: 66% negative **Geographic location:** U.S. **Dates:** 1992-94 **Healthcare setting:** All U.S. radiation oncology facilities **Results:** Radiation therapy details: Many factors considered indicative of high-quality radiation therapy were measured in the survey. For example, radiation therapy field arrangement was AP/PA in 11% of patients, 3 or 4 fields in 92%, and unknown in < 0.5%. For full details, see Table 4, p. 2545. Chemotherapy details: Receipt of chemotherapy was documented in the study but the study did not address adherence to treatment guidelines with respect to chemotherapy. Surgery details: Type of surgery performed was documented but no attempt was made to determine if the “correct” surgical procedure was done, or to assess surgical complication rates.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 3 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 3 Validity: 3 Adaptability: 5 Adequacy of risk adjustment: 1

Evidence Table 9 – Question 2d (Published Literature) – continued

Study

Morris, Billingsley, Baxter, et al., 2004

#32200

Characteristics of Quality Measure

Quality measure (QM): Rate of radiation therapy use for stage II, III rectal cancer

Basis of QM: Not specified, but appears to be NIH Consensus conference

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: No explicit outcome link, but presumably to decreased rates of LRR or improved OS

Intent of QM: Aim of the study was to investigate racial variation in the performance of sphincter-sparing procedures for patients with stage II and III rectal cancer who underwent surgery, and to study race and delivery of any surgical treatment, neoadjuvant therapy, and radiation therapy to these patients, with implications for quality of care.

Definition of denominator/numerator:
Denominator:
Number of blacks/whites diagnosed with rectal cancer and entered into the SEER database 1988-1999.

Exclusion criteria: Prior diagnosis of CRC, prior diagnosis of cancer requiring surgery or radiotherapy in the pelvis, or < age 35.

Numerator:
Number of above patients who received various treatments for CRC including surgery (also type of operation) and radiation (timing of RT also evaluated).

Data sources: SEER registry

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N = 52,864

	White	Black
n	44010	3851
Age (%)		
35-64	35	49
65-79	46	40
80+	20	12
Male (%)	55	52
Tumor stage (%)		
insitu	9	8
I	3	28
II	21	20
III	19	18
IV	14	17
unstaged	8	10

Geographic location: SEER regions

Dates: 1988-1999

Healthcare setting: U.S. healthcare facilities

Results:

N = 18,927	Radiation Treatment rate (%)		Adjusted OR (95% CI)
	Any	None	
White	47	53	1.30 (1.15-1.47)
Black	44	56	

N = 18,560	Neoadjuvant Radiation Treatment Rate (%)		Adjusted OR (95% CI)
White	7	93	1.04 (.87-1.36)
Black	7	93	

Comments/Quality Scoring

General comments: None

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 4
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 5
  - Reliability: 3
  - Validity: 3
  - Adaptability: 5
  - Adequacy of risk adjustment: 1

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Neugut, Fleischauer, Sundararajan, et al., 2002 **#18450**	**Quality measure (QM):** Use of radiotherapy in stage II and III rectal cancer patients among the elderly **Basis of QM:** Clinical practice guideline (NIH and NCCN) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Rates of LRC, DM, and OS **Intent of QM:** Not specified (aim of the study was to investigate the use of treatment with adjuvant 5-FU-based chemotherapy and radiation therapy among patients over 65 years of age with surgically resected stage II or III rectal cancer) **Definition of denominator/numerator:** Denominator: Denominator: Number of patients with histologically confirmed primary rectal cancer, diagnosed 1992-1996, stage II-III, age ≥ 65, s/p surgical tumor resection, eligible for Medicare Parts A and B in the 12 mo before diagnosis and 120 days after diagnosis, and had survived more than 4 mo after diagnosis. Excluded members of HMO in the 12 mo before and 4 mo after their diagnosis. Numerator: Number of above patients who received radiation therapy. **Data sources:** SEER-Medicare database **Recommended frequency of data collection:** No recommendation	**Study population:** N: 1,807 Age: 65-85+ Race: 1592 non-Hispanic white Sex: 964 female Tumor stage: II (983). III (824) Performance status: NR Charlson-Deyo comorbidity score: 0 (1098), 1 (299), > 1 (410) **Geographic location:** SEER geographic regions **Dates:** 1992-96 **Healthcare setting:** U.S. facilities **Results:** 48% of cohort received radiation therapy (11% received postoperative radiation therapy alone, 37% received chemoradiotherapy). Age was associated with the overall use of radiation.	**General comments:** Impossible from this dataset to ascertain if the frequency of adjuvant use was “optimal” in the population under study. For example, omission of chemotherapy in an elderly patient with stage III rectal cancer may be a medically sound decision if the patient has significant comorbidities. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 4 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 3 Validity: 3 Adaptability: 5 Adequacy of risk adjustment: 1

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Newcomb and Carbone, 1993 **#3760**	**Quality measure (QM):** Rate of adjuvant radiation therapy for colorectal cancer **Basis of QM:** None mentioned, but presumably practice guideline **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Not specified, but presumably survival **Intent of QM:** Not specified (aim of the study was to evaluate the selection of cancer treatment among the elderly) **Definition of denominator/numerator:** Denominator: Number of women residents of Wisconsin aged 20-74 at the time of diagnosis with a new diagnosis of carcinoma of the large bowel during 1989-1991, and who had a listed telephone number and spoke English, and whose physician consented to their participation, and who agreed to a telephone interview, and were among the 628 consecutive participants interviewed September 1, 1990 through November 30, 1990. Numerator: Number of subjects receiving radiation therapy. **Data sources:** Registry for staging information and patient interviews (for the treatment information) **Recommended frequency of data collection:** No recommendation	**Study population:** N: 121 with colorectal Age: 20-74 Race: NR Sex: Female Tumor stage: All stages Performance status: NR **Geographic location:** Wisconsin **Dates:** Sep 1 through Nov 30, 1990 **Healthcare setting:** None (all participants were outpatients contacted by phone) **Results:** 14% of patients < 65 years of age and 18% ≥ 65 received radiation therapy.	**General comments:** Relying on recall of patients for whether they received a treatment is open to bias. The data on radiation treatment is not arranged by stage or location of large bowel cancer. Only rectal cancer and locally advanced colon cancer would typically be radiated. Therefore the results may not be conclusive. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 3 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 4 Validity: 4 Adaptability: 5 Adequacy of risk adjustment: 1

Evidence Table 9 – Question 2d (Published Literature) – continued

Study

O'Connell, Maggard, Liu, et al., 2004

#45210

Characteristics of Quality Measure

Quality measure (QM)
Radiation therapy rate

Basis of QM: NIH Consensus Conference Guidelines for adjuvant therapy for colorectal cancer

Type of QM:
(a) Process
(b) General

Intent of QM: Not specified. Aim of study was to compare rectal cancer patient outcomes between young and older populations.

