Optimal Resources for Rectal Cancer Care

2020 Standards | Effective July 2020

facs.org/naprc
Table of Contents

Disclaimer and Confidentiality Requirements

Acknowledgments

About the National Accreditation Program for Rectal Cancer

Accreditation Process

1 Institutional Administrative Commitment

1.1 Administrative Commitment

2 Program Scope and Governance

2.1 Rectal Cancer Multidisciplinary Care

2.2 Rectal Cancer Program Director

2.3 Rectal Cancer Program Coordinator

2.4 Rectal Cancer Multidisciplinary Team Meetings

2.5 Rectal Cancer Multidisciplinary Team Attendance

3 Facilities and Equipment Resources

3.1 Commission on Cancer Accreditation

4 Personnel and Services Resources

Fulfilled by Commission on Cancer standard requirements
Disclaimer

These standards are intended solely as qualification criteria for National Accreditation Program for Rectal Cancer (NAPRC) accreditation. They do not constitute a standard of care and are not intended to replace the medical judgment of the physician or health care professional in individual circumstances.

“Standard” as used in this manual is defined as a “qualification for accreditation,” not standard of care.

For a program to be found compliant with the NAPRC standards, the program must be able to demonstrate compliance with the entire standard as outlined in the Definition and Requirements, Documentation, and Measure of Compliance sections under each standard.

The Documentation and Measure of Compliance sections under each standard are intended to provide summary guidance on how compliance must be demonstrated but are not intended to stand alone or supersede the Definition and Requirements.

In addition to verifying compliance with the standards as written in this manual, the NAPRC may consider other factors not stated herein when reviewing a program for accreditation and reserves the right to withhold accreditation on this basis.

Confidentiality Requirements

The American College of Surgeons (ACS) and the National Accreditation Program for Rectal Cancer (NAPRC) expect programs to follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Acknowledgments

The National Accreditation Program for Rectal Cancer (NAPRC) and the Commission on Cancer (CoC) are thankful to the representatives of the CoC member organizations, the OSTRiCh Consortium (Optimizing the Surgical Treatment of Rectal Cancer) Standards Committee, and the members of the NAPRC Steering Committee for their efforts to improve the care and treatment of rectal cancer patients in the United States.

Specifically, the NAPRC acknowledges the many contributions of the following people who were vital to the creation of this standards manual.

Volunteer Contributors
- Ovunc Bardakcioglu, MD, FACS
- Mariana Berho, MD, FCAP
- David Dietz, MD, FACS, FASCRS
- Linda Farkas, MD, FACS, FASCRS
- Fergal Fleming, MD, FACS
- Daniel Herzig, MD, FACS
- Ron G. Landmann, MD, FACS, FASCRS
- Daniel McKellar, MD, FACS
- John RT Monson, MD, FACS, FRCS Ire(Hon), FRCS Eng(Hon), FRCS Glasg(Hon), FASCRS
- George Nassif, DO, FACS
- Samuel Oommen, MD, FACS, FASCRS
- Walter Peters, Jr., MD, MBA, FACS, FASCRS
- Steven Wexner, MD, PhD(Hon), FACS, FRCS Eng, FRCS Ed, FRCSI(Hon), FRCS Glasg(Hon)

Staff Contributors
- David Winchester, MD, FACS
- Asa Carter, CTR, MBA
- Erin DeKoster, JD, MS
- Allison Knutson, CCRP
About the National Accreditation Program for Rectal Cancer

Background
The National Accreditation Program for Rectal Cancer (NAPRC) was developed through collaboration between the OSTRiCh Consortium (Optimizing the Surgical Treatment of Rectal Cancer) and the Commission on Cancer (CoC), a quality program of the American College of Surgeons (ACS).

During the last 20 years, the outcomes of rectal cancer have repeatedly been shown to be tremendously variable and highly contingent upon specialization, training, and volume. Some of these very important and highly statistically significant variations relate to rates of postoperative mortality, incidence of local recurrence, incidence of construction of permanent colostomy, and five-year survival.1-3 Recently these variations have been confirmed in the United States. Baek noted that patients in the state of California were as likely to be operated upon at a low-volume as a medium-volume or high-volume hospital.5 There were highly significant differences in favor of high-volume hospitals relative to mortality and rates of sphincter preservation.

Ricciardi assessed 20,000 proctectomies undertaken between 2002 and 2004 and analyzed county data in 21 states.5 Fifty percent of patients underwent construction of permanent stoma and only 20 percent of the 21 counties offered colostomy rates less than 40 percent. This same problem had existed in Europe, but through numerous initiatives in Sweden, Denmark, Spain, Belgium, The Netherlands, Norway, and the United Kingdom, outcomes have been improved.7-11 Specific measurable improvements have been noted in the rates of complete total mesorectal excision, the rates of permanent stoma construction, the incidence of local recurrence, and overall survival.

Based on the significant variability in the United States and the fact that a number of European countries were able to, on a national level, improve the quality of rectal cancer care, the OSTRiCh Consortium convened in 2011. Since that time the OSTRiCh Consortium has performed several analyses, culminating in a series of publications highlighting the problem of tremendous variability of rectal cancer care on a national level in the United States.12-17

The OSTRiCh Consortium reported these findings to the Accreditation Committee of the Commission on Cancer and the officers and rectors of the American College of Surgeons. Thereafter, the NAPRC was developed.

References


Accreditation Process

Processes for accreditation are detailed and updated on the National Accreditation Program for Rectal Cancer (NAPRC) website and/or the NAPRC Quality Portal. The NAPRC reserves the right to revise accreditation processes as needed.

Accreditation Awards

<table>
<thead>
<tr>
<th>Accreditation Status</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accredited</td>
<td>The program has completed a site visit and demonstrated full compliance with all applicable standards and has provided all requisite documentation to support compliance.</td>
</tr>
<tr>
<td>Accredited-Corrective Action Required Renewal Applicants Only</td>
<td>The program is non-compliant with one or more applicable standards. The program will receive an Accreditation Report documenting all non-compliant standards and will be given a corrective action timeframe to provide all necessary data and documentation required to verify full compliance with all applicable standards. The corrective action timeframe is documented in the Accreditation Report. During the corrective action timeframe, the program will continue to be recognized as a NAPRC-accredited program.</td>
</tr>
<tr>
<td>Not Accredited-Corrective Action Required Initial Applicants Only</td>
<td>The program is non-compliant with one or more applicable standards. Accreditation is pending until the program resolves all non-compliant standards identified during the application process or at the time of the site visit. The program will receive an Accreditation Report documenting all non-compliant standards and will be given a corrective action timeframe to provide all necessary data and documentation required to verify full compliance with all applicable standards. The corrective action timeframe is documented in the Accreditation Report. During the corrective action timeframe, the center will not be recognized as a NAPRC-accredited program.</td>
</tr>
<tr>
<td>Not Accredited</td>
<td>The program is unable to demonstrate compliance with the required standards. The program must submit a new Pre-Review Questionnaire (PRQ) if it wishes to continue pursuing NAPRC accreditation.</td>
</tr>
</tbody>
</table>
1 Institutional Administrative Commitment
Rationale

Institutional commitment is essential for the development and success of a National Accreditation Program for Rectal Cancer (NAPRC) program. Resource allocation (such as equipment, personnel, and administrative support), a commitment to patient safety, and an enduring focus on continuous quality improvement are the hallmarks of strong institutional administrative support that help facilitate the success.
1.1 Administrative Commitment

Definition and Requirements

Programs provide a letter of authority from facility leadership (CEO or equivalent) demonstrating the commitment to the rectal cancer program, which includes, but is not limited to:

- A high-level description of the rectal cancer program
- Any initiatives involving the rectal cancer program during the accreditation cycle that were initiated for the purposes of quality and safety
- Facility leadership's involvement in the rectal cancer program
- Examples of the current and future financial investment in the rectal cancer program

Documentation

Submitted with Pre-Review Questionnaire

- Letter of authority from facility leadership that includes all required elements

Measure of Compliance

Once each accreditation cycle, the rectal cancer program fulfills the compliance criteria:

1. Rectal cancer program authority is established and documented by the facility through a letter from facility leadership that includes all required elements.

