Quality of Care Issues in Colorectal Cancer

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Abstract

Colorectal cancer is a common, detectable, and treatable malignancy. Given the aging of the population, the number of patients diagnosed with colorectal cancer will likely increase; thus, efforts to improve the quality and delivery of appropriate care to patients with colorectal cancer are needed. The overarching goal of this article is to summarize recent efforts to evaluate and improve the quality of colorectal cancer care through the use of selective referral, quality performance measures, and assessment of outcomes. First, we provide a framework for quality of care assessment, including a discussion of the structural, process, and outcome components of care for colorectal cancer. Second, we discuss the current level of assessment of colorectal cancer care quality, highlighting four potential targets for quality improvement: increased provider volume for colorectal cancer resection, process-based quality measures for colorectal cancer care (including measures specific to colorectal cancer surgery), data collection and feedback programs for colorectal cancer care, and evaluation of health-related quality of life in patients with colorectal cancer. Further research is needed to evaluate both the implementation and effectiveness of these quality improvement strategies for improving outcome in patients with colorectal cancer.

Why Focus on the Quality of Colorectal Cancer Care?

Colorectal cancer is the third most common cause of new cancer diagnosis and the second most common cause of cancer death (1). In 2006, an estimated 106,680 new cases of colorectal cancer were diagnosed, with 55,170 deaths (1). Yet, early detection of colorectal cancer is possible with current screening techniques. Moreover, even in colorectal cancer that is not detected early, multiple chemotherapeutic agents are currently available for adjuvant treatment of advanced disease. Colorectal cancer is common, detectable, and treatable; thus, it is an ideal cancer for both quality assessment and improvement.

Colorectal cancer is primarily a disease of the elderly. Sixty-seven percent of patients with colorectal cancer are older than 65 years, and the median age of those afflicted is 71 years (2, 3). According to the U.S. Census Bureau, individuals older than 65 years are one of the fastest growing segments, with an expected increase of >50% by the year 2020 (4, 5). Given these data, an increase in the number of colorectal cancer diagnoses, which could strain health care resources, is possible. Because a comparable increase in the number of providers is unlikely, efforts must be made to improve both the quality and efficiency of care. The overarching goal of the current article is to summarize recent efforts to evaluate and improve the quality of colorectal cancer care through selective referral, quality performance measures, and outcome assessment.

What is Quality of Care?

The Institute of Medicine provides a commonly cited definition of quality of care: the degree to which health services achieve a level of care that is desired by health services and consistent with current professional knowledge (6). Although succinct and inclusive, this definition does not easily discern whether a given provider or hospital is providing quality care for colorectal cancer. Perhaps a more practical definition of quality of care would be the degree to which health services achieve a level of care deemed adequate by evidence-based quality measures of the structure, process, and outcomes of care. This proposed definition suggests that providers would be compared with evidence-based quality measures, which are based on the three components of the Donabedian quality of care model: structure, process, and outcome (7).

Structural components of care are characteristics of the hospital or provider. An example specific to colorectal cancer is an annual volume of sphincter-sparing operations. With the exception of volume, most studies have had difficulty in consistently linking structural variables to patient level outcome. However, structural quality measures have received significant attention, in part due to the Leapfrog group and the relation of high volume to improved outcomes (8).

Process components of care are the interactions between a provider (i.e., physician) and patient. An example specific to colorectal cancer is providing timely postoperative chemotherapy to patients with stage III colon cancer. The main issue with choosing process measures is identifying those that are linked to improved outcomes. However, the advantage (over outcome
measures) is that they do not require risk adjustment and is, thus, a fair way to judge providers, regardless of case mix.

Providers are most familiar with outcome components of care (e.g., morbidity and mortality). An example specific to colorectal cancer is local tumor recurrence rate. Although outcomes represent the end-goal of quality care, it is not clear whether such measures are useful in judging individual providers. For example, issues of small sample size and inadequate risk adjustment have led to significant provider resistance.

