Colorectal Cancer Screening and Treatment: Review of Outcomes Research

Dawn Provenzale, Rebecca N. Gray

Background: Colorectal cancer is the second leading cause of cancer deaths in the United States each year. Screening is effective in reducing colorectal cancer mortality; however, compliance with screening is poor, and factors associated with its compliance are poorly understood. The outcomes of treatment of colorectal cancer (surgery, radiation therapy, and chemotherapy) may have profound effects on quality of life (QOL). Furthermore, colorectal cancer screening and treatment may be expensive, and the costs are important from a policy perspective. This review examines patient-centered outcomes research related to colorectal cancer screening and treatment and outlines the work that has been done in several areas, including patient preferences, QOL, and economic analysis. Methods: The literature on the health outcomes associated with colorectal cancer screening and treatment was reviewed. A MEDLINE search of English language articles published from January 1, 1990 through February 2001, was conducted and was supplemented by a review of references of obtained articles. Criteria for study inclusion were identified a priori. A standardized data abstraction form was developed. Summary statistical analyses were performed on the results. Results: Six hundred eighty-six articles were selected for review. In total, 530 articles were excluded because they either did not include patient-centered outcomes, were duplicate articles, or could not be obtained. There were 156 articles included in the analysis; 67 addressed screening, 18 examined surveillance of high-risk groups, 22 concerned treatment of local disease, 10 examined treatment of local and metastatic disease, and 19 considered treatment of metastatic disease only. One study examined end-of-life care. In 19 studies, the phase of care was unspecified. Conclusions: Standardized, disease-specific QOL instruments should be applied in clinical trials so that the results may be compared across different types of interventions. Valid and reliable methods that accurately capture patient preferences regarding screening and treatment should be developed. [J Natl Cancer Inst Monogr 2004;33: 45-55]

Background

Colorectal cancer is the second leading cause of cancer deaths in the United States each year. It was estimated that in the year 2002 there would be 148,300 new cases and 56,000 deaths from colorectal cancer (1). Because most colorectal cancers are diagnosed after local or regional spread, nearly one-half of all patients diagnosed with this cancer will die of the disease. Colorectal cancer can be prevented with screening, however, and can be cured if diagnosed in an early stage. Thus, screening is important in improving health outcomes associated with colorectal cancer (2). Compliance rates for fecal occult blood testing, however, range from 9% to 88% (3–15), whereas compliance rates with sigmoidoscopic screening range from 30% to nearly 100% (16–23). Screening colonoscopy is gaining acceptance but has been recommended only recently, and data on compliance are few. Factors associated with poor compliance with screening include the following: the fear of further tests and surgery, the avoidance of the unpleasantness of screening, and the lack of education regarding the benefits of screening. Research that identifies effective interventions to promote screening is needed.

It is widely agreed that patient preferences, quality of life (QOL), and the economic impact of colorectal cancer screening and treatment are important; however, until recently, few studies have addressed these outcomes in patients undergoing evaluation or treatment of colorectal cancers. With the morbidity and toxicity associated with colorectal cancer chemotherapy and the potential long-term effects of surgery (colostomy), QOL is an important outcome of cancer screening and treatment programs. Furthermore, in this era of limited resources, the economic impact of the burden of the disease, technologic advances, and new chemotherapeutic regimens must be evaluated to identify groups that will benefit from them.

Outcomes research is the area of scientific inquiry designed to systematically assess clinical practice and focuses specifically on outcomes that are relevant to patients, including mortality, morbidity, QOL, functional status, patient satisfaction, and cost. These patient-specific outcomes can overtly quantify the patient’s experience and serve as a guide to physicians and policymakers for appropriate medical and surgical interventions. Important outcomes for colorectal cancer screening and treatment programs would be patient satisfaction and compliance with screening measures, QOL associated with screening programs, and QOL associated with surgery and chemotherapy for colorectal cancer. Costs of screening, treatment, and terminal care are important from a policy perspective. The cost-effectiveness of colorectal cancer screening programs and alternative therapeutic regimens are critical issues for planning patient-centered approaches to colorectal cancer management with a limited health care budget. Areas for potential research must be clearly defined, and the existing work in this area must be delineated.