Bibliography

2 Program Scope and Governance
Rationale

The Rectal Cancer Multidisciplinary Team (RC-MDT) provides the structure, process, and personnel to obtain and maintain the National Accreditation Program for Rectal Cancer’s standards. This includes the leadership who provide cohesion in the structure of the program.
2.1 Rectal Cancer Multidisciplinary Care

Definition and Requirements

Cancer outcomes are better when patients are managed according to the principles of multidisciplinary team (MDT) care. There is increasing evidence that MDTs are associated with improved clinical decision making, clinical outcomes, and patient experience in several cancer types, including rectal.\(^1\)\(^-\)\(^10\) Implementation of an MDT approach to rectal cancer care in several European countries has resulted in lower rates of permanent stoma, reduced rates of local recurrence, greater delivery of evidence-based care, and improved overall survival.\(^11\)\(^-\)\(^15\)

The Rectal Cancer Multidisciplinary Team (RC-MDT) must include at least one appointed physician member from each of the following specialties: surgery, pathology, radiology, medical oncology, and radiation oncology.

Programs may choose to appoint more than one required member from each specialty. All surgeons, excluding fellows and residents, who perform rectal cancer surgery at the facility must be a required member of the RC-MDT. Each of the following specialties may appoint up to eight physicians to the RC-MDT: pathology, radiology, radiation oncology, and medical oncology. A lead physician must be chosen for each of the following specialties: pathology, radiology, medical oncology, and radiation oncology.

Requirements for individual attendance at RC-MDT meetings are detailed in Standard 2.5.

Additional required members of the RC-MDT are the Rectal Cancer Program Director (Standard 2.2) and the Rectal Cancer Program Coordinator (Standard 2.3).

Identification of RC-MDT membership must take place at the first meeting of each calendar year and must be recorded in the RC-MDT meeting minutes. It is recommended that the RC-MDT meetings are held separately from other cancer sites. However, at the discretion of the rectal cancer program, RC-MDT meetings may be held in conjunction with another cancer site(s) as long as required RC-MDT members and specialties are present and all NAPRC requirements are met.

Documentation

Submitted with Pre-Review Questionnaire
- RC-MDT minutes that document the appointment of all RC-MDT members and, if applicable, membership changes

Measure of Compliance

Each calendar year, the rectal cancer program fulfills the compliance criteria:

1. A defined Rectal Cancer Multidisciplinary Team roster is established and documented in the minutes at the first meeting.
2. The membership of the Rectal Cancer Multidisciplinary Team includes at least one appointed physician member from surgery, pathology, radiology, medical oncology, and radiation oncology. Each of the following specialties may appoint up to eight physicians to the Rectal Cancer Multidisciplinary Team: pathology, radiology, radiation oncology, and medical oncology.
3. A lead physician is selected for each of the following specialties: pathology, radiology, medical oncology, and radiation oncology.
4. All surgeons, excluding fellows and residents, who perform rectal cancer surgery at the rectal cancer program are members of the Rectal Cancer Multidisciplinary Team.
5. The Rectal Cancer Program Director and the Rectal Cancer Program Coordinator are members of the Rectal Cancer Multidisciplinary Team.

References


2.2 Rectal Cancer Program Director

Definition and Requirements
Each calendar year, the facility appoints a Rectal Cancer Program (RCP) Director who chairs the Rectal Cancer Multidisciplinary Team (RC-MDT). The RCP Director serves as the chair of the RC-MDT and as a liaison to the facility’s Commission on Cancer (CoC) committee. The RCP Director must be an active physician member of the facility’s medical staff who provides care and treatment to rectal cancer patients. A co-director may be appointed at the discretion of the RCP.

The RCP Director is a required member of the RC-MDT. The identification of the RCP Director or, if applicable, the RCP co-directors must take place at the first meeting of each calendar year and must be recorded in the RC-MDT meeting minutes. If co-directors are appointed, both must individually meet the attendance requirements in Standard 2.5. If the RCP Director cannot continue to serve on the RC-MDT, a new physician must be identified at the next RC-MDT meeting.

Internal Audit Responsibilities
The RCP Director is responsible for overseeing RC-MDT activity. As dictated under the “internal medical record review” heading in each Chapter 5 standard, the RCP Director is responsible for overseeing internal audits of the RCP’s performance and the development of any necessary action plans.

The RCP Director may delegate responsibility for specific audits and any necessary action plans to appropriately credentialed physician members of the RC-MDT.

CoC Committee Liaison Responsibilities
Each calendar year, the RCP Director must attend one of its facility’s CoC committee meetings and present a report on the RCP’s activities. At a minimum, the RCP Director’s report must include the results of the audits required in each Chapter 5 standard.

Data Interpretation Responsibilities (In Development)
The RCP Director must be authorized to access facility-specific information that is maintained in the National Accreditation Program for Rectal Cancer (NAPRC) Quality Portal and the National Cancer Database (NCDB). The RCP Director must evaluate the quality of rectal cancer care by monitoring, interpreting, and providing updated reports of the program’s data from the NCDB. At a minimum of four separate RC-MDT meetings each calendar year, the RCP Director must report and discuss the RCP’s performance and response to the rectal cancer quality measure data. Reports must include program-specific data.

The RCP Director is responsible for overseeing that any necessary action plans are developed and implemented (see requirements under Standard 7.1). The RCP Director may delegate responsibility for specific action plans to appropriately credentialed physician members of the RC-MDT.

Documentation
Submitted with Pre-Review Questionnaire
- RC-MDT minutes documenting the appointment of the RCP Director
- RC-MDT minutes documenting required RCP Director reports on RCP data from the NCDB, including actions and responses
- RC-MDT minutes documenting the results of all Chapter 5 audits and any necessary action plans
- CoC committee minutes documenting the RCP Director’s report to the CoC committee

Measure of Compliance
Each calendar year, the rectal cancer program fulfills the compliance criteria:
1. A Rectal Cancer Program Director is identified and the identification is documented in the minutes of the first yearly Rectal Cancer Multidisciplinary Team meeting.
2. The results of all Chapter 5 audits and any necessary action plans are reported and discussed at a Rectal Cancer Multidisciplinary Team meeting and documented in the minutes.
3. The Rectal Cancer Program Director attends at least one of its facility’s Commission on Cancer committee meetings.
4. The Rectal Cancer Program Director reports the results of all required Chapter 5 audits to its facility’s Commission on Cancer committee at least once. The report is documented in the Commission on Cancer committee minutes.
5. At a minimum of four meetings, it is documented in the Rectal Cancer Multidisciplinary Team minutes that the Rectal Cancer Program Director reports and discusses rectal cancer program data from the National Cancer Database.
2.3 Rectal Cancer Program Coordinator

**Definition and Requirements**

The Rectal Cancer Program (RCP) Coordinator provides comprehensive administrative support to Rectal Cancer Multidisciplinary Team (RC-MDT) meetings, including the management of accurate and timely information to enable clinical decision making at the RC-MDT meeting. The RCP Coordinator is a required member of the RC-MDT. The role involves registering and monitoring of patients with suspected and confirmed rectal cancer throughout their diagnostic and treatment pathways. The RCP Coordinator oversees that patient care pathways are followed according to agreed guidelines, including time targets for relevant interventions.

Policies and procedures are in place to define patient coordination activity, including, but not limited to, communication between departments within the facility, referring physicians, and patients; coordinating patient appointments; and oversight of data collection. The RCP Coordinator liaises with relevant departments within the facility to assemble all pertinent information for RC-MDT meetings. Additionally, the RCP Coordinator communicates with referring organizations or providers to capture all relevant patient details for discussion at the RC-MDT meetings.

The RCP Coordinator proactively coordinates patient pathways with health care providers/organizations, overseeing that all appointments, diagnostic tests, and treatments are booked within the time targets defined by the National Accreditation Program for Rectal Cancer (NAPRC) Standards. This is not exclusively a navigation position prioritizing interacting with patients; rather, it is a behind-the-scenes position coordinating patient care with health care providers. It is recognized that the RCP Coordinator may need to contact the patient to obtain information about dates, locations, and results of tests and treatments performed outside of the accredited RCP.

The identification of the RCP Coordinator or, if applicable, the co-coordinators must take place at the first meeting of each calendar year and must be recorded in the RC-MDT meeting minutes. If the appointed RCP Coordinator cannot continue to serve on the RC-MDT, a new RCP Coordinator must be appointed at the next RC-MDT meeting. Whether the RCP Coordinator is dedicated to the RCP full-time is left to the discretion of the RCP/facility.