### Does Increased Provider Volume Improve Outcome in Colorectal Cancer?

The volume to outcome relationship has been frequently proposed as a structural quality measure in surgery. This movement has been led by the Leapfrog group, which promoted evidence-based hospital referral, with minimum annual case-load standards at the hospital level for five different complex surgical procedures: coronary artery bypass grafting ($\geq 450$), percutaneous coronary intervention ($\geq 2400$), abdominal aortic aneurysm repair ($\geq 50$), pancreaticoduodenectomy ($\geq 11$), and esophagectomy ($\geq 13$; ref. 9). The Institute of Medicine did a systematic review of 88 studies published since 1980 on the volume to outcome relationship for eight surgical procedures. Despite suboptimal study quality, a positive volume to outcome relationship was held in 75% of studies and across all eight procedures (10).

A systematic review by Halm et al. (11) of 20 different surgical procedures again found a positive volume to outcome relationship in ~70% of 135 studies reviewed. Ten studies specifically evaluated colorectal cancer surgery. Forty percent of hospital volume studies and 80% of surgeon volume studies showed a statistically significant positive relationship between colorectal cancer surgery provider volume and outcomes. However, unlike the large difference in median mortality between high-volume and low-volume providers of pancreaticoduodenectomy (13%), as an example, the absolute difference in median mortality for colorectal cancer surgery was only 1.9% (11). The mechanism behind this relationship is unknown. Birkmeyer et al. (12–15) have published multiple studies supporting surgeon and hospital volume as a predictor of colorectal cancer surgery outcome, but were unable to identify differences in care between high-volume and low-volume providers that explained the observed differences in outcome in a recent study using Medicare claims data.

Although the volume to outcome relationship in colorectal cancer surgery seems smaller in magnitude than that in other procedures, consideration must be given as to whether regionalization of colorectal cancer care is an appropriate mechanism for quality improvement. Regionalization to high-volume providers may be inefficient at reducing deaths, as the baseline mortality rate for elective colorectal cancer surgery is low (1.2%) using the 1996 Nationwide Inpatient Sample. In contrast, the baseline mortality rate for emergent surgery is 4.5%, suggesting that improved screening to detect colorectal cancer before obstruction or perforation would have a greater effect on outcome than regionalization (16). Furthermore, regionalization may increase existing racial and economic disparities in quality of care, as minorities and those with Medicaid or no insurance are less likely to receive care at high-volume hospitals than Whites and privately insured individuals (17).

Regionalization of colorectal cancer surgery is also probably not economically or logistically practical for patients and hospitals in rural areas (18, 19). Instead of regionalization, perhaps the focus should be on process-based quality measures that can potentially improve colorectal cancer care at all hospitals.

### What Potential Process-Based Quality Measures Exist in Colorectal Cancer Care?

Although certain groups, such as the Centers for Medicare and Medicaid Services, have not yet addressed colorectal cancer care—specific quality, measures do exist. The National Quality Forum/American College of Surgeons/Commission on Cancer and National Comprehensive Cancer Network/American Society of Clinical Oncology have identified four colorectal cancer measures. Three of the measures deal with adjuvant therapy: receipt of postoperative chemotherapy for stage II-III rectal cancer; preoperative or postoperative radiation for stage II-III rectal cancer; and adjuvant chemotherapy for stage III colon cancer. One of the measures is surgery/pathology-specific: ≥12 lymph nodes should be taken during curative stage II-III colorectal cancer surgery, if the patient has not received preoperative adjuvant therapy (20).

Colorectal cancer has also been the subject of several large studies addressing quality of care. For example, American Society of Clinical Oncology and others established the National Initiative on Cancer Care Quality to develop quality of cancer care measures for breast and colorectal cancer (21, 22). The National Initiative on Cancer Care Quality project team developed 25 process-based quality measures, spanning four domains of care: diagnostic evaluation (10 measures), surgery (4 measures), adjuvant therapy (10 measures), and surveillance (1 measure).