Definition of denominator/numerator:
Denominator:
Patients in the SEER database diagnosed with rectal cancer between 1991 and 1999. Tumors identified as "rectum" in location were selected. Specific histologies were chosen to include only adenocarcinomas.

Exclusion criteria: Patients with tumors identified as rectosigmoid. Mucinous, signet ring cell, carcinoid, sarcoma and lumphoma histologies were excluded along with those tumors classified as benign or in situ.

Numerator:
Number of above patients who received t radiation therapy subsequent to diagnosis.

Data sources: SEER databse

Frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N = 11,778

	20-40 yrs (young) N = 466	60-80 yrs (old) N = 11,312	P-value
Age	34.1± 4.5	70± 5.5	
Male %	54.9	60	.03
Race			
White	62.6	82.3	<.001
Black	12.7	6.1	<.001
Hispanic	8.8	3.7	<.001
Asian	7.5	6.4	NS
other	8.4	1.5	<.001
AJCC stage			
I	17	23.7	<.001
II	15.5	17.8	NS
III	27	20	<.001
IV	17.4	13.6	.02
Grade			
Well	7.5	9.4	NS
Moderate	50.4	61.2	<.001
Poorly	24.3	14	<.001
Anaplastic	1.7	.7	.008
Unknown	16.1	14.7	NS

Geographic location: U.S.

Dates: 1991- 1999

Healthcare setting: Hospital setting

Results:
More young patients received radiation therapy both overall and stage-for-stage. Overall, 57.4 percent of young patients and 39.7 of older patients received radiation (p < 0.0001). Similar results were found by stage where a greater share of younger patients received radiation compared to older patients.

Median survival was 24 months for the young group

Comments/Quality Scoring

General comments:
The SEER registry maintains stringent quality control measures to prevent coding errors and is regarded as one of the best population based databases; however, miscoding and inaccurate data may be present. The registry does not contain all clinically relevant data, such as family history, predisposing factors, etc. A third limitation of the SEER data is that tumor stage or grade was unknown for a number of patients. Another limitation of the study is the substantially smaller sample of young rectal cancer patients compared with the large number of older patients, leading to overestimation of differences.

Rating of quality measures as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
Importance: 2
Usability: 5
Scientific acceptability
  Precise specifications: 4
  Reliability: 3
  Validity: 3
  Adaptability: 3
  Adequacy of risk adjustment: 3

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
		and 27 months for the older group. Univariate analysis revealed overall 5-year survival was similar for the young group compared with the older (63.2 vs. 62.1%, p = NS). Five-year, stage-specific survival also was similar for all stages. Multivariate Cox regression analysis revealed that young, rectal cancer patients had a lower hazard of dying (hazard ratio, .693, p = 0.0004) when controlling for tumor stage, patient demographics, tumor characteristics and stage and treatment.	

Evidence Table 9 – Question 2d (Published Literature) – continued

Study

Roetzheim, Pal, Gonzalez, et al., 2000

#23910

Characteristics of Quality Measure

Quality measure (QM): Percentage of patients with a colon or rectal cancer diagnosis who received radiation therapy

Basis of QM: None stated (see General comments)

Type of QM:
(a) Process
(b) General

Outcome to which the QM is linked: Mortality

Intent of QM: Not specified (aim of the study was to explore the influence of race/ethnicity and insurance payer on the treatment of and outcomes for colorectal cancer patients in Florida)

Definition of denominator/numerator:
Denominator:
Number of incident cases of colon or rectal cancer occurring in Florida in 1994 as listed in the state tumor registry.

Numerator:
Number of the above patients who also received radiation therapy within 4 months of initiation of therapy (stratified by colon or rectal cancer).

Data sources: Florida state cancer registry (Florida Cancer Data System = FCDS); Florida Agency for Health Care Administration AHCA discharge abstracts (admissions to all nonfederal acute care hospitals and patient visits to ambulatory surgical centers, freestanding radiation therapy centers and diagnostic imaging centers)

Recommended frequency of data collection: No recommendation

Testing of Quality Measure

Study population:
N: 9,548

Patient characteristic	Percent
Male	51
Race	
White	85
Black	6
Hispanic	8
Diagnosis stage	
In situ	6
Local	30
Regional	42
Distant	16
Unstaged	6
Anatomic site	
Colon	84
Rectal	16
Comorbidity index	
0	71
1	21
≥ 2	8

Geographic location: Florida

Dates: 1994

Healthcare setting: Multiple

Results:
26% of patients received radiation therapy but no validity testing was done for radiation therapy.

There were no racial differences in the use of radiation therapy. Among Medicare patients, those having HMO insurance types were less likely to receive radiation therapy, an effect that was primarily restricted to patients with colon cancer. Among Non-Medicare patients, there were no insurance-related differences in the receipt of radiation therapy. Other predictors of using radiation therapy included younger age, lower levels of income, non-urban residence, being married, having rectal cancer, and having lower

Comments/Quality Scoring

General comments:
Existing guidelines are for stage III colon cancer and stage II or III rectal cancer only, so measuring and reporting data on all radiation therapy for all stages of colon or rectal cancer is not guideline- or evidence-driven.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 4
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 3
  - Validity: 3
  - Adaptability: 3
  - Adequacy of risk adjustment: 1