**Documentation**

*Submitted with Pre-Review Questionnaire*

- RC-MDT minutes documenting the appointment of the RCP Coordinator
- Policies and procedures for coordinating RC-MDT activity and that patients move through the RC-MDT process appropriately

**Measure of Compliance**

Each calendar year, the rectal cancer program fulfills the compliance criteria:

1. A Rectal Cancer Program Coordinator is identified. The identification is documented in the minutes of the first yearly RC-MDT meeting.
2. Policies and procedures are in place to define Rectal Cancer Program Coordinator patient and Rectal Cancer Multidisciplinary Team coordination activity.
2.4 Rectal Cancer Multidisciplinary Team Meetings

Definition and Requirements

Each calendar year, the Rectal Cancer Multidisciplinary Team (RC-MDT) must meet at least twice each calendar month. The RC-MDT may choose to convene more frequently so patients are discussed in a timely manner and to allow for timely management decisions.

A calendar year is defined as January 1–December 31. A calendar month is defined as the first day of the month through the last day of the month (for example, March 1 to March 31).

For the RC-MDT meeting to qualify under Standard 2.4, at least one RC-MDT member from surgery, pathology, radiology, medical oncology, and radiation oncology must be in attendance.

All meeting minutes must contain sufficient detail to accurately reflect the activities of the RC-MDT as well as demonstrate compliance with National Accreditation Program for Rectal Cancer requirements.

Measure of Compliance

Each calendar year, the rectal cancer program fulfills the compliance criteria:

1. The Rectal Cancer Multidisciplinary Team meets at least twice each calendar month.
2. At least one Rectal Cancer Multidisciplinary Team member from surgery, pathology, radiology, radiation oncology, and medical oncology attends each meeting.

References

See references listed in Standard 2.1.

Documentation

Submitted with Pre-Review Questionnaire

- Minutes that document the RC-MDT’s twice-monthly meetings and standard compliance activities

Note: Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.
2.5 Rectal Cancer Multidisciplinary Team Attendance

Definition and Requirements

Each calendar year, individual members of the Rectal Cancer Multidisciplinary Team (RC-MDT) meet minimum RC-MDT meeting attendance requirements per specialty/position:

<table>
<thead>
<tr>
<th>Specialty/Role</th>
<th>Minimum RC-MDT Meeting Attendance Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeons</td>
<td>50%</td>
</tr>
<tr>
<td>Pathologists</td>
<td>20%</td>
</tr>
<tr>
<td>Radiologists</td>
<td>20%</td>
</tr>
<tr>
<td>Radiation Oncologists</td>
<td>20%</td>
</tr>
<tr>
<td>Medical Oncologists</td>
<td>20%</td>
</tr>
<tr>
<td>Rectal Cancer Program Director</td>
<td>50%</td>
</tr>
<tr>
<td>Rectal Cancer Program Coordinator</td>
<td>50%</td>
</tr>
<tr>
<td>Lead pathologist, radiologist, medical oncologist, and radiation oncologist</td>
<td>30%</td>
</tr>
</tbody>
</table>

Attendance at RC-MDT meetings may include participation through teleconference if the tele-attendee can participate in discussions and has access to necessary meeting materials, including, but not limited to, radiographic images, specimen photographs, and pathologic reports and/or slides.

The Rectal Cancer Program Director monitors attendance each year and addresses attendance outliers that do not meet the established attendance policy.

Measure of Compliance

Each calendar year, the rectal cancer program fulfills the compliance criteria:
1. Each individual Rectal Cancer Multidisciplinary Team member meets minimum attendance requirements per specialty/role.
2. The Rectal Cancer Program Director monitors attendance and addresses attendance outliers that do not meet the established policy.

Documentation

Submitted with Pre-Review Questionnaire
- RC-MDT minutes that include the membership attendance for all RC-MDT meetings held during each calendar year.
3 Facilities and Equipment Resources
Rationale

Commission on Cancer (CoC) accreditation requires that the cancer program maintains or provides referrals for optimal resources for the care of patients with cancer. Accordingly, the rectal cancer program must be part of a CoC-accredited facility.
3.1 Commission on Cancer Accreditation

Definition and Requirements

The facility must be accredited by the Commission on Cancer (CoC) before earning accreditation by the National Accreditation Program for Rectal Cancer.

The CoC is a consortium of professional organizations dedicated to improving survival and quality of life for cancer patients through standard setting, prevention, research, education, and the monitoring of comprehensive quality care. CoC accreditation is only granted to facilities that voluntarily commit to providing high-quality cancer care and comply with established CoC standards.

High-quality rectal cancer care involves the same principles that underlie CoC accreditation. Accordingly, NAPRC accreditation is only granted to facilities that currently hold CoC accreditation status of Three-Year with Commendation Accreditation, Three-Year Accreditation, or Three-Year Accreditation with Contingency.

Measure of Compliance

The rectal cancer program fulfills the compliance criteria:

1. The facility has a Commission on Cancer accreditation status of Three-Year with Commendation Accreditation, Three-Year Accreditation, or Three-Year Accreditation with Contingency.
4 Personnel and Services Resources
Rationale

Patients with cancer have a multitude of needs. Cancer programs must oversee that patients receive appropriate care by qualified professionals. The facility must maintain optimal resources for the care of patients with cancer.

The responsibility is upon the cancer program to appropriately care for patients and develop criteria relative to the cancer program’s available resources and experience.
Fulfilled by the Commission on Cancer standard requirements.
5 Patient Care: Expectations and Protocols
Patient care expectations are the backbone of the accreditation program, including diagnostic workup, multidisciplinary presentation, and completeness of MRI, operative, and pathology reports.

These standards are intended solely as qualification criteria for National Accreditation Program for Rectal Cancer accreditation. They do not constitute a standard of care and are not intended to replace the medical judgment of the physician or health care professional in individual circumstances.
5.1 Review of Diagnostic Pathology

**Definition and Requirements**

Adenocarcinomas account for the vast majority of malignant tumors of the rectum in the United States. Other histologic types are rare, accounting for an estimated 2 to 5 percent of colorectal tumors. Every effort must be made to document the histopathological diagnosis of invasive adenocarcinoma of the rectum before the initiation of treatment.

The rectal cancer program (RCP) must confirm the diagnosis of rectal cancer before the initiation of treatment at the accredited RCP. The RCP must establish policies and procedures to obtain and review the outside biopsy pathology slides and/or biopsy pathology reports and include them in the patient's medical record. Additionally, for patients who are previously undiagnosed and previously untreated, the RCP must establish policies and procedures for confirming rectal cancer diagnosis by biopsy prior to initiation of treatment.

For patients who are diagnosed elsewhere, pathology slides must be obtained whenever possible. RCPs must track the number of slides obtained for patients diagnosed elsewhere.

**Rectal Cancer Patients Diagnosed Elsewhere with No Previous Treatment**

Before the initiation of definitive treatment at the RCP:
- Biopsy pathology slides are obtained and reviewed by an appointed pathology member of the Rectal Cancer Multidisciplinary Team (RC-MDT).
- If slides cannot be obtained, biopsy pathology reports are obtained and reviewed by an appropriate, appointed member of the RC-MDT.
- If pathology slides or reports for a biopsy performed elsewhere cannot be obtained, the RCP must re-biopsy the patient.
- Review of biopsy pathology slides and/or reports is documented in the patient medical record.

**Rectal Cancer Patients Previously Undiagnosed and Untreated**

Before the initiation of definitive treatment at the RCP:
- Ninety-five percent of previously undiagnosed, previously untreated rectal cancer patients must undergo a biopsy at the RCP for confirmation of rectal cancer diagnosis.

**Internal Medical Record Review**

At a minimum, a random sample of 20 percent of eligible patient medical records or a maximum of 100 cases are reviewed by the RCP Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

**Documentation**

**Reviewed on-site**
- The site reviewer will evaluate preselected medical records to confirm compliance with the standard.