After development of the National Initiative on Cancer Care Quality measures, compliance was determined using multiple sources (e.g., hospital cancer registries and patient surveys) in a sample of stage II-III colon cancer survivors in five metropolitan areas ~4 years after diagnosis. Overall compliance was 78% for all 25 measures. By domain, compliance was 87% for diagnostic evaluation, 93% for surgery, 64% for adjuvant therapy, and 50% for surveillance. Of interest, these figures are much higher than the 55% compliance rate found in most types of care (23). Potential causes of higher compliance may be the urgency of a cancer diagnosis (beyond chronic conditions, such as diabetes) and the multidisciplinary approach to cancer treatment. However, selection bias may have increased compliance, as the National Initiative on Cancer Care Quality study only examined 4-year survivors, and it is possible that those who died received lower quality care.

Similarly, the National Cancer Institute has funded the Cancer Care Outcomes Research and Surveillance consortium to conduct an observational study evaluating the reasons for differences in cancer treatment and outcomes in patients with colorectal or lung cancer (24). The study will be novel in that it will use multiple data sources, including patient, provider, and medical record. Structural, process, and outcome factors will be examined. Ultimately, the Cancer Care Outcomes Research and Surveillance consortium will provide much needed population-based data regarding patient experience and outcome across the continuum of cancer care (25).
What Potential Quality Measures Exist in Colorectal Cancer Surgery?

Although surgical resection is currently the mainstay of curative treatment in colorectal cancer, most previously developed measures address adjuvant therapies. However, a systematic review of the surgical literature yielded two articles that provide a comprehensive view of colorectal cancer surgical quality (26, 27). In both articles, expert opinion and a systematic review of the literature were used to identify candidate quality indicators. More specifically, Gagliardi et al. (27) used a three-step modified Delphi approach, whereas McGory et al. (26) used the RAND/University of California-Los Angeles appropriateness method (28, 29) to determine the validity of candidate indicators using colorectal cancer experts.

Gagliardi and colleagues identified 45 candidate indicators, of which 37 (82%) were considered valid by the panel. McGory and colleagues identified 142 candidate indicators, of which 92 (65%) were considered valid. In the former study, panelists were asked to rank candidate indicators; the investigators reported only the top 15 prioritized quality indicators as their final recommendation for improving the quality of colorectal cancer surgery. Although such reporting does present a parsimonious set of quality indicators, the detailed list of quality indicators presented in the latter study is comprehensive and encompasses the entire perioperative time period, including preparation of the patient for surgery, intraoperative issues, and postoperative processes of care. In that regard, the focus of the quality indicators is an interesting difference between the two studies.

Gagliardi and colleagues focused on four outcome measures (e.g., 30-day mortality) and four measures evaluated at the province level (e.g., 5-year survival). In contrast, McGory and colleagues focused on process and structural measures and did not include any outcome measures. The latter investigators presented six quality domains spanning the 92 quality indicators in the latter study is comprehensive and encompasses the entire perioperative time period, including preparation of the patient for surgery, intraoperative issues, and postoperative processes of care. In that regard, the focus of the quality indicators is an interesting difference between the two studies.

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Data Collection and Feedback Programs

Because provider quality is measured by outside entities, programs that allow providers to track and improve their own performance are now available. Two such programs are American Society of Clinical Oncology's Quality Oncology Practice Initiative and American College of Surgeons’s Electronic Quality Improvement Packets (30, 31). Quality Oncology Practice Initiative is an oncologist-led, practice-based system of quality assessment, wherein its goal is to promote excellence in cancer care by helping practices create a culture of self-examination and improvement. Selected quality measures for colorectal cancer are used to determine the quality of a practitioner’s care and identify possible areas for improvement. A pilot study (32) conducted in seven oncology groups used two rounds of medical record reviews to evaluate Quality Oncology Practice Initiative. The results showed that participants universally found Quality Oncology Practice Initiative to be helpful; significant variation in quality measures across providers was noted, and variation in quality measure adherence decreased between survey rounds.

