PAN-CANADIAN STANDARDS

Rectal Cancer Surgery

CANADIAN PARTNERSHIP AGAINST CANCER
PARTENARIAT CANADIEN CONTRE LE CANCER

Canadian Society of Colon and Rectal Surgeons

MARCH 2019

Colorectal cancer is the second most common cause of cancer death in Canadians, accounting for 12% of all cancer mortality.

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MESSAGE FROM CO-CHAIRS

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While treating all patients with colorectal cancer can be challenging, the management of rectal cancer is particularly complicated.[2]

Integration of radiation and chemotherapy, both before and after surgical treatment, necessitates coordination across specialties throughout the patient's cancer journey. Furthermore, innovative treatment techniques have dramatically reduced rectal cancer recurrence, permanent colostomy rates and perioperative pain and suffering. Unlike some other surgically managed cancers, rectal cancer complexity is highly variable at presentation; while some patients may be successfully treated with transluminal surgery alone, others will require neoadjuvant chemoradiotherapy followed by en bloc resection of the rectum with adjacent organs to effect a cure. Therefore, surgeons must collaborate across institutions to ensure that every patient with rectal cancer is managed in the centre that can provide the best care, tailored to their specific cancer, as close to home as possible.

It is our hope that this document will serve as a decision-making resource to support the delivery of consistent, high-quality care to all Canadians requiring rectal cancer surgery. The document provides high-level guidance and discussion on the foundational resources and requirements that need to be in place to improve cancer surgical care and outcomes. It is our goal that the actionable recommendations included herein will help address current gaps, be forward thinking (serve as a document for the future) and elevate the delivery of rectal cancer surgical care in Canada. Development of the standards has been informed by environmental scans, literature review and evidence-informed expert consensus. The document focuses on a number of key areas such as the Royal College of Physicians and Surgeons of Canada's (RCPSC) system for evaluating and formally certifying training. The importance of systems of care and devotion of a significant portion of practice and maintenance of competency to rectal cancer has been highlighted in the document.

Optimal rectal cancer care requires more than the rectal cancer surgeon; the supporting health care team should be well-trained and adequately resourced to provide timely access to care.

In particular, there is a heavy reliance on timely coordination of diagnostic imaging, radiotherapy, chemotherapy, surgery, pathology and other ancillary recovery and survivorship services whose resource allocation and governance fall to the region and institution. As a result, implementation of any standard depends on the successful collaboration of rectal cancer surgeons with those disciplines.

The document also highlights the importance of advanced human resource support, and allied health professionals, and that manpower planning needs to be comprehensive and systematic to meet targets for care. Quality processes, such as routine data collection and population of a national database, should be thoughtfully embedded into existing health care processes to catalyze self-evaluation and continuous quality improvement. In addition, careful consideration should be given to regionalizing specialized services for patients with complex rectal cancer to improve patient outcomes, while accounting for patient choice and travel time. Health care planners and providers can utilize this information to organize care in a way that maximizes patient outcomes, while maintaining reasonable access to care. This report is one component of a family of reports to be developed for disease-site specific national standards of surgical cancer care.

We look forward to working with you to improve the quality of complex surgical cancer care in Canada.

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The Rectal Cancer Surgery Expert Panel was instrumental in the development of standards through a comprehensive review of academic literature, objective analysis, in-person discussions and document review.

The production of this report was made possible through the dedicated efforts of many individuals. We express our gratitude to them for their contributions and assistance in the development of these recommendations.

The Rectal Cancer Surgery Expert Panel was instrumental in the development of standards through a comprehensive review of academic literature, objective analysis, in-person discussions and document review. We would like to acknowledge the contribution of **Laura Banfield**, Librarian at McMaster University, who conducted a comprehensive literature search at the onset of this project. In addition, we express our gratitude to the invaluable contributions of the **Canadian Society of Colon and Rectal Surgeons (CSCRS)** for their endorsement of this document.

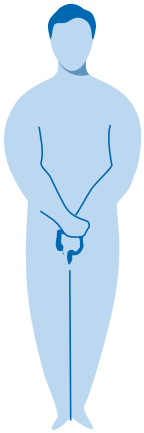
Strategic oversight of the development of this document was provided by the Canadian Partnership Against Cancer (CPAC) by **Dr. Craig Earle**, Vice-President, Cancer Control. Process development, report production and dissemination were led by the Quality Initiatives, Diagnosis and Clinical Care team at CPAC: **Dr. Mary Argent-Katwala**, Director; **Anubha Prashad**, Program Manager; **Michele Mitchell**, **Natasha Camuso**, Analysts; and **Zahrah Khalid**, Delivery Manager.