**Submitted with Pre-Review Questionnaire**
- Policies and procedures to obtain, review, and document the review of biopsy pathology slides and/or reports of patients diagnosed elsewhere who receive definitive treatment at the RCP
- Policies and procedures for confirming rectal cancer diagnosis by biopsy in previously undiagnosed, previously untreated patients who receive definitive treatment at the RCP

**Note:** Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.
Measure of Compliance

Each accreditation cycle, the rectal cancer program fulfills the compliance criteria:

1. Before the initiation of definitive treatment, when available, pathology slides for patients diagnosed elsewhere are obtained and reviewed by a pathology member of the Rectal Cancer Multidisciplinary Team.
2. Before the initiation of definitive treatment, all rectal cancer patients diagnosed elsewhere who received no previous treatment must have slides or a pathology report obtained from a biopsy completed either outside the facility or at the accredited rectal cancer program. Outside biopsy slides and/or pathology reports are reviewed by an appropriate, appointed Rectal Cancer Multidisciplinary Team member. The pathology report is included in the patient’s medical record.
3. Before initiation of treatment at the accredited facility, all patients diagnosed elsewhere who received treatment elsewhere must have documentation confirming a rectal cancer diagnosis in the patient’s medical record.
4. Before initiation of treatment at the accredited facility, 95 percent of previously undiagnosed, previously untreated rectal cancer patients undergo a biopsy at the accredited facility.
5. All required policies and procedures are in place.

Reference

5.2 Staging before Definitive Treatment

Definition and Requirements

Thorough and accurate pretreatment American Joint Committee on Cancer (AJCC) clinical staging of a rectal cancer patient forms the essential basis for the individualized treatment-planning discussion that occurs at Rectal Cancer Multidisciplinary Team (RC-MDT) meetings. Clinical staging of rectal cancer has two components: “systemic staging” to diagnose distant metastatic disease (for example, liver and lung metastases) and “local tumor staging” to define the extent of the primary tumor in the rectum and involvement of regional pelvic lymph nodes (for example, mesorectal and iliac).1

Ninety-five percent of all previously untreated rectal cancer patients are staged (systemic and local tumor) before definitive treatment.

Systemic staging for rectal cancer is completed by Computerized Tomography (CT) or Positron Emission Tomography-Computed Tomography (PET/CT) scan of the chest, abdomen, and pelvis.2 Systemic staging must be completed by CT whenever possible; however, a combined PET/CT scan is an acceptable alternative. A PET scan without the CT scan does not meet this standard.

Local tumor is staged by Magnetic Resonance Imaging (MRI) of the pelvis using a rectal cancer protocol.3 The MRI of the pelvis is designed to highlight the depth of tumor penetration into the mesorectum, status of the circumferential resection margin, involvement of adjacent organs, lymph node involvement, extramural venous invasion, and relation to the anal sphincter complex.3

Patients with documented contraindications to CT, PET/CT, and/or MRI scanning are exempt from the standard.

Internal Medical Record Review

At a minimum, a random sample of 20 percent of eligible patient medical records or a maximum of 100 cases are reviewed by the Rectal Cancer Program (RCP) Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed on-site
- The site reviewer will evaluate preselected medical records to confirm compliance with the standard.

Submitted with Pre-Review Questionnaire
- Policy and procedure for systemic staging of rectal cancer using CT or PET/CT exam of the chest, abdomen, and pelvis
- Policy and procedure for local tumor staging of rectal cancer using MRI of the pelvis

Note: Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

Each accreditation cycle, the rectal cancer program fulfills the compliance criteria:
1. Ninety-five percent of previously untreated rectal cancer patients are American Joint Committee on Cancer staged (systemic and local tumor) before definitive treatment.
2. All required policies and procedures are in place.

References

5.3 Standardized Staging Reporting for Magnetic Resonance Imaging Results

**Definition and Requirements**

Magnetic Resonance Imaging (MRI) has replaced endorectal ultrasound (EUS) as the primary imaging modality used for the local staging of rectal cancer. MRI’s significant advantages over EUS include: the ability to have independent review, improved accuracy of extramural depth of invasion and extramural vascular invasion, detection of the anticipated circumferential margin clearance, and the ability to compare pre- and posttreatment studies.¹⁻⁴

The protocol for MRI staging of rectal cancer has been refined and standardized by European experts.⁵ For MRI staging to be effective, the technique of acquiring and interpreting the images must be uniform and the results must be reported in a standardized report.⁶,⁷ Without standardized reporting, less than 40 percent of MRI reports contain all of the necessary information to make treatment decisions.⁸

Ninety percent of pretreatment MRI exams for previously untreated rectal cancer patients are read by a radiologist who is a member of the Rectal Cancer Multidisciplinary Team (RC-MDT).

MRI staging results for 95 percent of all previously untreated rectal cancer patients who complete MRI exams are recorded in a standardized report containing the minimum required elements. These elements are defined on the NAPRC website. The standardized report is included in the patient’s medical record.

**Internal Medical Record Review**

At a minimum, a random sample of 20 percent of eligible patient medical records or a maximum of 100 cases are reviewed by the Rectal Cancer Program (RCP) Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard an action plan must be developed and implemented.

**Documentation**

**Reviewed on-site**

- The site reviewer will evaluate preselected medical records to confirm compliance with the standard.

**Submitted with Pre-Review Questionnaire**

- Example template for standardized synoptic reporting of MRI staging results

Note: Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

**Measure of Compliance**

Each accreditation cycle, the rectal cancer program fulfills the compliance criteria:

1. Ninety percent of pretreatment Magnetic Resonance Imaging exams for rectal cancer patients are read by a radiologist who is a member of the Rectal Cancer Multidisciplinary Team.
2. Ninety-five percent of Magnetic Resonance Imaging staging results for rectal cancer patients are reported in standardized format containing all required elements. The report is included in the patient’s medical record.

**References**


5.4 Carcinoembryonic Antigen Level

Definition and Requirements

Testing for Carcinoembryonic Antigen (CEA) Level, a glycoprotein that is released from tumor cells into patient serum, is recommended by the National Comprehensive Cancer Network (NCCN) guidelines for both colon and rectal cancer.\textsuperscript{1,2} Testing is recommended before initiation of treatment in patients with rectal cancer, as the result can be used as a baseline for surveillance after treatment.\textsuperscript{3-8}

Each calendar year, a CEA level is obtained before definitive treatment for 75 percent of all previously untreated rectal cancer patients and the pretreatment CEA level is recorded in the patient's medical record. Policies and procedures are in place for obtaining and tracking pretreatment CEA levels for all previously untreated rectal cancer patients.

Internal Medical Record Review
At a minimum, a random sample of 20 percent of eligible patient medical records or a maximum of 100 cases are reviewed by the Rectal Cancer Program (RCP) Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the Rectal Cancer Multidisciplinary Team. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed on-site
- The site reviewer will evaluate preselected medical records to confirm compliance with the standard.

Submitted with Pre-Review Questionnaire
- Policies and procedures for obtaining and tracking pretreatment CEA levels for all previously untreated rectal cancer patients

Note: Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

Each accreditation cycle, the rectal cancer program fulfills the compliance criteria:

1. A carcinoembryonic antigen level is obtained before definitive treatment and is recorded in the patient's medical record for 75 percent of previously untreated rectal cancer patients.
2. All required policies and procedures are in place.

References

**5.5 Rectal Cancer Multidisciplinary Team Treatment Planning Discussion**

**Definition and Requirements**

All rectal cancer patients who undergo treatment at a National Accreditation Program for Rectal Cancer-accredited program, excluding emergency patients, must be discussed at a Rectal Cancer Multidisciplinary Team (RC-MDT) meeting before beginning definitive treatment. Definitive treatment is defined as neoadjuvant therapy, surgical resection, or initiation of palliative care.

Emergency patients who do not require a treatment planning discussion are those that present with tumor-related complications that require immediate or urgent treatment. Examples of emergent conditions include, but are not limited to: rectal tumor perforation, life-threatening tumor hemorrhage, and acute large bowel obstruction.

The RC-MDT treatment planning discussion must include, but is not limited to:

- **Review of diagnostic and staging studies**
  - Colonoscopy report (location of primary tumor and synchronous lesions) if present/available
  - Biopsies of primary rectal cancer and metastases if present/available (Standard 5.1)
  - CT scan or PET/CT of chest, abdomen, and pelvis (Standard 5.2)
  - Rectal cancer Magnetic Resonance Imaging (Standard 5.2)
  - Pretreatment carcinoembryonic antigen level (Standard 5.4)

- **Assignment of clinical stage**
  - Clinical stage according to the American Joint Committee on Cancer (AJCC)

- **Creation of individualized treatment plan**
  - Neoadjuvant therapy regimen, when indicated
  - Anticipated surgical procedure, when indicated
  - Referral to radiation oncology, when indicated
  - Referral to medical oncology, when indicated
  - Palliative care, when indicated

The rectal cancer program (RCP) consults with its legal and/or risk management department(s) to conform to local policy and requirements for conducting and documenting multidisciplinary team treatment discussions and communicating with the patient.