The objective of this study was to survey the literature on outcomes research related to colorectal cancer screening and treatment and to make recommendations about study design, populations, and measures that should be used in future research about the outcomes for colorectal cancer. This review is organized according to phase of care, beginning with screening for
colorectal cancer and moving to treatment and then end-of-life care. Recommendations for areas of further study are provided in each of these domains and arenas.

The article reviews the data on health outcomes for the spectrum of colorectal cancer care, including screening, treatment, survival, and death. An important component of this review was to examine the racial/ethnic background and sex of the subjects of the published studies to understand the full spectrum of patients for whom outcomes data are known and to identify groups in whom outcome data are needed. The review was designed to provide information for discussion, identification, and planning for future research into the outcomes of colorectal cancer screening and treatment.

**METHODS**


The search was conducted in two phases: 1) The initial search, performed on August 3, 1999, identified citations with a publication date of 1990 through 1999; and 2) an update conducted in February 2001 identified citations with an entry date (date of entry in the PubMed database) of August 1999 through February 8, 2001. For the update, the term “colorectal neoplasms [majr]” was substituted for the term “(colorectal neoplasms [majr:noexp] OR colorectal neoplasms, hereditary nonpolyposis [majr]).” As the search strategy suggests, citations were limited to English-language articles whose publication type was “journal article.”

The computerized search was supplemented by a review of references of obtained articles. Approximately 1600 citations were identified and screened for possible inclusion.

The “Methods” and the “Results” sections of the abstracts were reviewed for eligibility by the principal author (D. Provenzano). Study inclusion criteria included being published in a peer-reviewed journal as a full manuscript (abstracts were not included) and presenting data on a patient-centered health outcome, such as QOL, patient preferences, and patient satisfaction (Table 1). Case reports were not included because, although they typically describe an interesting clinical problem or an unusual presentation of a disorder, they rarely focus on the patient-centered outcomes of interest for this study (Table 1). Likewise, systematic reviews may summarize patient-centered outcomes, but our goal in this review was to examine the original research to more completely review study design methods. Thus, reviews were excluded as well.

For eligible studies, the following data were abstracted: title, type of study, intervention or program under examination, data collection period, geographic location of the study, demographic and clinical characteristics of the patient population, and outcomes of interest. For economic analyses, essential elements that reflect recent recommendations were noted. These included the perspective of the analysis, i.e., from whose perspective the analysis was performed (e.g., the perspective of the patient, the health maintenance organization [HMO], or the third-party payer), the inclusion of an appropriate incremental analysis in which each strategy is compared with the next most effective and expensive strategy, and discounting, in which the differential timing of costs and outcomes is considered.

**Data Analysis**

The data are summarized here (Tables 1–5) and are presented in detail online (http://jncicancerspectrum.oupjournals.org/jcimono/content/vol2004/issue33). Data were abstracted by one author (R. N. Gray), and the abstraction was checked by the principal author.

### Table 1. Types of outcomes measured

<table>
<thead>
<tr>
<th>Type of outcome</th>
<th>No. of studies*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost-effectiveness/cost-utility</td>
<td>45</td>
</tr>
<tr>
<td>Quality of life</td>
<td>36</td>
</tr>
<tr>
<td>Cost/resource use</td>
<td>28</td>
</tr>
<tr>
<td>Compliance with screening/genetic testing</td>
<td>16</td>
</tr>
<tr>
<td>Attitudes toward screening, barriers and enabling factors</td>
<td>11</td>
</tr>
<tr>
<td>Knowledge of colorectal cancer</td>
<td>7</td>
</tr>
<tr>
<td>Patient preferences</td>
<td>7</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>6</td>
</tr>
<tr>
<td>Functional status</td>
<td>6</td>
</tr>
<tr>
<td>Psychological distress/mental health</td>
<td>5</td>
</tr>
<tr>
<td>Perceived risk of colorectal cancer</td>
<td>3</td>
</tr>
<tr>
<td>Compliance with treatment</td>
<td>2</td>
</tr>
<tr>
<td>Quality of care</td>
<td>2</td>
</tr>
<tr>
<td>Other†</td>
<td>11</td>
</tr>
</tbody>
</table>