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
		levels of comorbidity.	
Rogers, Ray, and Smalley, 2004 **#30130**	**Quality measure (QM):** Percentage of patients with a diagnosis of stage III colorectal cancer receiving radiation therapy for rectal cancer **Basis of QM:** Not stated **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Not stated, but presumably survival or recurrence of colorectal cancer **Intent of QM:** Not specified (aim of the study was to examine the effect of race on CRC outcomes in patients who had identical health care coverage) **Definition of denominator/numerator:** Denominator: Number of patients enrolled in both Tennessee Medicaid and Medicare and hospitalized with a diagnosis of colorectal cancer. Numerator: Number of above patients who received radiation therapy within 180 days of diagnosis. **Data sources:** Medical records, administrative files from the Tennessee Medicaid program, Tennessee death certificates, and the National Death Index **Recommended frequency of data collection:** No recommendation	**Study population:** N: 969 total (19.3% rectal cancer) Age: 78.9 ± 7.5 years Race: 272 black (28%), 697 white (72%) Sex: 73.9% female (whites), 72.4% female (Blacks) Tumor stage: 75.6% (whites) and 72.1% (blacks) had stage III disease Performance status: Charlson Deyo score of 0 in 64% (whites) and 69% in Blacks **Geographic location:** Tennessee **Dates:** 1984-1994 **Healthcare setting:** Patients identified from hospitalizations **Results:** 4.3% of whites and 12.9% of blacks received radiation therapy (p = 0.001). There was no difference in survival between whites and blacks.	**General comments:** Study concluded that when there was equal access to care, outcomes were equal in whites and blacks. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 5 Validity: 5 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Schrag, Gelfand, Bach, et al., 2001 **#21280**	**Quality measure (QM):** Percentage of patients with stage II or III rectal cancer receiving chemoradiotherapy **Basis of QM:** NIH consensus statement **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** None is specified, but presumably it would be pelvic recurrence **Intent of QM:** Not specified (aim of the study was to examine the relationship between patient characteristics and the use of adjuvant radiotherapy with and without chemotherapy among patients 65 years of age and older with stage II and II rectal cancer) **Definition of denominator/numerator:** Denominator: Number of patients aged 65 years and older enrolled in Medicare A and B, diagnosed with primary rectal adenocarcinoma stage II or III, in a SEER area during the years 1991-1996 and not part of an HMO, and who had rectal cancer surgery performed within 6 months of primary diagnosis and who survived more than 6 months and who did not have a secondary cancer within 6 months. Numerator: Number of patients who received radiotherapy (and chemotherapy) within 6 months of surgery. **Data sources:** Linkage of SEER population-based cancer registries with Medicare database of HCFA **Recommended frequency of data collection:** No recommendation	**Study population:** N: 1,411 Age: > 65 Race: 88% white, 4% black, 8% other Sex: Male 54% Tumor stage: Stage II, III Performance status: NR **Geographic location:** 5 states and 6 U.S. metropolitan areas **Dates:** 1992-1996 **Healthcare setting:** Hospitals **Results:** 57% of patients received radiotherapy (42% with chemotherapy and 15% radiation alone).	**General comments:** The data for this study were generated prior to 1990 so it may not reflect more modern recommendations for management. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 4 Adequacy of risk adjustment: 3

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Steele Jr., 1994 **#35390**	**Quality measure (QM):** Percentage of patients with stage II or III rectal cancer receiving chemoradiotherapy **Basis of QM:** None **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** None specified, but presumably it would be survival **Intent of QM:** Not specified (aim of the study was to assess cancer patient care and outcomes on a national basis) **Definition of denominator/numerator:** Denominator: Number of patients with stage II, III rectal cancer in 1990 reported to the National Cancer Data Base (NCDB). Numerator: Number of above patients receiving chemoradiotherapy. **Data sources:** Registry information reported to National Cancer Data Base (NCDB) **Recommended frequency of data collection:** No recommendation	**Study population:** N: 5,495 Age: Median 69.3 years for rectal cancer Race: For entire study: African American, 9.1% for colon cancer and 6.5% for rectal cancer; Hispanic, 2.7% for colon cancer and 3.5% for rectal cancer. 1.4% of cases were Asian. The rest were Caucasian. Sex: Male 57.2% (rectal). Tumor stage: All included (4.7% stage 0, 22.1% stage I, 29.2% stage II, 22.2% stage III, 18.7% stage IV, 3.0% unknown Performance status: NR **Geographic location:** Entire U.S. **Dates:** Calendar years 1983 and 1988 **Healthcare setting:** Hospitals **Results:** Not specifically stated, but can be calculated form Table 19. 43% of stage II or III patients received surgery and radiation (with or without chemotherapy).	**General comments:** This paper addresses similar issues as in Beart et al. (1995; #990). **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 3 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Steele, 1994, #35840	**Quality measure (QM):** Percentage of stage II and III rectal cancer patients who underwent radiation therapy **Basis of QM:** Clinical practice guideline It is implicit that the AHCC guidelines be followed but these are not actually cited in the article. There are also guidelines for chemotherapy in stage III colon cancer and chemo/radiation therapy for stage II and III rectal cancer (NCC), but these are not cited by the authors. **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** No outcome is exactly linked to the above but is said to be a marker of appropriate cancer diagnosis and treatment. No citation is provided for this statement. **Intent of QM:** Not specified (aim of the study was to assess cancer patient care and outcomes on a national basis) **Definition of denominator/numerator:** Denominator: Number of patients in the National Cancer Daba Base (NCDB) with a new diagnosis of rectal cancer (rectosigmoid junction, rectum and anal canal) in the years 1985-1986 or 1991. Numerator: Number of the above who underwent radiation therapy. **Data sources:** National Cancer Data Base (NCDB) **Recommended frequency of data collection:** No recommendation	**Study population:** *Data given as patients (year)* N: 18,418 (85/86); 17,348 (91) Age: Median 72.7 (85/85); 73.0 (91) Race: Non-hispanic whites 88.0% (85/85) 86.9% (91) Hispanics 1.6/2.3 African-Americans 4.7/6.3 Asian 1.2/2.2 Unknown 4.5/2.3 Sex: Male 55.3% (85/85) 55.7% (91) Tumor stage: 85-86/91 0 5.8/5.0 1 15.2/18.6 2 10.5/17.4 3 12.2/20.0 4 5.0/7.8 Unknown 51.3/31.2 Performance status: NR **Geographic location:** National sample; note that the sample is not probabilistic and represented different hospitals in different years **Dates:** 1991 and outcomes for 1985-86 **Healthcare setting:** 464 hospital in 1985, 474 hospitals in 1986, 937 hospitals in 1991 **Results:** Treatment trends showed effects of trial data, as a greater percentage of patients were reported as having treatment (including chemotherapy) beyond surgery in 1991 as compared to 1985/86. Hispanics and African American patients were noted to have more advanced stage cancer (rectal).	**General comments:** Some “treatment” data are presented, but these are not stratified by stage or location (colon vs. rectum) and therefore do not provide sufficient information to count as a QM. Only survival would be a potential QM from this paper. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 4 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 3 Adequacy of risk adjustment: 4