In rectal cancer programs with 100 or more cases, the RCP Director may develop criteria to determine which patients must be presented to the RC-MDT for a treatment planning discussion. These criteria must be documented in a policy and procedure. Regardless of criteria put in place, at least 100 cases must be presented for treatment planning discussion in accordance with this standard each year. The patients who are not presented to the RC-MDT must still meet the requirements of all other standards.

**Internal Medical Record Review**

At a minimum, a random sample of 20 percent of eligible patient medical records or a maximum of 100 cases are reviewed by the RCP Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

**Documentation**

**Reviewed on-site**

- The site reviewer will evaluate preselected medical records to confirm compliance with the standard.

**Submitted with Pre-Review Questionnaire**

- Policies and procedures for pretreatment discussion of all rectal cancer patients at a RC-MDT meeting
- For programs with more than 100 rectal cancer patients per year, policy and procedure detailing criteria used to determine which patients are discussed at the RC-MDT for treatment planning

**Note:** Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

**Measure of Compliance**

Each accreditation cycle, the rectal cancer program fulfills the compliance criteria:

1. Excluding emergency patients, an individualized treatment planning discussion is conducted at a Rectal Cancer Multidisciplinary Team meeting for all rectal cancer patients before initiation of definitive treatment.
2. All required policies and procedures are in place.
5.6 Treatment Evaluation and Recommendation Summary

Definition and Requirements

A lack of substantial information in treatment summaries has been recognized to negatively affect rectal cancer patient outcomes. The standardized evaluation and treatment recommendation summary provides documentation of information pertinent to the treatment of the patient's rectal cancer and communicates this information to the patient's treating physician in order to improve coordination and delivery of care.

A treatment evaluation and recommendation summary must be provided to the treating physician for at least 50 percent of rectal cancer patients. It is anticipated that many rectal cancer programs (RCPs) will exceed the minimum 50 percent required by this standard.

Treating physician is defined as the provider of record treating the patient's rectal cancer who seeks the opinion of the Rectal Cancer Multidisciplinary Team (RC-MDT). The treating physician is responsible for ensuring communication of evaluation and treatment recommendations to the patient.

The standardized evaluation and treatment recommendation summary includes, but is not limited to:

- Tumor location in the rectum (lower, middle, or upper third)
- Indication of sphincter involvement
- Clinical (pretreatment) American Joint Committee on Cancer (AJCC) stage
- Pretreatment circumferential resection margin status (involved, threatened, or not threatened)
- Carcinoembryonic antigen level
- Neoadjuvant therapy recommendation
- Type and duration of neoadjuvant therapy recommended
- Anticipated date and type of surgical procedure
- Clinical research study eligibility and/or enrollment

Internal Medical Record Review

At a minimum, a random sample of 20 percent of eligible patient medical records or a maximum of 100 cases are reviewed by the RCP Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed on-site

- The site reviewer will evaluate preselected medical records to confirm compliance with the standard.

Submitted with Pre-Review Questionnaire

- Policies and procedures for completing the evaluation and treatment recommendation summary and providing it to the treating physician
- A template for the standardized evaluation and treatment recommendation summary

Note: Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

Each accreditation cycle, the rectal cancer program fulfills the compliance criteria:

1. Before the initiation of definitive treatment, a standardized evaluation and treatment recommendation summary is completed and provided to the patient's treating physician for at least 50 percent of rectal cancer patients.
2. All required policies and procedures are in place.

Reference

5.7 Definitive Treatment Timing

Definition and Requirements

Once a diagnosis of a rectal cancer has been made, the rectal cancer program (RCP) is responsible for patients receiving a thorough and efficient evaluation for prompt initiation of therapy. A patient-centered approach dictates minimal delay between diagnosis and treatment to avoid undue patient anxiety.

Eighty percent of previously untreated patients begin definitive treatment within 60 days of the patient’s initial clinical evaluation for rectal cancer at the accredited RCP. The treatment plan is documented in the patient’s medical record.

Delays due to documented patient noncompliance or failure of payers to authorize recommended treatment in a timely fashion shall not be considered a failure to meet this standard.

Internal Medical Record Review

At a minimum, a random sample of 20 percent of eligible patient medical records or a maximum of 100 cases are reviewed by the RCP Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the Rectal Cancer Multidisciplinary Team. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed on-site

- The site reviewer will evaluate preselected medical records to confirm compliance with the standard.

Note: Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

Each accreditation cycle, the rectal cancer program fulfills the compliance criteria:

1. Eighty percent of previously untreated rectal cancer patients begin definitive treatment within 60 days of the patient’s initial clinical evaluation for rectal cancer at the accredited rectal cancer program.

References


5.8 Surgical Resection and Standardized Operative Reporting

**Definition and Requirements**

**Surgery Standardization**
Surgeon specialization has been shown to improve rectal cancer outcomes. Proper surgical technique is vital to optimizing oncological outcome and minimizing morbidity in rectal cancer surgery. The operative technique of total mesorectal excision (TME) is technically demanding and a clear correlation exists between surgeon experience and knowledge and patient outcomes, which may partially explain observed discrepancies between high- and low-volume surgeons. To encourage standardization and adherence to standards, rectal cancer surgery must be performed by a member of the Rectal Cancer Multidisciplinary Team (RC-MDT).

Each calendar year, 80 percent of all surgical resections for rectal cancer patients are performed by a surgeon who is an appointed member of the RC-MDT.

**Standardized Synoptic Reporting**
The use of checklists for complex processes is widely advocated in many fields, including medicine, where particular attention has been paid toward procedural-based specialties like surgery. Checklist implementation is credited with significant reductions in rates of inpatient complications and perioperative mortality in both developing and mature health care systems. Checklists help eliminate omission of crucial steps, particularly during uncommon procedures or at times when information complexity may reduce situational awareness. The management of rectal cancer fulfills these criteria as the majority of patients with rectal cancer in North America are treated by surgeons who perform 10 or fewer cases annually, and the disease requires a high level of coordination between multiple specialists.

Recognizing the value of checklists in improving patient safety and outcomes, the Quality and Safety Assessment Committee of the American Society of Colon and Rectal Surgeons (ASCRS) developed a comprehensive rectal cancer surgery checklist as a guide to enhance safety and quality of care for patients with rectal cancer undergoing surgery, to incorporate best practices in treating these patients, to raise general awareness of the importance of each individual checklist item, and to serve as a potential foundation for building centers of excellence in rectal cancer treatment. Additionally, the use of synoptic operative reporting in rectal cancer has been shown to increase the completeness and reliability of documentation of critical elements when compared to narrative reporting.

The OSTRiCh Standardized Synoptic Operative Report Committee subsequently utilized the ASCRS rectal cancer checklist as a guide in the development of its standardized synoptic operative report. The required elements are defined in Table 1 in the Appendix of this manual.

Each calendar year, operative reports for 95 percent of all rectal cancer patients who undergo surgical resection are recorded in a standardized synoptic report containing the minimum required elements. Local excision is excluded from these requirements.

**Internal Medical Record Review**
At a minimum, a random sample of 20 percent of eligible patient medical records or a maximum of 100 cases are reviewed by the Rectal Cancer Program (RCP) Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

**Documentation**

**Reviewed on-site**
- The site reviewer will evaluate preselected medical records to confirm compliance with the standard.

**Submitted with Pre-Review Questionnaire**
- Example template for standardized synoptic reporting of operative reports

**Note:** Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.
Measure of Compliance

Each accreditation cycle, the rectal cancer program fulfills the compliance criteria:

1. Rectal cancer surgery is performed by a surgeon member of the Rectal Cancer Multidisciplinary Team for 80 percent of patients undergoing surgical resections for rectal cancer.

2. Operative reports for 95 percent of surgical resections for rectal cancer are reported in standardized synoptic format containing all required elements and are included in the patient’s medical record.