*Some studies reported more than one outcome of interest.
†“Other” outcomes (one study each) included differences in treatments received by blacks and whites; differences in treatments, discussions about care topics, do-not-resuscitate orders, and cost in patients of various ages; demands of illness; financial impact of colorectal cancer (CRC) on patient/family; caregiver experiences; attitudes toward follow-up; content and length of doctor–patient communications; patient perspectives on CRC; and readiness of an educational leaflet on CRC screening. Also included under “Other” were two decision analyses (expected utility of local excision ± radiotherapy versus abdominal perineal resection in patients with early low rectal cancer and quality-adjusted life-years gained with colonoscopic surveillance versus prophylactic colectomy in patients with hereditary nonpolyposis colorectal cancer mutations).
RESULTS

Studies Identified

In total, 686 articles were selected for review. Five hundred thirty were excluded because they either did not include the patient-centered outcomes of interest or were duplicate articles. Forty-four articles could not be obtained. There were 156 articles included in the analysis. The types of outcomes measured, e.g., economic, QOL, or patient preferences, are shown in Table 1. The results and stratified by phase of care are listed in Table 2. Table 3 lists the most commonly used instruments for the measurement of health-related QOL, functional status, mental health, and knowledge of colorectal cancer among the articles reviewed. The study design of the included articles is listed in Table 4 and is stratified by phase of care. Table 5 lists the arenas of application or the purpose of the different studies, e.g., to inform patient care, to describe patterns of care, and to monitor or measure QOL. Sixty-seven articles addressed screening or early diagnosis of colorectal cancer, 18 examined surveillance of high-risk groups, 22 concerned treatment of local disease, and 10 examined treatment of local and metastatic disease. There were 19 articles that considered treatment of metastatic disease only, and one study examined end-of-life care. In 19 studies, the phase of care was unspecified.

Screening

Sixty-seven articles (7,17,18,24–87) addressed screening and early diagnosis. These articles are summarized in Appendix Table 1 (http://jncicancerspectrum.oupjournals.org/jncimono/content/vol2004/issue/33). Sixteen articles (7,24–29,32,35,37–39,42–44,74) evaluated the patient’s attitudes toward colorectal cancer screening, preferences for screening modalities, acceptability of screening tests, or the patient’s or physician’s compliance with recommended screening protocols. Most of the studies included populations that were at least 70% white. Other articles evaluated demographic and socioeconomic factors that might be associated with attitudes and knowledge of colorectal cancer screening and treatment. In most articles, the instruments that were used for these measurements were not standardized, making comparisons among studies difficult.

There were 40 articles (17,25,46–54,56–63,65–73,75–79,81–86,88) that evaluated the costs associated with screening or the cost-effectiveness of screening techniques for the average-risk individual. Most of these studies examined the cost-effectiveness of fecal occult blood testing with or without other strategies, such as flexible sigmoidoscopy. The articles typically included direct medical costs and were based on computer models. Charges were used rather than costs. Although standard methodology for performing economic analyses has been published (89), adherence to these methods was variable. For example, the perspective of the articles was infrequently stated, and few studies performed the recommended incremental analysis (89). Only two of the screening articles (25,63) examined QOL associated with screening and/or colorectal cancer treatment, using standardized instruments. Although many of the earlier articles were quite limited in scope and methodology, the articles published in the latter half of the decade were more likely to conform to published methods for performing economic analyses (89).

The remainder of the articles (30,31,33,34,40,42,64,80) examined educational programs for screening, screening by non-physicians, dietary interventions to improve screening tests, and intervention projects to improve screening acceptance and compliance. These articles are useful adjuncts for clinical decision making.