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Steele and Jessup, 1995 **#35850**	**Quality measure (QM):** Percentage of patients with stage II or III rectal cancer receiving chemoradiotherapy **Basis of QM:** None **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** None specified, but presumably it would be survival **Intent of QM:** Not specified (aim of the study was assess cancer patient care and outcomes on a national basis) **Definition of denominator/numerator:** Denominator: Number of stage II, III rectal cancer patients in 1992 reported to the National Cancer Data Base (NCDB). Numerator: Number of above patients receiving chemoradiotherapy. **Data sources:** Registry information reported to National Cancer Data Base (NCDB) **Recommended frequency of data collection:** No recommendation	**Study population:** N: 9,465 Age: All Race: All Performance status: Not stated Other: Not stated **Geographic location:** Entire U.S. **Dates:** Calendar year 1986/7 and 1992 **Healthcare setting:** Hospitals **Results:** Not specifically stated, but can be calculated form Tables 5-13 that 46% of stage II or III patients received surgery and radiation (with or without chemotherapy).	**General comments:** This paper addresses similar issues as Beart et al. (1995; #990), and Steele Jr. (1994; #35390) except that it includes data from 1992, whereas the others have data ending in 1988 and 1990. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 2 Reliability: 2 Validity: 3 Adaptability: 5 Adequacy of risk adjustment: 1

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Temple, Hsieh, Wong, et al., 2004 **#29890**	**Quality measure (QM):** Radiotherapy rate for stage IV colon or rectal cancer **Basis of QM:** Clinical practice guideline (National Comprehensive Cancer Network Guideline) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Practice patterns of patients with stage IV cancer **Intent of QM:** Quality improvement (aim of the study was to evaluate surgical practice patterns for patients 65 years of age and older with stage IV colorectal cancer) **Definition of denominator/numerator:** Denominator: Number of Medicare-enrolled patients aged 65 and older, initially diagnosed with stage IV colon or rectal cancer in a SEER area during the years 1991-1999. Age, sex, race, ethnicity, comorbidity, year of diagnosis, and socioeconomic status were collected and data were risk-adjusted. Exclusion criteria: Cohort restricted to those with a histologic diagnosis consistent with adenocarcinoma. Diagnoses exclusively on death certificates or at autopsy were excluded, as were those in which the month of diagnosis was unknown. Patients enrolled in HMOs were excluded. Numerator: Number of patients who received radiotherapy within 4 months of diagnosis. **Data sources:** SEER data base, Medicare claims **Recommended frequency of data collection:** No recommendation	**Study population:** N = 9,011 Age: 21% 65-69; 25% 70-74; 23% 75-79; 18% 80-84; 13% ≥ 85 Sex: 48% male, 52% female Race: 84% white, 9% black, 7% other Comorbidities: 90% had 0; 5% had 1; 5% had 2+ **Geographic location:** U.S. **Dates:** 1991-1999 **Healthcare setting:** Five states and six U.S. metropolitan areas. **Results:** Only 12% of patients received palliative radiotherapy within 4 months of diagnosis (majority with rectal cancer). Patients who underwent primary cancer-directed surgery were more likely to receive radiation therapy (12% vs. 15%, p = 0.01) during their life span when compared with those in the no cancer-directed surgery group.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 3 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 3 Adaptability: 4 Adequacy of risk adjustment: 2

Evidence Table 9 – Question 2d (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Wudel Jr., Chapman, Shyr, et al., 2002 **#18640**	**Quality measure (QM):** Percentage of patients with colon or rectal cancer who had radiation therapy **Basis of QM:** None stated **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Mortality **Intent of QM:** Not specified (aim of the study was to determine the outcome of patients with colorectal cancer treated in the same city at 2 nearby medical centers, a university hospital and a city hospital, and to explore disparities in colorectal cancer outcomes between black and white patients) **Definition of denominator/numerator:** Denominator: Number of patients with a diagnosis of primary colorectal cancer between 1/1/90 and 12/21/99 in the tumor registry databases at each of 2 institutions (university hospital and a city hospital). Excluded patients who were non-white and non-black. Numerator: Number of the above patients who received radiation therapy. **Data sources:** Hospital tumor registries **Recommended frequency of data collection:** No recommendation	**Study population (university hospital = UH, city hospital = CH)** N: 565 UH; 77 CH Age: Median 69 UH, 74 CH Race: 10.6% black UH; 53% black CH Sex: 53.3% male UH; 62.7% male CH Tumor stage: UH: I 31.7% II 21.9% III 23.7% IV 22.7% CH: I 29.9% II 20.8% III 16.9% IV 32.5% Performance status: NR **Geographic location:** Nashville, TN **Dates:** 1/1/90 and 12/21/99 (retrospective review) **Healthcare setting:** University hospital, city hospital **Results:** There was no difference in the various treatment modalities identified – i.e., curative resection, chemotherapy, and radiation therapy – between institutions or ethnic groups.	**General comments:** Mortality was the primary endpoint of the study and the data for other potential QMs (% receiving “curative” surgery, chemo, or radiation therapy) are much weaker, poorly defined, and do not follow guidelines. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 3 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 2 Validity: 2 Adaptability: 4 Adequacy of risk adjustment: 1

Evidence Table 10 – Question 3 (Published Literature): *What quality-of-care measures are available and what evidence is available for measures of colonoscopic surveillance for colorectal cancer?*

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Cooper, Yuan, Chak, et al., 1999 **#27430** ***and*** **Cooper, Yuan, Chak, et al., 2000** **#35900**	**Quality measure (QM):** Percentage of patients with non-metastatic colorectal cancer who had a followup colonoscopy **Basis of QM:** Clinical practice guideline (see ref 5 [ASCRS guidelines, Dis Colon Rectum 1992]) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** No definite link to mortality – possible link to earlier detection of recurrence **Intent of QM:** Not specified (aim of the study was to understand geographic and patient variations among Medicare beneficiaries in the use of followup testing after surgery for non-metastatic colorectal carcinoma) **Definition of denominator/numerator:** Denominator: Number of patients with invasive colorectal cancer in a merged SEER-Medicare database which included only those patients > 64 years of age living in a SEER area (9 total) in 1991. Exclusion criteria: Distant metastasis or unstaged cancer, did not undergo resection, not enrolled in Medicare part B, enrolled in an HMO, died within 6 months of diagnosis, or did not have complete data in the merged database. Numerator: Number of the above subjects who underwent colonoscopy during the followup period. **Data sources:** Merged SEER and Medicare administrative (inpatient and Part B – outpatient) database **Recommended frequency of data collection:** No recommendation	**Study population:** N: 5,716 Age: Mean 74.8 ± 7.0 Race: 6% African-American Sex: 51% F Tumor stage: 50% local, 50% regional Performance status: NR **Geographic location:** 9 SEER regions (Atlanta, Detroit, Seattle-Puget Sound, San Francisco-Oakland, Connecticut, Hawaii, Iowa, New Mexico, Utah) **Dates:** Diagnosis in 1991 and followup through the end of calendar year 1994 **Healthcare setting:** Non-HMO (Medicare) **Results:** One or more procedures of interest (colonoscopy, sigmoidoscopy, abdominal CT, pelvic CT, barium enema, abdominal ultrasound, chest X-ray, liver enzymes, CEA) were performed in 87.5%of patients. Of these patients, 52.4% had colonoscopy and 35.3% had CEA. There was a significant variation in rates of testing across the 9 SEER areas. Older patients were less likely than younger patients to undergo followup colonoscopy; there were no differences by race or sex.	**General comments:** Two papers report on same cohort and study. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 4 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 2 Reliability: 3 Validity: 2 Adaptability: 2 Adequacy of risk adjustment: 2