American College of Surgeons Commission on Cancer recently initiated the Electronic Quality Improvement Program, a data audit and feedback program that uses an existing electronic system to communicate data for quality improvement. American College of Surgeons analyzes data received from 1,400+ Commission on Cancer hospitals and sends back the tabulated results. The performance measures discussed above have been used, giving participating hospitals an evaluation of their performance on each measure. Importantly, hospitals are given feedback not only on measure performance, but also on the quality of raw data submitted (e.g., are there areas of missing data?). Similar to Quality Oncology Practice Initiative, preliminary findings have shown variation in concordance rates across measures, but importantly, feedback of the data has led to improvement in both quality of care (i.e., concordance) and quality of data being resubmitted. Upcoming plans for Electronic Quality Improvement Packets include a rapid case ascertainment system, such that data audit, analysis, and feedback are done within 4 to 6 months of diagnosis, potentially leading to real-time improvement of ongoing care.

Colorectal Cancer Patient-Reported Outcome

Although providers predominantly focus on quality measures that ultimately lead to increased quantity of life, patients are increasingly concerned with quality of life. In fact, studies have shown that patients are willing to trade quantity for quality of life (33, 34). Thus, another realm of quality for colorectal cancer care is health-related quality of life (HRQOL) in cancer survivors. At present, there are an estimated 10 million adult cancer survivors in the United States, and given that the rate of cancer deaths is decreasing faster than the rate of new cancer diagnoses, the number is expected to increase (35). A systematic review of the literature yielded three studies on HRQOL in colorectal cancer survivors. A retrospective study of 307 women in Wisconsin found that decreased HRQOL was associated with increased age, comorbidities, and weight; however, this finding was comparable in similarly aged women in the population who did not have colorectal cancer, suggesting that age and medical conditions affect HRQOL more than does colorectal cancer (36). Similarly, Wilson et al. (37) showed that preoperative performance status, stoma, diarrhea, constipation, and age of ≥65 years were all negatively associated with HRQOL. A study using both generic and disease-specific surveys compared 158 male veterans at a single institution at least 6 months after three types of colorectal surgery (benign, malignant, and malignant with adjuvant therapy; ref. 38). Veterans undergoing benign surgery had lower HRQOL than did those undergoing cancer surgery; additionally, no difference was noted between cancer patients treated with surgery alone and those treated with surgery and adjuvant therapy.

Preoperative HRQOL in colorectal cancer patients has also been shown to affect postoperative prognosis. Two prospective
single-center studies showed that lower preoperative HRQOL is associated with longer length of stay and increased complications (39, 40). Even in patients with metastatic disease, self-reported HRQOL acts as a prognostic survival measure while controlling for biomedical variables (41).

Conclusion

Colorectal cancer is a common malignancy that can be effectively treated with surgery and adjuvant therapy. Current research efforts on colorectal cancer quality include evaluation of the volume to outcome relationship, development of quality measures specific to colorectal cancer care, feedback performance of these measures to providers, and evaluation of HRQOL in colorectal cancer survivors. Future research efforts should evaluate the implementation of colorectal cancer-specific quality measures, the effect of quality improvement programs on colorectal cancer outcomes and survivor quality of life, and the effect of payer-based incentives for providers of colorectal cancer care, such as pay-for-performance.

References

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Discussion: Surgical Issues in Colon and Rectal Cancers

Dr. Anton Bilchik: How does one know whether to radiate a patient where the pathology/surgical report says rectosigmoid or sigmoid/rectal cancer?

Dr. Michael Stamos: It is a somewhat arbitrary decision. The first and most obvious indication is tumor bulkiness and/or sphincter salvage. The Japanese investigators use the relationship to the sacral bones, which is fixed. If we could ever get to the point of agreeing on some bony landmarks (e.g., where the mesorectum begins), we would be able to speak more accurately.