References


5.9 Pathology Reports after Surgical Resection

Definition and Requirements

Beyond the important staging characteristics of tumor depth of invasion (T-category) and nodal status (N-category), important diagnostic and prognostic information can be gained from an evaluation of the completeness of the mesorectal excision, the status of the circumferential margin, and the response of the tumor to neoadjuvant therapy (Tumor Regression Grade).\(^1\)\(^-\)\(^5\)

Pathologic assessment of the resected rectal cancer specimen provides critical information for prognosis, forms the basis for decisions on adjuvant therapy, serves as an important indicator of quality of surgery, and can validate the soundness of the Rectal Cancer Multidisciplinary Team (RC-MDT) discussion process.

Ninety percent of definitive rectal cancer surgical resection specimens of the primary tumor are read and the pathology report completed by a pathologist who is an appointed member of the RC-MDT.

Pathology results for 95 percent of rectal cancer patients undergoing a definitive surgical resection performed at the accredited rectal cancer program must:

- Include all required data elements as outlined in the College of American Pathologists (CAP) rectal cancer protocols
- Use a standardized synoptic format
- Be completed within two weeks of the definitive surgical resection

Internal Medical Record Review

At a minimum, a random sample of 20 percent of eligible patient medical records or a maximum of 100 cases are reviewed by the Rectal Cancer Program (RCP) Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed on-site

- The site reviewer will evaluate preselected medical records to confirm compliance with the standard.

Submitted with Pre-Review Questionnaire

- Example template for standardized synoptic reporting of pathology specimens

Note: Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

Each accreditation cycle, the rectal cancer program fulfills the compliance criteria:

1. Ninety percent of definitive rectal cancer surgical resection specimens of the primary tumor performed at the accredited rectal cancer program are read and the pathology report completed by a pathologist who is an appointed member of the Rectal Cancer Multidisciplinary Team.

2. Pathology reports for 95 percent of rectal cancer patients undergoing a definitive surgical resection of the primary tumor at the accredited rectal cancer program are completed within two weeks of the definitive surgical resection, contain all required College of American Pathologists data items, and are in standardized synoptic format.

References


5.10 Photographs of Surgical Specimens

Definition and Requirements

The integrity of the mesorectum correlates with oncologic outcomes. The plane in which the surgeon performs the dissection of the rectum will influence the completeness of the mesorectum and therefore reflects the quality of the surgery. The presence of mesorectal tears or defects predisposes to both local and distant recurrence. Photographs of the surgical specimens displaying the integrity of the mesorectum provide useful feedback to the surgeon.

A minimum of 65 percent of rectal cancer specimens are photographed to document the quality of the mesorectum and include anterior, posterior, and two lateral views. Photographs of the fresh or formalin fixed ex-vivo specimen may be obtained using any standard digital camera in either the operating room or in the pathology laboratory. These images are shown and discussed at Rectal Cancer Multidisciplinary Team (RC-MDT) meetings and are electronically stored with a patient identifier. If the specimen is photographed but not presented and discussed at an RC-MDT meeting, then it does not qualify for the 65 percent required for compliance with this standard.

Internal Medical Record Review

At a minimum, a random sample of 20 percent of eligible patient medical records or a maximum of 100 cases are reviewed by the Rectal Cancer Program (RCP) Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed on-site
- The site reviewer will evaluate preselected medical records to confirm compliance with the standard.

Submitted with Pre-Review Questionnaire
- Policies and procedures for obtaining, displaying, and storing photographs of rectal cancer specimens

Note: Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

Each accreditation cycle, the rectal cancer program fulfills the compliance criteria:
1. A minimum of 65 percent of all eligible surgical specimens are photographed to include anterior, posterior, and two lateral views and are presented to and discussed by the Rectal Cancer Multidisciplinary Team and electronically stored with the patient identifier.
2. All required policies and procedures are in place.

References

5.11 Multidisciplinary Team Post-Surgical Treatment Outcome Discussion

**Definition and Requirements**

After completion of definitive surgical treatment, all rectal cancer patients treated at an NAPRC-accredited program must be discussed at an Rectal Cancer Multidisciplinary Team (RC-MDT) meeting. The post-surgical treatment outcome discussion must occur within four weeks of the patient's definitive surgical treatment.

The four primary steps of the post-surgical treatment outcome discussion for rectal cancer patients are:

1. **Presurgical Evaluation and Treatment**
   - Clinical stage according to American Joint Committee on Cancer (AJCC)
   - Neoadjuvant therapy
2. **Review of the outcome of the surgery**
   - Proctectomy or local excision
   - Approach (open, laparoscopic, robotic)
   - Presence or absence of stoma and type of stoma
   - Postoperative complications that may impact further treatment
   - Unexpected findings (for example, metastatic disease, adjacent organ involvement, grossly involved margins after resection)
   - Specimen photographs
3. **Review of the final pathology report and stage**
   - Circumferential Resection Margin and distal margin status
   - Tumor regression grade
   - Mesorectal grade
   - Pathological stage or posttherapy y-pathological stage according to the AJCC
4. **Recommendation for adjuvant treatment**
   - Adjuvant therapy regimen, when indicated
   - Referral to medical oncology, when indicated
   - Referral to radiation oncology, when indicated
   - Palliative care, when indicated

In rectal cancer programs with 100 or more cases, the Rectal Cancer Program (RCP) Director may develop criteria to determine which patients must be presented to the RC-MDT for a treatment outcome discussion. These criteria must be documented in a policy and procedure. Regardless of criteria put in place, at least 100 cases must be presented for treatment outcome discussion in accordance with this standard each year. The patients who are not presented to the RC-MDT must still meet the requirements of all other standards.

**Internal Medical Record Review**

At a minimum, a random sample of 20 percent of eligible patient medical records or a maximum of 100 cases are reviewed by the RCP Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

**Documentation**

**Reviewed on-site**
- The site reviewer will evaluate preselected medical records to confirm compliance with the standard.

**Submitted with Pre-Review Questionnaire**
- Policies and procedures used to monitor treatment completion status for each rectal cancer patient and that the patient is scheduled for presentation at an RC-MDT meeting following completion of definitive surgery
- For programs with more than 100 rectal cancer patients per year, policy and procedure detailing criteria used to determine which patients are discussed at the RC-MDT for treatment outcome discussion

**Note:** Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

**Measure of Compliance**

Each accreditation cycle, the rectal cancer program fulfills the compliance criteria:

1. **Within four weeks of definitive surgical treatment completion**, an individualized post-surgical treatment outcome discussion occurs for all rectal cancer patients at a Rectal Cancer Multidisciplinary Team meeting.
2. **All required policies and procedures are in place.**
5.12 Post-Surgical Treatment Outcome Discussion Summary

Definition and Requirements

The standardized post-surgical treatment summary provides documentation of the treatment provided for the patient’s rectal cancer and prognostic information based on tumor staging and other pathology factors. The post-surgical treatment summary must be provided to at least 50 percent of patients’ treating physicians within four weeks of the Standard 5.11 post-surgical treatment outcome discussion. It is anticipated that many programs will exceed the minimum 50 percent required by this standard.

The post-surgical treatment summary must include, but is not limited to, the following information:

- Clinical (pretreatment) stage according to American Joint Committee on Cancer (AJCC)
- Pretreatment carcinoembryonic antigen level
- Neoadjuvant therapy before surgery
- Type of neoadjuvant therapy
- Neoadjuvant therapy date of completion
- Surgical procedure
- Date of surgery
- Final pathological stage or posttherapy y-pathological stage according to AJCC
- Tumor Regression Grade
- Microsatellite instability status
- Circumferential Resection Margin
- Distal Resection Margin
- Mesorectal Grade
- Recommendation for adjuvant therapy and, if applicable, adjuvant therapy regimen

Internal Medical Record Review

At a minimum, a random sample of 20 percent of eligible patient medical records or a maximum of 100 cases are reviewed by the Rectal Cancer Program (RCP) Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the Rectal Cancer Multidisciplinary Team. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed on-site

- The site reviewer will evaluate preselected medical records to confirm compliance with the standard.

Submitted with Pre-Review Questionnaire

- A template for the standardized content of the post-surgical treatment outcome discussion summary
- Policies and procedures to generate and disseminate post-surgical treatment outcome discussion summaries to patients’ treating physician(s)

Note: Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

Each accreditation cycle, the rectal cancer program fulfills the compliance criteria:

1. The post-surgical treatment summary is provided to the treating physician for 50 percent of patients within four weeks of the Standard 5.11 Rectal Cancer Multidisciplinary Team Post-Surgical Treatment Outcome Discussion.
2. All required policies and procedures are in place.