Evidence Table 10 – Question 3 (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Keating, Landrum, Meara, et al., 2005 **#36080**	**Quality measure (QM):** Rate of complete colonoscopy pre- and perioperatively **Basis of QM:** Clinical practice guideline (not cited, but appears to be 1990 NCI Consensus Statement) **Type of QM:** (a) Structure (b) General **Outcome to which the QM is linked:** Not stated **Intent of QM:** Not specified (aim of the study was to examine associations between increases in managed care market share and changes in the quality of care delivered to cancer patients in the fee-for-service sector; breast and colorectal cancer studied) **Definition of denominator/numerator:** Denominator: Number of patients with a first diagnosis of stage III CRC in 1993-1999 in a given SEER county who had undergone surgery, were alive and enrolled in fee-for-service Medicare (parts A and B) through month 4. Numerator: Number of above patients with stage I,II III CRC in a given county who received complete pre- or perioperative colonoscopy. **Data sources:** SEER-Medicare dataset; 1990 U.S. Census **Recommended frequency of data collection:** No recommendation	**Study population:** N: 48,027 Age: 66-85+ Race: 88 white Sex: 46% male Tumor stage: NR Performance status: NR Other: Income, % high school graduates in census tract of residence, comorbidity score, market share of managed care **Geographic location:** SEER geographic regions **Dates:** 1993-1999 **Healthcare setting:** Not stated **Results:** 92.5% of patients with stage II or III CRC underwent complete pre- or perioperative colonoscopy. Increased market share of managed care in a given county resulted in significant increase in the % of patients with complete colonoscopy pre- or perioperatively.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 3 Validity: 5 Adaptability: 5 Adequacy of risk adjustment: 1

Evidence Table 10 – Question 3 (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Keating, Landrum, Meara, et al., 2005 **#36080**	**Quality measure (QM):** Rate of colonoscopy 7 to 18 months after diagnosis **Basis of QM:** Clinical practice guideline (not cited) **Type of QM:** (a) Structure (b) General **Outcome to which the QM is linked:** Generally, reduced rate of recurrence **Intent of QM:** Not specified (aim of the study was to examine associations between increases in managed care market share and changes in the quality of care delivered to cancer patients in the fee-for-service sector; breast and colorectal cancer studied) **Definition of denominator/numerator:** Denominator: Number of patients with a first diagnosis of stage I, II, or III CRC in 1993-1999 in a given SEER county who had undergone surgery, were alive and enrolled in fee-for-service Medicare (parts A and B) through month 4. Numerator: Number of above patients who received colonoscopy 7 to 18 months after diagnosis. **Data sources:** SEER-Medicare dataset; 1990 U.S. Census **Recommended frequency of data collection:** No recommendation	**Study population:** N: 48,027 Age: 66-85+ Race: 88 white Sex: 46% male Tumor stage: NR Performance status: NR Other: Income, % high school graduates in census tract of residence, comorbidity score, market share of managed care **Geographic location:** SEER geographic regions **Dates:** 1993-1999 **Healthcare setting:** Not stated **Results:** Number of patients with stage I, II, III CRC with colonoscopy 7 to 18 months after diagnosis was 53%. Increased market share of managed care in a given county resulted in no significant change in colonoscopy during months 7 to 18 after diagnosis.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 3 Validity: 5 Adaptability: 5 Adequacy of risk adjustment: 1

Evidence Table 10 – Question 3 (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
LaFata, Johnson, Ben-Menachem, et al., 2001 **#22140**	**Quality measure (QM):** Percentage of patients with colorectal cancer who received a posttreatment colonoscopy **Basis of QM:** Clinical practice guideline (ASCRS, Dis Col Rectum 1992; Desch [ASCO] 1999; NCCN, Oncology 1996; Winawer [AGA, ACG, et al.], Gastroenterology 1997) **Type of QM:** (a) Process; (b) General **Outcome to which the QM is linked:** No definite link to mortality – possible link to earlier detection of recurrence **Intent of QM:** Not specified (aim of the study was to examine differences in receipt of colorectal cancer surveillance care by race and income) **Definition of denominator/numerator:** Denominator: Number of patients diagnosed with colorectal cancer between 1/1/1990 and 12/31/1995 (identified in the tumor registry maintained by a large multispecialty group in Southeast Michigan) who were also enrolled in the affiliated HMO at the time of diagnosis, aged ≥ 40 at time of diagnosis, treated with curative intent (as determined by ICD-9 and CPT procedure codes for endoscopic or surgical resection). Exclusion criteria: Ulcerative colitis, Crohn's disease, familial polyposis or IBD (by diagnostic encounter ICD-9 codes). Numerator: Number of above patients who received a colonoscopy posttreatment (defined as 2 months to 8 years postresection with curative intent) **Data sources:** Tumor registry of a large multi-specialty practice, health plan membership files, HMO administrative and claims databases (including encounter, hospitalization, pharmacy) state vital	**Study population:** N: 251 Age: Mean 65 Race: 157 white, 94 minority Sex: 62% male Tumor stage: I 28%, II 36%, III 36% Performance status: NR **Geographic location:** Southeast Michigan **Dates:** 1/1/1990-12/31/1995 for diagnosis plus 18 months of followup to 12/31/1997 **Healthcare setting:** HMO **Results:** Whites were more likely than non-whites to receive a colon exam. The likelihood of receiving a colon exam also increased with median household income.	**General comments:** None **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 4 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 4 Adaptability: 3 Adequacy of risk adjustment: 1