Dr. Heidi Nelson: It would be nice to have a universal metric. We have endoscopic, intraoperative, and peritoneal reflection. The Japanese investigators use the relationship to the sacral bones, which is fixed. If we could ever get to the point of agreeing on some bony landmarks (e.g., where the mesorectum begins), we would be able to speak more accurately.

Dr. Lee Rosen: Would this require data collection or just agreement?

Dr. Nelson: Validation is necessary.

Dr. Christopher Willett: It's very important to do a rigid proctoscopy on a patient with rectal cancer to define the location of the lesion from the anal verge.

Dr. Bilchik: What landmarks do you use, Dr. Lynch, and are your surgeons mostly happy with your description of distance from the anal verge?

Dr. Patrick M. Lynch: All surgeons at M. D. Anderson do a rigid proctoscopy.

Dr. Robert W. Beart, Jr.: I am most concerned about lateral vessels coming off of the rectum. Would MRI or some other technique provide lateral lymph node evaluation?

Dr. Carolyn C. Compton: From the standpoint of the pathologist, I believe that it is important for surgeons to have some standardized method of communicating where the peritoneal reflection is (and is not) on the specimen. Once the specimen is out of the patient and out of the operating room, it is not always easy to locate the circumferential margin. If the surgeon could at least put a stitch on the peritoneal reflection so that the nonperitonealized area of the specimen could be more easily identified, the quality of the pathology examination would be greatly improved.

Dr. Bilchik: Our Japanese colleagues have spent a lot of time describing nodal compartments when they perform a rigid proctoscopy on a patient with rectal cancer to define the level of the tumor in relation to surrounding structures.

Dr. Lee Rosen: And if you have both?

Dr. Nelson: It's operator dependent and still an art form. Who's reading it? Who is the best person?

Dr. Rosen: To say that one or the other is necessary is a good point. What percentage of patients receives neither?

Dr. Nelson: When I ask surgeon audiences if they have endorectal ultrasound or MRI as a way of staging, no more than 50% of the surgeons say they do, which has not changed in 10 years.

Dr. Beart: I don’t think it’s either/or. Ultrasound and MRI answer different questions. Ultrasound is better at looking at depth of invasion and perhaps lymph nodes, whereas MRI will look at lymph nodes to some degree but is really better for judging relationships with surrounding structures. It really depends on the setting of the patient — and don’t know that you necessarily need both.

Dr. Bilchik: Dr. Stamos presented some very sobering statistics: 18% local recurrence with transanal excision of T1 rectal cancers. Now, you may argue that 50% of such patients that recur are salvageable by an abdominoperineal resection, so cure is still possible if they recur locally. Are you prepared to say into high, medium, and low risk according to tumor position. They perform a limited barium enema on every patient to show exactly where the tumor is relative to the sacral bones, and they can look at the relationship between nodal disease and rectal cancer location. These results determine whether an extended lateral lymphadenectomy is necessary in a patient who has node-positive disease.

Dr. Beart: Results must be reproducible, which takes rectal examination off the table, even though I happen to be a big fan of it and I think it can be done well. I just don’t think that it’s a good standard.

Dr. Stamos: Do you think it’s off the table or not important? I think if you have both, you probably shouldn’t be managing mid and distal rectal cancers.

Dr. Rosen: And if you have both?

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then that a T1 lesion with favorable prognostic factors can be treated with a transanal excision in 2007? What are some favorable prognostic factors?

Dr. Stamos: The risk is very acceptable if ideal factors (most importantly, confirmation of T1 level of invasion, absence of lymphovascular invasion, absence of poor differentiation, and adequate margins) are satisfied. What is an adequate margin? Some studies have said ≥3 mm, and I think that 3 mm is probably reasonable. In reality, we know that a 1-cm fresh surgical margin will shrink with fixation. As was pointed out with the low anterior and coloanal, a clear margin is important. How clear? We really don’t know the answer. The 1- or 2-cm rule — whatever we want to call it — is not by any means hard and fast.