In summary, several articles pertaining to screening examined the attitudes, preferences, and QOL of individuals with and without colorectal cancer. Compliance with screening was addressed; however, in general, the studies on compliance were lacking standardized measures, making comparisons between

Table 2. Phases of care

<table>
<thead>
<tr>
<th>Phase of care</th>
<th>No. of studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening/diagnosis</td>
<td>67</td>
</tr>
<tr>
<td>Local disease treatment</td>
<td>22</td>
</tr>
<tr>
<td>Metastatic disease treatment</td>
<td>19</td>
</tr>
<tr>
<td>Surveillance</td>
<td>18</td>
</tr>
<tr>
<td>Local and metastatic disease treatment</td>
<td>10</td>
</tr>
<tr>
<td>End of life</td>
<td>1</td>
</tr>
<tr>
<td>Not specified/unclear</td>
<td>19</td>
</tr>
</tbody>
</table>

Table 3. Most commonly used instruments for the measurement of health-related quality of life, knowledge of colorectal cancer, mental health, and functional status*

<table>
<thead>
<tr>
<th>Outcome/instrument</th>
<th>No. of studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of life</td>
<td></td>
</tr>
<tr>
<td>EORTC QLQ-C30</td>
<td>12</td>
</tr>
<tr>
<td>Rotterdam Symptom Checklist</td>
<td>6</td>
</tr>
<tr>
<td>Hospital Anxiety and Depression Scale</td>
<td>5</td>
</tr>
<tr>
<td>EORTC QLQ-CR38</td>
<td>3</td>
</tr>
<tr>
<td>SF-36 Physical and Mental Health Subscales</td>
<td>3</td>
</tr>
<tr>
<td>SF-36 Health Survey</td>
<td>2</td>
</tr>
<tr>
<td>Functional Assessment of Cancer Therapy Scale</td>
<td>2</td>
</tr>
<tr>
<td>Colorectal Carcinoma (FACT-C)</td>
<td>2</td>
</tr>
<tr>
<td>Sickness Impact Profile</td>
<td>2</td>
</tr>
<tr>
<td>Visual analog scales</td>
<td>2</td>
</tr>
<tr>
<td>Spitzer Uniscale</td>
<td>2</td>
</tr>
<tr>
<td>Spitzer Quality of Life Index</td>
<td>1</td>
</tr>
<tr>
<td>Health Utilities Index</td>
<td>1</td>
</tr>
<tr>
<td>Symptom Distress Scale</td>
<td>1</td>
</tr>
<tr>
<td>Functional Living Index—Cancer</td>
<td>1</td>
</tr>
<tr>
<td>Medical Outcomes Study Short Form (MOS SF-20)</td>
<td>1</td>
</tr>
<tr>
<td>Picture-face scale</td>
<td>1</td>
</tr>
<tr>
<td>Investigator-designed questionnaires</td>
<td>4</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
</tr>
<tr>
<td>Knowledge of colorectal cancer</td>
<td></td>
</tr>
<tr>
<td>Colorectal Cancer Knowledge Questionnaire</td>
<td>1</td>
</tr>
<tr>
<td>Investigator-designed questionnaires</td>
<td>7</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td></td>
</tr>
<tr>
<td>Investigator-designed questionnaires</td>
<td>6</td>
</tr>
<tr>
<td>Functional status</td>
<td></td>
</tr>
<tr>
<td>Katz Index of Independence in Activities of Daily Living</td>
<td>2</td>
</tr>
<tr>
<td>Enforced Social Dependency Scale</td>
<td>1</td>
</tr>
<tr>
<td>Physical Functioning Subscale of SF-36</td>
<td>1</td>
</tr>
<tr>
<td>Duke Activity Status Index</td>
<td>1</td>
</tr>
<tr>
<td>ECOG Performance Status Scale</td>
<td>1</td>
</tr>
<tr>
<td>Hulter–Asberg’s Instrumental Index of Activities of Daily Living</td>
<td>1</td>
</tr>
<tr>
<td>Psychological distress/mental health</td>
<td></td>
</tr>
<tr>
<td>Bipolar Profile of Mood States</td>
<td>1</td>
</tr>
<tr>
<td>Beck Depression Inventory</td>
<td>1</td>
</tr>
<tr>
<td>Mental Health Subscale of SF-36</td>
<td>1</td>
</tr>
<tr>
<td>Profile of Mood States (Anxiety and Depression Subscales)</td>
<td>1</td>
</tr>
<tr>
<td>Center for Epidemiologic Studies Depression Scale</td>
<td>1</td>
</tr>
</tbody>
</table>

*ECOG = Eastern Cooperative Oncology Group; EORTC = European Organization For Research and Treatment of Cancer.
them difficult. Economic analysis of screening programs was another important focus of the screening articles. Most of the studies compared alternative screening modalities with each other, with a few comparisons of screening to other medical practices. In general, the economic analysis studies did not conform to standard methods, although there was a trend toward improved adherence to these methods in the latter portion of the decade.