Evidence Table 10 – Question 3 (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
	statistics, SSA Death Index **Recommended frequency of data collection:** No recommendation		
Retchin and Brown, 1990 **#7970**	**Quality measure (QM):** Percentage of colorectal cancer patients having a surveillance colonoscopy (or sigmoidoscopy) after surgery **Basis of QM:** Other (physician advisory panels were selected to develop quality-of-care criteria for the outpatient detection, surgical management, and postoperative followup of colorectal cancer) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** None stated **Intent of QM:** Not specified (aim of the study was to compare the quality of care received by Medicare patients with colorectal cancer in HMOs vs. fee-for-service [FFS] plans) **Definition of denominator/numerator:** Denominator: Number of Medicare patients with colorectal cancer from either an HMO or FFS plan who had undergone surgery. Numerator: Number of above who had a colonoscopy or sigmoidoscopy within 6 months after surgery. **Data sources:** Medicare claims files and HMO plan data **Recommended frequency of data collection:** No recommendation	**Study population:** N: 119 HMO and 137 FFS patients Age: 72.3 years for HMO, 70.1 years for FFS Race: 95.2% white in HMO, 86.7% white in FFS Sex: 41.3% female in HMO, 50.6% female in FFS Tumor stage: All Performance status: NR **Geographic location:** "4 geographic areas" **Dates:** January 1983-March 1986. **Healthcare setting:** Hospitals/HMOs **Results:** 22.7% of HMO patients and 22.6% of FFS patients had a colonoscopy in the first 6 months after surgery.	**General comments:** The data for this paper comes from prior to 1990. This paper has a number of potential quality measures that physician advisory panels had chosen for study, but none of them are validated and many are debatable as to whether they constitute useful determinants of quality. A list of these measures includes: questions asked during the medical history (statement of the presence of melena, statement of family history, statement of past GI diseases), physical exam (abdominal exam, digital rectal exam, fecal occult blood test), lab tests (hematocrit, chemistries, CEA, LFTs), imaging (chest X-ray, endoscopy), procedures (laparotomy), and followup (CEA, hemoccult, abdominal and lymph node exam, colonoscopy, chest X-ray). Of these, the surveillance colonoscopy seems to have the greatest face validity and so was included here. The time from symptoms until diagnosis of colon cancer was also evaluated and found to be longer for the HMO patients. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 4 - Usability: 5 - Scientific acceptability (five criteria): Precise specifications: 5 Reliability: 5 Validity: 4 Adaptability: 5 Adequacy of risk adjustment: NA

Evidence Table 10 – Question 3 (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring
Rulyak, Mandelson, Brentnall, et al., 2004 **#31170**	**Quality measure (QM):** Percentage of patients with local or regional CRC who had colon surveillance after diagnosis **Basis of QM:** Clinical practice guideline (Fleischer [AGA/ASGE], JAMA 1989; Desch [ASCO], J Clin Onc 1999; NCCN 1996; Can Soc of Surg Oncol and the Can Soc of Colon and Rectal Surgeons, Can J Surg 1997; ACS/AGA, CA Cancer Journal for Clinicians 1997; Winawer, Gastroenterol 1997; Winawer, Gastroenterol 2003; ASCO, J Clin Oncol 2000) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** No definite link to mortality – possible link to earlier detection of recurrence **Intent of QM:** Not specified (aim of the study was to investigate the utilization of endoscopic surveillance procedures in a population-based cohort of patients with colon or rectal cancer) **Definition of denominator/numerator:** Denominator: Number of patients who were members of GHC and diagnosed with colon or rectal cancer 1993-1999. Exclusion criteria: Stage IV disease, unknown stage, not treated with resection (surgical or endoscopic), s/p total proctocolectomy, survival < 6 months, IBD. Numerator: Number of the above patients who had colonoscopy or flexible sigmoidoscopy + barium enema (FSBE) after diagnosis. **Data sources:** Administrative claims data from HMO, HMO pathology database, SEER database for Seattle **Recommended frequency of data collection:** No recommendation	**Study population:** N: 1,002 Age: < 50 8.7% 50-59 13.3% 60-69 24.4% 70-79 3506% ≥ 80 18.0% Race: 92.7% white, 3.5% African-American, 3.8% other Sex: 50.3% M Tumor stage: 0 8.7% I 32.5% II 33.8% III 25.0% Performance status: NR **Geographic location:** Washington state **Dates:** Diagnosis between 1/1993-12/1999, followup at 18 months and 5 years **Healthcare setting:** HMO **Results:** Colon exams were performed in 61% of patients within 18 months of diagnosis, and in 80% within 5 years of diagnosis. Patients over 80 years of age and those with rectal cancer were less likely to undergo surveillance. Patients of higher socioeconomic status, or who were married, were more likely to undergo colon surveillance. There was a trend toward lower utilization of colon surveillance among African-American patients.	**General comments:** Indication for colonoscopy could have been investigation of symptoms rather than surveillance. **Rating of quality measure as presented in this study** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 4 - Usability: 4 - Scientific acceptability (five criteria): Precise specifications: 4 Reliability: 3 Validity: 4 Adaptability: 3 Adequacy of risk adjustment: 2

Evidence Table 11 – Question 3 (Grey Literature): *What quality-of-care measures are available and what evidence is available for measures of colonoscopic surveillance for colorectal cancer?*

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Institute of Medicine report, 2005 **#36680**	**Quality measure (QM):** Followup colonoscopy after treatment for Stage I to Stage III colorectal cancer **Basis of QM:** Clinical practice guideline (National Comprehensive Cancer Network [NCCN] guidelines) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** reduction in CRC mortality rate **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of stage I to stage III colorectal cancer cases. Numerator: Number of above cases with a colonoscopy within 1 year of surgery. **Data sources:** Surveillance, Epidemiology, and End Results Program (SEER)-Medicare dataset, special studies of medical records **Recommended frequency of data collection:** No recommendation	**General comments:** Local practice patterns and patient-related factors affect the use of endoscopic procedures. Key references cited: Cooper et al., 2000 Fisher et al., 2003 NCCN, 2004 Rulyak et al., 2004 Winawer et al., 2003 **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 11 – Question 3 (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
National Committee for Quality Assurance, 2005 **#36580**	**Quality measure (QM):** Percent of colon cancer cases (all stages) that received a followup colonoscopy within 36 months of surgical treatment **Basis of QM:** Clinical practice guideline (National Comprehensive Cancer Network [NCCN] guidelines) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Improved health status **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of patients with colon cancer surgery in a 12-month period. Numerator: Number of above patients who received a colonoscopy exam within 36 months of surgical treatment. **Data sources:** Cancer registry, claims data **Recommended frequency of data collection:** No recommendation	**General comments:** None **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 11 – Question 3 (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
National Committee for Quality Assurance, 2005 **#36580**	**Quality measure (QM):** Percentage of rectal cancer cases (all stages) that received a postsurgical endoscopic exam within 12 months postsurgery **Basis of QM:** Clinical practice guideline (National Comprehensive Cancer Network [NCCN] guidelines) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** Improved health status **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of patients with rectal cancer surgery (all stages) over a 12-month period. Numerator: Number of above who received an endoscopic exam within 12 months postsurgical treatment. **Data sources:** Cancer registry, claims data **Recommended frequency of data collection:** No recommendation	**General comments:** Long-term followup may not be feasible. **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 12 – Question 4 (Published Literature): *What measures are available and what evidence is available for measures to assess the adequacy and completeness of documentation of pathology, operative, and chemotherapy reports?*