Dr. Compton: I think in more simplistic terms. In reviewing cases for a study from Mass General — which is arguably a good institution — my colleagues and I couldn’t determine where the margin was about half of the time, because the specimen had been taken out piecemeal, and that is something that you didn’t mention here at all.

Dr. Stamos: I said that 60% of specimens didn’t fulfill ideal criteria, but I should have included “in one piece”.

Dr. Compton: Another issue related to estimating margin negativity after neoadjuvant therapy is how long after radiation you take out the specimen. Additionally, how do you definitively differentiate a dead cell from a viable cell under the microscope?

Dr. Bilchik: So, necrosis is not a good definition for response to neoadjuvant therapy?

Dr. Compton: No. How do you recognize necrosis with complete certainty?

Dr. Stamos: I asked the question because we tend to wait a minimum now of 5 to 6 weeks and more commonly wait 10 or 12 weeks or longer.

Dr. Compton: I am thinking simplistically about cells at the margin. You see a cell at the margin; is it a dead cell, and should I care?

Dr. Stamos: If you see a cancer cell at the margin, it doesn’t matter if it’s dead or alive — it’s not a good margin.

Dr. Rosen: Neoadjuvant therapy might be too good in a traditional world where people are using radiation and radiation/5-FU, with hopes of achieving a greater chance of sphincter preservation. We have now added oxaliplatin and maybe even some biologic therapy. You might not necessarily be helping that much more with sphincter preservation and are now causing problems of margins and complete responses.

Dr. Compton: There is no accepted definition as to what constitutes a partial and complete response pathologically. Until we all use the same yardstick to measure outcome, we will be unable to answer important questions.

Dr. Rosen: One could ask how a complete response affects the nature of the surgery that is being performed.

Dr. Bilchik: Complete response is not well defined.

Dr. Compton: Right, because we cannot always distinguish a living cell from a dead cell, and some people will say that it’s a complete response if they see cells but think they are dead.

Dr. Willett: Wouldn’t you agree that a pathological complete response should be, no cells present in the surgical specimen after neoadjuvant therapy?

Dr. Compton: Sometimes, but it depends on how long it has taken the cells to undergo karyorexis and be resorbed. The cells can look pyknotic or eosinophilic instead and haven’t gone anywhere.

Dr. Nelson: I have heard that 5 mm is the resolution of the lesion on a regular CAT scan. Histopathology must also have “resolution” limits. Resolution limits for histopathology must reflect the extensiveness of sampling and the ability of the human eye to detect rare events. I have been told that limits of the microscopic resolution occurs at roughly one tumor cell for 200 normal cells. Then you must ask, is this biologically meaningful?

Dr. Stamos: We think of pathology as being the gold standard, but you are saying that it is not quite the gold standard.

Dr. Nelson: It is the gold standard clinically, but what is the relationship between a pathologic complete response in rectal cancer and the rate of cure? If a patient had a complete response to radiation and chemotherapy, firstly, how can you be certain it was 100% complete? Secondly, does that mean cure? In the liver metastases field, we know that when chemotherapy is administered and there is no evidence of tumor on CT, there is an 85% chance of finding viable tumor at surgery.

Dr. Bilchik: Should all patients be considered for laparoscopic colectomy? What about a patient who goes to a surgeon who doesn’t perform laparoscopic colectomy, is that surgeon ethically obliged to refer the patient elsewhere for a laparoscopic colectomy?

Dr. Nelson: Patients receiving laparoscopic colectomy do have shorter hospital stays and faster recovery, but quality of life is not markedly different, and there is no survival or oncologic advantage. Therefore, I don’t think it’s a requirement for a surgeon who does a good open surgery — whatever that is — to offer laparoscopy as an option. Patients who want another option will look for it on their own.

Dr. Beart: Issues pertaining to quality or length of life (e.g., a 20% reduction in morphine use or less hospital time) are more important than economic issues.

Dr. Compton: Administrators will care.

Dr. Stamos: Patients will care.