Finally, there were articles that examined education about screening, implementation of screening programs, and methods to improve compliance with screening. In general, the methods used to examine these important components of screening were diverse, making comparisons difficult.

Further research is needed to identify predictors of compliance with colorectal cancer screening, determinants of patient preferences for, and satisfaction with, screening, and reassurance associated with a negative test.

**Surveillance**

There were 18 articles (88,90–106) that addressed surveillance (the ongoing follow-up of individuals at increased risk of colorectal cancer) of high-risk individuals, including those with a family history of colorectal cancer, hereditary nonpolyposis colorectal carcinoma, ulcerative colitis, hereditary predisposition to cancer or familial adenomatous polyposis, and those with a history of colorectal cancer and adenomatous polyps (88,90–106). These articles, which are summarized in Appendix Table 2 (http://jncicancerspectrum.oupjournals.org/jncimonobcontest/vol2004/issue/33), evaluated attitudes regarding surveillance and QOL associated with it, as well as educational programs, compliance, effectiveness, and costs. Two articles examined the economic impact of surveillance for recurrence after curative surgery for colorectal cancer. One (103) was simply a cost analysis using average charges. The other (104) was a cost-utility analysis that described three surveillance strategies, including no follow-up. Cost and QOL measures were included but not described. The article (104) reported on the results of a computer simulation, but the details of the model, the sources of the cost estimates, and the QOL measures used were not described. Neither article performed an incremental analysis or included discounting of future costs, rendering comparisons with other economic analyses virtually impossible. In addition, two studies (105,106) examined the QOL of patients at high risk of developing colorectal cancer, namely, those with familial adenomatous polyposis coli. Prophylactic colectomy before the development of cancer is the standard of care for these patients, although surgical techniques vary somewhat. These two articles (105,106) examined QOL postoperatively in this high-risk group, using standardized instruments (the SF-36 and the European Organization for Research and Treatment of Cancer [EORTC] QLQ-CR38), providing new information about the outcomes of care for this group.

To summarize, an examination of screening and surveillance publications over the decade of the 1990s revealed the following trends: The publication of analyses related to screening and surveillance increased dramatically after 1997, the year that recommendations for colorectal cancer screening in the average-risk individual were released by the consortium of gastroenterology and surgical societies (107). Although there were generally few articles that addressed the QOL associated with screening and surveillance, those that considered this outcome were published during the latter part of the decade. In general, the economic analyses that we reviewed established the cost-effectiveness of colorectal cancer screening compared with not screening. Their results inform both health policy and clinical decision making.

**Treatment of Colorectal Cancer**

The remainder of the articles in this review focus on the treatment of colorectal cancer. Treatment is stratified according to stage of cancer, and we report our review on the outcomes...
associated with treating local disease, both local and metastatic disease, metastatic disease, and a group of articles for which the stage of disease was not specified.

**Treatment of Local Disease**

There were 22 articles (108–129) that focused on the treatment of local disease. These articles are summarized in Appendix Table 3 (http://jncicancerspectrum.oupjournals.org/jncimonon/content/vol2004/issue/33). Four studies (115–117,119) examined perspectives on colorectal cancer, QOL after surgery, or QOL associated with having colorectal cancer. There were 12 studies (108–110,112,113,116–118,122,123,125) that examined the outcomes of surgery for colorectal cancer, including functional status, survival, and QOL. An additional two articles (111,128) examined these outcomes in patients undergoing adjuvant chemotherapy. Four studies (122,126,127,129) evaluated the economic impact of colorectal cancer treatment. Finally, two studies (120,121) examined colorectal cancer therapy in alternative settings (HMO versus fee for service).