Study

Wei, Miller, Woosley, et al., 2004

#31910

Characteristics of Quality Measure

Quality measure (QM): Adherence to individual Association of Directors of Anatomic and Surgical Pathology (ADASP) recommended items in pathology reports

Basis of QM: Clinical practice guideline (Association of Directors of Anatomic and Surgical Pathology [ADASP] recommendations)

Type of QM:
(a) Process
(b) Technical

Outcome to which the QM is linked:

Intent of QM: Quality improvement (aims of the study were to describe the completeness of pathology reporting for colon carcinoma, evaluate potential variation in reporting by laboratory type or hospital case volume, and identify areas for improvement using the recommendations of the ADASP)

Definition of denominator/numerator:
Denominator: Number of subjects with surgically resected colon carcinoma of tumor stages T2-T4 with available surgical pathology reports

Numerator:
(a) Number of above subjects with reports that described how specimens were received
(b) Number of above subjects with reports that described how specimen was identified
(c) Number of above subjects with reports that described part included
(d) Number of above subjects with reports that described tumor site
(e) Number of above subjects with reports that described proximity to nearest margin
(f) Number of above subjects with reports that described macroscopic subtype
(g) Number of above subjects with reports that described tumor dimensions

Testing of Quality Measure

Study population:
N: 438 reports
20 Community hospital labs: 264 reports
5 Teaching hospital labs: 115 reports
6 Contract hospital labs: 59 reports
6 Low-volume institutions: 31 reports
9 Medium-volume institutions 126 reports
10 High-volume institutions: 222 reports

Geographic location: North Carolina

Dates: 1997-2000

Healthcare setting: Pathology laboratories: contract, teaching hospitals, community hospital

Results: (Global scores were not reported)

Low-volume hospital labs were less likely to report some items compared with high-volume labs

Macro-scopic description	Hospital Volume		
	High (n = 222)	Medium (n = 126)	Low (n = 31)
How specimen was received	76.0	67.5	45.2
Specimen identified	73.9	76.2	32.3
Part included	100	100	100
Tumor site	100	100	93.6
Proximity to nearest margin	96.4	91.3	93.6

(Data table continued on next page)

Comments/Quality Scoring

General comments:
Colon and rectal carcinoma data have not been separated. Labs may be utilizing other protocols for reporting. When quality is being compared it would be essential to understand if the same protocols are being used in the albs being evaluated. Alternatively, elements of the protocol could be compared instead of the entire protocol, and items that represent significant leverage points could be selected for comparisons.

Rating of quality measure as presented in this study (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal):
- Importance: 5
- Usability: 5
- Scientific acceptability (five criteria):
  - Precise specifications: 4
  - Reliability: 5
  - Validity: 5
  - Adaptability: 5
  - Adequacy of risk adjustment: 5

Evidence Table 12 – Question 4 (Published Literature) – continued

<table>
<tr><th>Study</th><th>Characteristics of Quality Measure</th><th>Testing of Quality Measure</th><th>Comments/Quality Scoring</th></tr>
<tr>
<td></td>
<td>(h) Number of above subjects with reports that described macroscopic depth of penetration
(i) Number of above subjects with reports that described appearance of serosa adjacent to the tumor
(j) Number of above subjects with reports that described status of residual bowel
(k) Number of above subjects with reports that described histologic type
(l) Number of above subjects with reports that described histologic grade
(m) Number of above subjects with reports that described depth of infiltration
(n) Number of above subjects with reports that described lymph node metastases
(o) Number of above subjects with reports that described involvement of margins

Data sources: Pathology reports

Frequency of data collection: No recommendation</td>
<td>
<table>
<tr><th rowspan="2">Macro-scopic description</th><th colspan="3">Hospital Volume</th></tr>
<tr><th>High (n = 222)</th><th>Medium (n = 126)</th><th>Low (n = 31)</th></tr>
<tr><td>Macro-scopic subtype</td><td>99.6</td><td>100</td><td>100</td></tr>
<tr><td>Tumor dimensions</td><td>94.6</td><td>96.0</td><td>87.1</td></tr>
<tr><td>Macro-scopic depth of penetration</td><td>83.8</td><td>89.6</td><td>64.5</td></tr>
<tr><td>Appearance of serosa adjacent to tumor</td><td>53.9</td><td>57.9</td><td>51.6</td></tr>
<tr><td>Appearance of residual bowel</td><td>72.1</td><td>78.6</td><td>71.0</td></tr>
<tr><td>Histologic information</td><td></td><td></td><td></td></tr>
<tr><td>Histologic type</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>Histologic grade</td><td>97.7</td><td>99.2</td><td>96.8</td></tr>
<tr><td>Depth of infiltration</td><td>97.3</td><td>98.4</td><td>96.8</td></tr>
<tr><td>Lymph node metastases</td><td>99.1</td><td>99.2</td><td>100</td></tr>
<tr><td>Involvement of margins</td><td>97.3</td><td>93.7</td><td>64.5</td></tr>
</table>

Community labs were less likely to report several items compared with contract or medical school-affiliated labs.