Reference

Definition and Requirements

National Comprehensive Cancer Network (NCCN) guidelines recommend that patients with clinical or pathological Stage II and III rectal cancer undergo adjuvant chemotherapy after curative surgical resection of the primary tumor. Both overall and disease-free survival are improved with 5-fluorouracil-based systemic therapy.

Reviews of randomized, controlled trial data suggest that adjuvant chemotherapy should be initiated four to eight weeks after surgery. Delay in the initiation of adjuvant chemotherapy beyond this time leads to a progressive decrease in the efficacy of chemotherapy to improve both overall and disease-free survival.

Fifty percent of all eligible rectal cancer patients who elect to initiate recommended adjuvant treatment regimen begin within eight weeks of definitive surgical resection of the primary tumor.

Policies and procedures are in place to track the timely initiation of adjuvant chemotherapy.

Referrals for adjuvant treatment are evaluated and monitored each calendar year by the Rectal Cancer Program (RCP) Coordinator who reports results to the Rectal Cancer Multidisciplinary Team (RC-MDT). The review is documented in the RC-MDT meeting minutes.

Standard Exceptions

Delays due to documented patient noncompliance or failure of payers to authorize recommended treatment in a timely fashion shall not be considered a failure to meet this standard.

Internal Medical Record Review

At a minimum, a random sample of 20 percent of eligible patient medical records or a maximum of 100 cases are reviewed by the RCP Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Submitted with Pre-Review Questionnaire

- Policies and procedures to track and monitor eligible patients electing to receive adjuvant treatment and when the adjuvant treatment was initiated
- RC-MDT meeting minutes that document the annual evaluation and monitoring of the referral process for adjuvant therapy

Note: Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

Each accreditation cycle, the rectal cancer program fulfills the compliance criteria:

1. Fifty percent of eligible rectal cancer patients who elect to initiate recommended adjuvant treatment regimen begin treatment within eight weeks of definitive surgical resection of the primary tumor.
2. Referrals for adjuvant treatment are evaluated and monitored by the Rectal Cancer Program Coordinator, reported to the Rectal Cancer Multidisciplinary Team, and documented in the Rectal Cancer Multidisciplinary Team meeting minutes.
3. All required policies and procedures are in place.

References

6 Data Surveillance and Systems
Rationale

High-quality data are critical to inform quality improvement and measure the performance of programs. All required cases must be submitted to the National Cancer Database using nationally standardized data item and coding definitions.

Data are validated through multiple mechanisms that are continuously updated to optimize the quality of the data collected.
Fulfilled by the Commission on Cancer Requirements.
7 Quality Improvement
Rationale

In support of quality improvement efforts, the rectal cancer program must develop a culture of collaboration in order to analyze and implement strategies based on data to drive improvement in the quality of care. Continuous quality improvement must be reflected in the results of such efforts.
7.1 Accountability and Quality Improvement Measures

Definition and Requirements

The National Accreditation Program for Rectal Cancer (NAPRC) requires accredited cancer programs to treat cancer patients according to nationally accepted accountability and quality improvement measures indicated by the National Cancer Database (NCDB) quality reporting tools.

The cancer committee monitors the program’s expected Estimated Performance Rates (EPR) for accountability and quality improvement measures selected by the NAPRC. Details on the quality measures for this standard may be referenced on the NCDB website and/or NAPRC Quality Portal, which includes measure specifications, years for performance evaluation, and quality measure performance thresholds for this standard. Facility performance rates for these quality measures will be extracted from the NCDB reporting tools.

If the program is not meeting the expected EPR of a measure(s), then a corrective action plan must be developed and executed in order to improve performance. The corrective action plan must document how the program will investigate the issue for each measure with the goal of resolving the deficiency and improving compliance.

The Rectal Cancer Multidisciplinary Team’s (RC-MDT) review of compliance with required accountability and quality improvement measures and monitoring activity is documented in the RC-MDT minutes. Any action plans and corrective action taken are included in the documentation. Programs with no cases eligible for assessment in a selected measure are exempt from requirements for that individual measure.

Documentation

Submitted with Pre-Review Questionnaire

- RC-MDT minutes documenting the presentation and review of required accountability and quality improvement measures; documentation includes any required action plans

Note: Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

Each calendar year, the rectal cancer program fulfills the compliance criteria:

1. The Rectal Cancer Multidisciplinary Team monitors the program’s expected Estimated Performance Rates for accountability and quality improvement measures selected by the NAPRC.
2. The monitoring activity is documented in the Rectal Cancer Multidisciplinary Team minutes.
3. For each accountability and quality improvement measure selected by the NAPRC, the quality reporting tools show a performance rate equal to or greater than the expected Estimated Performance Rate specified by the NAPRC. If the expected Estimated Performance Rate is not met, the program has implemented an action plan that reviews and addresses program performance.

Reference

8 Education: Professional and Community Outreach
Rationale

The success of a rectal cancer program may vary based on the capability of the Rectal Cancer Multidisciplinary Team (RC-MDT) to follow specific principles, which are not uniformly present in the United States. As such, surgeon, radiology, and pathology members of the RC-MDT complete education modules specific to their specialties.
8.1 Rectal Cancer Program Education

Definition and Requirements

Current evidence supports the adoption of four main principles of rectal cancer care: (1) performing surgery that adheres to the principles of total mesorectal excision (TME); (2) pretreatment tumor assessment by specialized rectal cancer-protocol Magnetic Resonance Imaging (MRI) to identify patients at high risk for local tumor recurrence who may benefit from neoadjuvant therapies; (3) specific techniques of pathology assessment of the resected rectum that contribute to patient prognosis, need for adjuvant chemotherapy, and evaluation of the quality of surgery; and (4) a multidisciplinary team approach that identifies, coordinates, delivers, and monitors the ideal treatment for each individual patient.1

The success of a rectal cancer program may vary based on the capability of a facility’s Rectal Cancer Multidisciplinary Team (RC-MDT) to follow the above principles. The skills required to fulfill these principles, however, are not uniformly present in the United States. As such, a key component of an accredited rectal cancer program is the completion of education modules designed to train the facility’s RC-MDT members in these skill sets.

All surgeon, pathologist, and radiologist physician members of the facility’s RC-MDT must complete the relevant National Accreditation Program for Rectal Cancer (NAPRC)-endorsed education module specific to their medical specialties within 12 calendar months of joining the RC-MDT.

Surgery

Sound surgical technique is vital to optimizing oncological outcomes and minimizing complications and morbidity in rectal cancer surgery.

Proctectomy following the principles of TME maintains the integrity of the mesorectal fascial envelope by sharp, direct vision dissection of the plane between the mesorectal fascia and the presacral and endopelvic fascia. The ability of TME to lower local recurrence rates and increase survival has been widely documented.2-4

The training of surgeons and wide implementation of TME has been shown to reduce permanent stoma rates, decrease the incidence of local recurrence, and to improve five-year survival in population-based studies.5 This NAPRC-endorsed education module is being developed by the American Society of Colon and Rectal Surgeons.

Pathology

Pathologic assessment of tumor stage and margin status is widely known as the most important prognostic factor in rectal cancer. Pathology grading of the TME specimen has also been shown as an important indicator of surgical quality and resultant oncologic outcomes.6,7

Analysis of the plane of surgery and circumferential resection margin (CRM) status in patients enrolled in a large randomized, controlled trial of preoperative radiotherapy provides evidence for the association between surgical quality and outcomes and the role of the pathologist in surgical quality assessment.8

Pathologists who are trained in specialized methods of rectal cancer specimen assessment form an important component of the direct quality assurance of rectal cancer surgery. The College of American Pathologists (CAP) Protocol for the Examination of Resection Specimens From Patients With Primary Carcinoma of the Colon and Rectum is accessible, free of charge, from the CAP website and must be used by pathologists as a self-study. Supplemental education materials are provided by the NAPRC and must be used by pathologists as additional self-study. An attestation must be signed that the pathologist has reviewed and studied all required materials.

Pathologist members of the RC-MDT who process rectal cancer specimens and report rectal cancer findings at the NAPRC-accredited program must complete the pathology self-study portion of the NAPRC-endorsed education module at least once. At the discretion of the NAPRC, pathologists may be required to take an updated module in line with clinical advancements.