**Treatment of Local and Metastatic Disease**

There were 10 studies (130–139) that examined the outcomes related to the treatment of both local and metastatic disease. They are summarized in Appendix Table 4 (http://jncicancerspectrum.oupjournals.org/jncimonon/content/vol2004/issue/33). Most of these articles examined QOL associated with chemotherapy for colorectal cancer. Instruments used to measure QOL included the Hospital Anxiety and Depression Scale (137), the Rotterdam Symptom Checklist (137), the EORTC QLQ-30 (132,136), the Karnofsky scale (135), a linear analog scale (Priestman–Coates (131), and the Spitzer Uniscale (133). One article (134) examined challenges posed by missing data in these types of chemotherapy trials. Two articles (135,139) examined the economic impact of chemotherapy for colorectal cancer.

A unique study (130) within this group reported treatment differences between blacks and whites with colorectal cancer. This study identified an area for future research and intervention to improve the outcomes of colorectal cancer treatment among different racial/ethnic groups.

These treatment articles generally focused on chemotherapy and the QOL and costs associated with it. The QOL measures used were diverse, however, making comparisons among the studies difficult. In general, these articles provide important information on the patient-centered outcomes associated with treatment that can be used to inform clinical decision making and health policy.

**Treatment of Metastatic Disease**

Nineteen articles (140–158) focused on treatment of metastatic disease. These articles are summarized in Appendix Table 5 (http://jncicancerspectrum.oupjournals.org/jncimonon/content/vol2004/issue/33). There were 12 articles (140–151) within this group that examined chemotherapy and its effects on survival and QOL. Most of the articles in this group included the EORTC QLQ-30 as their QOL instrument, but other measures included the Rotterdam Symptom Checklist, the Hospital Anxiety and Depression Scale (151), and the Sickness Impact Profile (141). Six articles examined the economic impact of therapy for metastatic colorectal cancer. These typically used the results of randomized chemotherapy trials to examine the economic impact of these therapies. The articles published in the latter half of the decade tended to conform more closely to published methodology for performing economic analysis (89) than did the earlier ones. Finally, this group included one article that examined age differences in treatment patterns for patients with metastatic disease, including hospital length of stay, costs, and orders not to resuscitate (146). In general, the articles pertaining to treatment of metastatic disease focused on the QOL associated with these therapies and their costs. Treatment differences based on age were also examined, providing new information for clinical decision making.

In summary, colorectal cancer treatment articles focused primarily on alternative chemotherapeutic agents for colorectal cancer. QOL studies were included in most of these chemotherapeutic trials, providing new information to inform clinical decision making. For many of the studies, QOL data affirmed the results for the other clinical outcomes. In other words, QOL was associated with the other clinical outcomes, including survival and disease-free survival. The QOL measures used in these studies were diverse, particularly in the early part of the decade, making the comparisons of the effect of these alternate chemotherapeutic agents on QOL difficult. In the latter part of the decade, however, there was an increasing use of the EORTC QLQ-30 and the newer CR38 (159), which is specific for colorectal cancer.

The study by Ball and Elixhauser (130) that examines the treatment differences between blacks and whites has identified an area for future research and intervention to improve the outcomes of colorectal cancer treatment among different racial/ethnic groups. Likewise, the study by Rose et al. (146) on resource use and outcomes of care for older versus younger patients provides new information about disparities in care by age and can be used as a basis for the evaluation of the quality of care for colorectal cancer patients. Finally, the latter portion of the decade revealed an increased evaluation of surgical techniques for colorectal cancer treatment. QOL measures became increasingly more common in these studies, providing new information for patient care and clinical decision making.

**End-of-Life Care**

In this review, we found only one article (160) that measured a patient-centered outcome related to end-of-life care. This study, which is summarized in Appendix Table 6 (http://jncicancerspectrum.oupjournals.org/jncimonon/content/vol2004/issue/33), evaluated dying patients’ function, symptoms, and care preferences for the terminal phase of the disease. This unique article identifies the areas of importance to the terminally ill and provides crucial information for clinical decision making with colorectal cancer patients at the end of life.