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Evidence Table 12 – Question 4 (Published Literature) – continued

Study	Characteristics of Quality Measure	Testing of Quality Measure	Comments/Quality Scoring

Macroscopic description	Lab Type		
	Teaching (n = 115)	Contract (n = 59)	Community (n = 264)
How specimen received	68.7	54.2	71.5
Specimen identified	83.5	72.9	65.9
Part included	100	100	100
Tumor site	100	98.3	99.2
Proximity to nearest margin	97.4	88.1	93.2
Macroscopic subtype	100	96.6	99.6
Tumor dimensions	97.4	91.5	93.2
Macroscopic depth of penetration	90.4	66.1	81.4
Appearance of serosa adjacent to tumor	57.4	39.0	48.5
Appearance of residual bowel	76.5	67.8	73.1
Histologic information			
Histologic type	100	100	100
Histologic grade	98.3	96.6	98.1
Depth of infiltration	99.1	100	97.0
Lymph node metastases	100	100	98.9
Involvement of margins	95.7	96.6	92.4

Evidence Table 13 – Question 4 (Grey Literature): *What measures are available and what evidence is available for measures to assess the adequacy and completeness of documentation of pathology, operative, and chemotherapy reports?*

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Colon Cancer Workgroup, 2003 **#36650**	**Quality measure (QM):** Pathology reporting of the surgical specimen is concordant with the guidelines of the College of American Pathologists (CAP), including reporting of number of nodes resected, number of nodes positive, tumor characteristics (grade, depth of invasion), mucosal and radial margins **Basis of QM:** Clinical practice guideline (National Comprehensive Cancer Network [NCCN] guidelines) **Type of QM:** (a) Process (b) Technical **Outcome to which the QM is linked:** Pathology staging (and subsequent treatment planning and survival) **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of patients having colon cancer surgery. Numerator: Number of above patients with pathology reports in concordance with CAP guidelines. **Data sources:** Pathology, surgical reports **Recommended frequency of data collection:** No recommendation	**General comments:** None **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 13 – Question 4 (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Institute of Medicine, 2005 **#36680**	**Quality measure (QM):** Pathology reports on colorectal cancer surgical specimens that include College of American Pathologists (CAP) data elements as required by the American College of Surgeons' Commission on Cancer **Basis of QM:** Clinical practice guideline (CAP, Commission on Cancer) **Type of QM:** (a) Structure (b) General **Outcome to which the QM is linked:** Pathology staging (and subsequent treatment planning and survival) **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of pathology reports on colorectal cancer surgical specimens. Numerator: Number of above reports that include CAP data elements as required by the Commission on Cancer. **Data sources:** CAP, Commission on Cancer, baseline special studies **Recommended frequency of data collection:** No recommendation	**General comments:** Measurement goal should be 100 percent. Findings should be reported in the aggregate and individually by pathology laboratory. Key references cited: Compton (CAP), 2004 Commission on Cancer, 2003 Compton, 2003 Stocchi et al., 2001 **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

Evidence Table 13 – Question 4 (Grey Literature) – continued

Study	Characteristics of Quality Measure	Comments/Quality Scoring
Institute of Medicine, 2005 **#36680**	**Quality measure (QM):** Colorectal cancer cases in which pathologic staging preceded chemotherapy and radiation treatment **Basis of QM:** Clinical practice guideline (American College of Radiology, American Society of Clinical Oncology, Commission on Cancer, National Comprehensive Cancer Network) **Type of QM:** (a) Process (b) General **Outcome to which the QM is linked:** **Intent of QM:** Quality improvement **Definition of denominator/numerator:** Denominator: Number of new colorectal cancer cases with chemotherapy or radiation treatment. Numerator: Number of above cases with medical chart documentation of pathologic stage before chemotherapy or radiation is initiated. **Data sources:** Medical records **Recommended frequency of data collection:** No recommendation	**General comments:** None Key references cited: Compton (CAP), 2004 NCCN, 2004 American College of Radiology, 1999 Commission on Cancer, 2003 Greene et al., 2002 **Rating of quality measure as presented** (scale of 1-5, where 1 = poor, 3 = moderate, 5 = ideal): - Importance: 5 - Usability: 5 - Scientific acceptability (two criteria): Precise specifications: 4 Adaptability: 4

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Appendix F: Criteria Used To Assign Ratings to Quality Measures

(1) Assigning the rating for the *Importance* of a measure:
We accomplished this in two steps.
Step 1: We calculated the average of the scores assigned for each of the two criteria, Importance and Usability, for a measure for a given study.
Step 2: We assigned the highest average score allotted to the measure amongst all the studies that utilized it as the "I" rating for the measure.

(2) Assigning the rating for the *Scientific Acceptability* of a measure:
We accomplished this in two steps.
Step 1: We calculated the average of the scores assigned for each of the five criteria for scientific acceptability (precise specifications, validity, reliability, adaptability, adequacy of risk adjustment) for a measure for a given study.
Step 2: The highest average score for scientific acceptability, amongst all the studies that utilized it, was assigned as the "S" rating for the measure.

(3) Assigning the rating for the *Testing* of a measure:
We accomplished this in a multi-step process. This rating was based on (a) the number of studies that utilized this measure and (b) the extent to which these studies were scientifically acceptable (their "S" rating). Table 1 below summarizes the criteria used to combine the two concepts.

Table 1. Assigning the "T" rating

Considering all the studies utilizing the quality measure, if:	Then the assigned T rating was:
The highest average scientific acceptability score of the measure in all the studies was 1 or 2	1
The highest average scientific acceptability score of the measure was 3, and there was only one study with that score	2
The highest average scientific acceptability score of the measure in two or more studies was 3	3
The highest average scientific acceptability score of the measure was 4, and there was only one study with that score	4
The highest average scientific acceptability score of the measure was 4, and there were two or more studies with that score, *OR* the highest scientific acceptability score of the measure in at least one study was 5	5

In the following example, the quality measure "percentage of patients with stage III colon cancer receiving chemotherapy", was assigned a hypothetical quality rating of $I_5S_4T_4$ because of the scores attached to the measure in the two studies that the measure was abstracted from (Table 2):

Table 2. Example of Quality Measure Rating Algorithm*

Percentage of patients with stage III colon cancer receiving chemotherapy	important	usable	Importance rating or "I" average	precise specs	reliable	valid	adaptable	risk adjusted	Scientific acceptability or "S" rating average
Study 1	5	5	5	5	5	5	5	1	4
Study 2	4	4	4	4	4	3	3	3	3

* The data in this table are for illustrative purposes only and do not reflect actual ratings.

In this example, the overall Importance rating for "percent of patients with stage III colon cancer receiving chemotherapy, or "I" rating, would be a "5" because "5" represents the highest average score for the measure across both studies (studies 1 and 2) involved. The rating for Scientific Acceptability for this measure, or the "S" rating, would be a "4" because, again, this represents the highest average score across both studies involved.

The Testing, or "T" rating, would be a "4" because "4" was the highest average Scientific Acceptability score, and there was only one study that attained a Scientific Acceptability score of "4" (the other study had a Scientific Acceptability rating of "3").