Radiology

Imaging of rectal cancer has evolved significantly in the last decade. In Europe, MRI has become the standard for the pretreatment imaging of rectal cancer based on its accuracy in predicting the CRM, tumor invasion of adjacent pelvic structures, and, to a lesser degree, tumor (T)- and nodal (N)-stage.9,10

Routine use of MRI in the context of a multidisciplinary
assessments of rectal cancer has been used to plan neoadjuvant therapy and surgery and has been shown to reduce the incidence of positive circumferential margins.\textsuperscript{11,12} MRI-based treatment planning may also allow for the more efficient use of neoadjuvant therapy, an important factor in potentially reducing both the costs and morbidity of rectal cancer care.\textsuperscript{13} This NAPRC-endorsed education module was developed by the American College of Radiology.

Radiologist members of the RC-MDT who review and report rectal cancer imaging at the NAPRC-accredited program must complete the radiology portion of the NAPRC endorsed education module at least once. At the discretion of the NAPRC, radiologists may be required to take an updated module in line with clinical advancements.

### Documentation

**Submitted with Pre-Review Questionnaire**

- Certificates of completion or signed attestation for the NAPRC-endorsed education module for each surgeon, pathologist, or radiologist physician member of the RC-MDT

### Measure of Compliance

As required, the rectal cancer program fulfills the compliance criteria:

1. All surgeon, pathologist, and radiologist physician members of the facility's Rectal Cancer Multidisciplinary Team complete the NAPRC endorsed education module related to their respective specialties and provide documentation to confirm completion.

### References


Glossary

**Accession number:** A unique patient identifier assigned when the patient is abstracted in the cancer registry. The accession number consists of the year in which the patient was first seen at the reporting facility and the consecutive order in which the patient was abstracted.

**Accreditation report:** Document released to rectal cancer programs at the conclusion of the initial or reaccreditation site visit process. The accreditation report includes a compliance rating for each applicable standard and may include specific comments regarding the rectal cancer program's performance. The accreditation report also states the assigned accreditation award and, if applicable, the corrective action due date.

**Analytic cases:** Cases for which the hospital provided the initial diagnosis of cancer and/or for which the hospital contributed to first course of treatment, if those cancers were diagnosed on or after the hospital's reference date and are diseases the Commission on Cancer requires to be abstracted.

**Annually:** Once each calendar year.

**Appropriately-credentialed physician:** The Rectal Cancer Program Director has the discretion to delegate certain responsibilities to other physicians on the RC-MDT. Any delegated obligation must be given to a physician whose specialty relates to the subject matter of the audit or other responsibility. For example, a pathologist should be chosen to perform the audit for Standard 5.9: Pathology Reports after Surgical Resection.

**Calendar year:** January 1–December 31.

**Calendar month:** The first day of the month through the last day of the month. For example, March 1 to March 31 or April 1 to April 30.

**CAnswer Forum:** An interactive, virtual bulletin board for NAPRC constituents to review questions and answers regarding standard requirements. Users can search individual chapters or standards for topics on which they may have questions. If the question has not already been answered, users can post a question. Users must complete a one-time registration that includes creating a username and a password.

**CoC:** Commission on Cancer.

**Definitive treatment:** Neoadjuvant therapy, surgical resection, or initiation of palliative care.

**Elsewhere:** A hospital, facility, or health care organization that is not owned, co-owned, or part of the hospital licensure of the accredited facility. A network clinic or outpatient center owned by the facility is part of the facility.

**“In Development” Standard:** Standards and information that have components that are still in development by the NAPRC or its partners. Programs will not be held to components of the compliance requirements for these standards until an official announcement by the NAPRC. Further details, clarifications, and updates regarding these standards and NAPRC policies are provided on the NAPRC web page and/or in the NAPRC Quality Portal.

**Medical record review:** The review of randomly selected patient medical records to determine compliance with specific standard requirements.

**NAPRC:** National Accreditation Program for Rectal Cancer.

**On-site:** The rectal cancer program's facility or off-campus location(s) that are either owned by its facility or part of the same hospital licensure.
Glossary

Pre-Review Questionnaire (PRQ): An online reporting tool that is utilized to demonstrate compliance with NAPRC standards; formally known as the “Survey Application Record (SAR).”

Previously undiagnosed: Rectal cancer patients who receive the first diagnosis of rectal cancer at the rectal cancer program.

Previously untreated: Rectal cancer patients who have received no treatment for rectal cancer.

RCP: Rectal cancer program.

RCP Director: Rectal Cancer Program Director. See definition and requirements in Standard 2.2.

Referred services: Components of evaluation and management not under the control or accountability of the rectal cancer program and/or its facility.

RC-MDT: Rectal Cancer Multidisciplinary Team. See required members in Standard 2.1.

RCP Coordinator: Rectal Cancer Program Coordinator. See definition and requirements in Standard 2.3.

Site visit: An on-site visit by a NAPRC site reviewer to review cancer program data to aid in determining compliance with NAPRC standards and the respective accreditation award. After initial accreditation, the on-site visit occurs once every three years. Formally known as the “survey.”

Site Reviewer: NAPRC-trained physician who conducts on-site visits and reviews rectal cancer program activity documentation. The site reviewer assists in verifying whether the rectal cancer program is in compliance with the NAPRC standards. Formally known as the “surveyor.”

Standard: Qualification criteria for NAPRC accreditation (not standard of care).

Synoptic format: A structured format that includes all of the following:
  - All core elements must be reported (whether applicable or not)
  - All core elements must be reported in a “diagnostic parameter pair” format, in other words, data element followed by its response (answer)
  - Each diagnostic parameter pair must be listed on a separate line or in a tabular format to achieve visual separation
  - All core elements must be listed together in one location in the radiology, pathology, or operative report
### Appendix

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ASA score</td>
<td>I; II; III; IV; V</td>
</tr>
<tr>
<td>2. Case status</td>
<td>Elective; urgent (obstructed; bleeding; perforated)</td>
</tr>
<tr>
<td>3. Operation</td>
<td>LAR; APR; TPC</td>
</tr>
<tr>
<td>4. Modality</td>
<td>Open; laparoscopic; hand-assisted laparoscopic; robotic; TES</td>
</tr>
<tr>
<td>5. Location of tumor within rectum</td>
<td>High; middle; low</td>
</tr>
<tr>
<td>6. Height of lower edge of tumor from anal verge</td>
<td>0–20 cm</td>
</tr>
<tr>
<td>7. Mobilization of splenic flexure</td>
<td>Yes; no</td>
</tr>
<tr>
<td>8. Level of ligation of inferior mesenteric artery</td>
<td>IMA; SRA; none</td>
</tr>
<tr>
<td>9. Level of ligation of inferior mesenteric vein</td>
<td>High; low; none</td>
</tr>
<tr>
<td>10. Level of rectal transection distal to distal edge of tumor (distal margin)</td>
<td>0–20 cm</td>
</tr>
<tr>
<td>11. Type of reconstruction</td>
<td>Stapled end-end; stapled end-side; handsewn end-end; handsewn end-side; colon J-pouch; ileal pouch-anal anastomosis; coloplasty; none</td>
</tr>
<tr>
<td>12. Anastomotic testing method(s)</td>
<td>Rectal air infusion under pelvic fluid; rectal instillation of betadine, indigo, or other fluid; palpation; observation of circular stapler rings only; none</td>
</tr>
<tr>
<td>13. Creation of Stoma</td>
<td>Yes (ileostomy; colostomy); no</td>
</tr>
<tr>
<td>14. En bloc resection</td>
<td>Yes (bladder; vagina; prostate; ureter; small intestine; sacrum; other); no</td>
</tr>
<tr>
<td>15. Metastectomy</td>
<td>Yes (live; peritoneum; other); no</td>
</tr>
<tr>
<td>16. Completeness of tumor resection</td>
<td>R0; R1; R2</td>
</tr>
<tr>
<td>17. Intraoperative complications</td>
<td>Yes (ureter injury; rectal perforation; enterotomy; vascular injury; other); no</td>
</tr>
<tr>
<td>18. Blood transfusion</td>
<td>Yes; no</td>
</tr>
<tr>
<td>19. TME photographed</td>
<td>Yes—in pathology report; yes—in operative report; no</td>
</tr>
<tr>
<td>20. Short narrative</td>
<td>***</td>
</tr>
</tbody>
</table>

Reprinted with the permission of the OSTRiCh Standardized Synoptic Operative Report Committee.