**Phase of Care Unspecified**

There were 19 articles (159,161–178) for which the phase of care was unspecified. They are summarized in Appendix Table 7 (http://jncicancerspectrum.oupjournals.org/jncimonon/content/vol2004/issue/33). Nine of these studies examined either QOL of patients undergoing treatment (166,167), QOL of survivors of colorectal cancer (168), patient function related to comorbidities (164), coping behavior after treatment (169,170), and demands of illness (165,169,170).

Four articles (172,173,177,178) examined the perceptions of cancer and cancer risk. A unique report (174) focused on doctor–patient communication in the follow-up of colorectal cancer. This study exam-
Funding Increased funding for outcomes research related to colorectal cancer is essential. Research into the outcomes of care in alternative health care settings, e.g., health maintenance organization and fee-for-service settings, is needed, as its outcomes research in underserved populations.

Table 6. Recommendations for improving outcomes research related to colorectal cancer screening and treatment

<table>
<thead>
<tr>
<th>Area</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instruments</td>
<td>Develop a set of reliable, valid instruments to examine satisfaction and attitudes toward screening, patient compliance with screening and treatment, and quality of life with colorectal cancer and cancer treatment. These measures should be disease-specific and responsive to changes over time.</td>
</tr>
<tr>
<td>Population</td>
<td>Research that examines racial, ethnic, and multicultural differences in colorectal cancer care is lacking. Identification of factors that improve compliance with screening, access to care, and availability of colorectal cancer screening and treatment should be identified through clinical research.</td>
</tr>
<tr>
<td>Method</td>
<td>Outcomes studies, particularly economic analyses, should conform to published methodologic criteria. Quality-of-life studies should incorporate valid, reliable measurement tools. Careful attention to sample size, randomization, and comparability of treatment groups will be important.</td>
</tr>
<tr>
<td>Preferences</td>
<td>Valid, reliable methods that accurately capture patient preferences are needed. Measures that can be incorporated into economic analyses will be essential.</td>
</tr>
<tr>
<td>Outcomes</td>
<td>An emphasis should be placed on studies that focus on factors associated with compliance, quality of life with colorectal cancer, and patient preferences for alternative screening regimens. Economic analyses that conform to published standards should be supported.</td>
</tr>
<tr>
<td>Funding</td>
<td>Increased funding for outcomes research related to colorectal cancer is essential. Research into the outcomes of care in alternative health care settings, e.g., health maintenance organization and fee-for-service settings, is needed, as its outcomes research in underserved populations. A repository for outcomes research data should be supported.</td>
</tr>
</tbody>
</table>

Therapy Scale for Colorectal Carcinoma (FACT-C) to colorectal cancer patients, the Functional Assessment of Cancer Therapy Scale for Colorectal Carcinoma (FACT-C) (176) and the EORTC colorectal cancer-specific QOL questionnaire module (EORTC QLQ-CR38) (159). These latter studies established the validity and reliability of these instruments, thus providing new instruments that can be used to measure QOL in the clinical setting and among those enrolled in clinical trials.

SUMMARY

The articles summarized in this review reflect the variable quality and application of outcomes research to colorectal cancer screening and treatment. Fifty percent of the articles in this review represented economic analyses. There were, however, severe methodologic limitations to many of these economic analyses, including a lack of a stated perspective, the failure to incorporate discounting when appropriate, and the failure to perform incremental analyses. This is an area in which future research and analyses that conform to published standards are needed (89).

QOL studies and assessments of attitudes toward screening are also prominent among the outcomes studies of colorectal cancer screening and treatment. Regarding screening, the majority of screening articles focused on compliance and factors associated with compliance. Studies on patient satisfaction were lacking for the period of this review, but more recent data suggest that most of the participants are glad that they had the test and would encourage friends to undergo the test. Positive experiences were attributed largely to the attitudes and behavior of the medical and administrative staff (179).

The remainder of the studies focus on QOL after chemotherapeutic or surgical treatment of colorectal cancer and new instruments for QOL measurement. At least nine different validated scales were used among the studies, identifying the need for standardization among instruments so that the effects on QOL of alternative therapeutic regimens can be compared. A first attempt at evaluating the methods for measurement of health-related QOL was made in the two studies (161,175) that compared the tools for measuring overall health-related QOL in patients with advanced cancer and then related these measures with the measures of physical functioning. The evaluation of utility assessment (161) provided important information on the limitations of this technique. Future studies are needed that evaluate disease-specific, valid, and reliable instruments for measuring health-related QOL and utilities. In addition, standardized measures of patient preferences are needed, and measures that can be incorporated into economic analyses will be essential to future studies.

The need for standardized QOL measures is further illustrated in the treatment articles in which at least six different measures are used among the five articles that examine therapies for colorectal cancer, although the latter portion of the decade revealed a trend toward increased use of the EORTC QLQ-30 and EORTC QLQ-CR38 (159), which may be the beginning of a move toward standardization.

Another important finding of this review was that the race of participants in most studies either was unspecified or was white. The one study (130) that examined the treatment differences for colorectal cancer among blacks and whites is a retrospective database study with its associated methodologic limitations. In the future, prospective studies on treatment differences and dif-
ferences in survival among various racial/ethnic groups should be promoted.

Certain observations and time trends related to the measurement and reporting of patient-centered outcomes related to colorectal cancer screening and treatment are noteworthy. The latter half of the decade revealed a remarkable increase in the number of treatment studies that addressed QOL. Of note was the dramatic increase in studies examining the QOL associated with alternative surgical therapies for colorectal cancer. Regarding QOL measures, there was an increased use of the EORTC QLQ-CR30 and the newer QLQ-CR38 (159) in the latter half of the decade. This may represent an important and much needed trend toward standardization of measures for patient-centered outcomes surrounding colorectal cancer.

How can we provide a perspective for these results and in what settings might they be useful? First, the articles on screening provide us with a useful guide for planning future research. A national random-digit dialing telephone survey (the Behavioral Risk Factor Surveillance System) (180) in 1999 found that 44% of the people reported receiving the recommended colorectal cancer screening (181). Their estimates included 20.6% who had a fecal occult blood test within the past year and 33.6% who had a sigmoidoscopy or colonoscopy within the previous 5 years (181). These rates are strikingly low compared with rates of Pap smears in the previous 3 years in women with an intact cervix (84.7%) and mammography in the past 2 years in women over the age of 50 years (73.7%) (180). Our review provides insight into the etiologies of the strikingly low colorectal cancer screening rates nationwide. Factors associated with compliance are poorly understood, and perceptions about colorectal cancer and the effectiveness of screening are often misguided. In addition, there has been little investigation of individual preferences for screening modalities, items that are important predictors of compliance. Standardized methods to measure preferences and attitudes toward screening have not been implemented and will need to be developed.

The literature on screening is replete with economic analyses. However, there are few data on the actual societal costs to implement screening programs nationwide.

The outcomes literature regarding treatment of colorectal cancer focused heavily on the QOL associated with chemotherapy and surgery. QOL is influenced by the patient, by the provider, and by institutional factors. Because this measure can overtly quantify patients’ experiences and serve as a guide for appropriate medical and surgical interventions, it is an important measure of quality of care. Our review provides an overview of the QOL concerns surrounding colorectal cancer chemotherapy and has provided information on one aspect of quality of care. Other related areas for quality improvement include measurement of decision-making processes. Quality cancer care includes providing appropriate services with elements of shared decision making (182). Our review did not find studies that addressed decision making. Thus, measurement of the decision-making process for colorectal cancer treatment would be another important area for further investigation. In addition, our review noted that the majority of studies included patients who were primarily white. Sensitivity to racial/ethnic differences in measures of QOL, decision making, and communication is critical to providing quality cancer care. Our review identified few studies that considered these potential differences, identifying another area for investigation that might improve quality.

Thus, our review has outlined the existing literature on the patient-centered outcomes of colorectal cancer screening and treatment and has identified areas for future research. The results can be used to guide translational projects to improve compliance and satisfaction with screening. Furthermore, the results of this review can be used to guide quality-improvement efforts related to colorectal cancer care.

The state of the science has been outlined, and the areas for future research and intervention have been identified. This review may serve as a basis for future scientific inquiry and intervention into the patient-centered outcomes related to colorectal cancer.

Our recommendations for improving outcomes research related to colorectal cancer screening and treatment are summarized in Table 6.

REFERENCES