Colorectal cancer is the second most commonly diagnosed cancer in Canada (excluding non-melanoma skin cancers) and represents the second and third leading cause of death from cancer in men and women, respectively.

In **2017**, an estimated 14,900 new cases in men and 11,900 new cases in women were expected, representing 13% of all new cancer cases.[1]

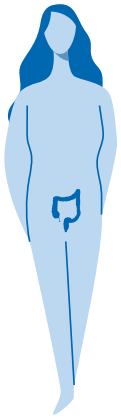
14,900

NEW CASES



11,900

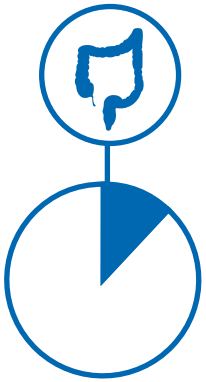
NEW CASES



AN ESTIMATED

12%

of the deaths caused by cancer will be caused by colorectal cancer.[1]



Rectal cancer represents a subset of colorectal cancers that has particularly challenging technical aspects and management decisions. Despite advancements in surgical techniques and therapies over the years, five-year survival rates in patients with advanced-stage rectal cancers including lymph node involvement (IIIC) or those that have spread to distant sites (IV) are low, at 58% and 12%, respectively.[3] On the other end of the spectrum, early stage rectal cancer is increasingly being treated with minimally invasive approaches that improve the morbidity suffered by patients without affecting survival. As with other complex cancers, the management and outcomes vary considerably.

The surgical management of patients with rectal cancer is further complicated by the heterogeneity of the patient population (age, medical comorbidities, etc.) and multimodal treatment options. Despite recent advances in radiation and chemotherapy, surgery continues to be the primary means of curative intent treatment and the optimal delivery of surgical care for these cancers is paramount. Although general surgeons, surgical oncologists and colorectal surgeons currently perform rectal cancer surgeries, there is evidence that experience and specialization in rectal cancer surgery greatly improve patient outcomes.[4-7] While definitions vary in the literature on what constitutes an appropriate volume threshold to assure "best care", most (but not all) population-based studies have shown that there are better outcomes associated with specialization in rectal cancer surgery, greater surgeon-specific procedural volume and surgery performance at high-volume centres when compared to low-volume centres.[8-17]

Rectal cancer surgical quality is important for both perioperative patient safety and to minimize local recurrence rates. With the introduction of total mesorectal excision (TME) as a standard of care, local recurrence rates have significantly decreased.[18-22] Furthermore, the surgeon's ability to achieve a clear resection margin and complete disease clearance, in some cases requiring multi-visceral resection and/or metastatectomy, can mean the difference between recurrence and disease-free survival in these patients. Surgical and hospital volume, as well as appropriate use of neoadjuvant therapy, have been demonstrated to be important with respect to sphincter-preserving surgery.[13, 14, 23] For patients with low rectal cancers, optimal management and technical excellence are key to avoiding unnecessary permanent colostomies, which are not preferred by the majority of patients.

Beyond the importance of technical excellence in the provision of TME surgery, the management options for patients with

rectal cancer have never been so varied. The use of radiotherapy in all stage II and III rectal cancer patients has been challenged and may lead to morbidity without benefit.[24-27] In patients with early rectal cancer, minimally invasive local excision techniques, with or without adjuvant therapy, are acceptable for select patients.[20, 28-30] Furthermore, in some locally advanced rectal cancers, non-operative management is under investigation for patients for whom a complete clinical response is achieved.[18-20, 31, 32] The importance of evidence-based rectal cancer management has never been more critical, and it is usually the surgeon who is the patient's first contact and facilitates their multidisciplinary care.

In this context, it is clear that surgical and institutional capabilities required by patients presenting with rectal cancer vary markedly. As such, this document distinguishes patients with complex rectal cancer and defines some of the special resources, both with respect to the team of surgeons often required for their care and the institutional commitment necessary to support more intense surgical interventions.

Beyond surgeon expertise in management and surgical care, preoperative and post-operative aspects of care are critical to patient outcomes. The benefits of standardized use of pretreatment staging with CT scan and magnetic resonance imaging (MRI) (with expert standardized interpretation and reporting), multidisciplinary conferences for treatment planning, and standardized pathology reporting, have been clearly demonstrated. Appropriate facilities and resources are also needed to ensure all Canadian surgeons have timely access to these critical aspects of comprehensive cancer care.

Based on the incidence of rectal cancer, evidence supporting improved outcomes with the aforementioned elements of rectal cancer care, as well as the disparities in care across the country, there is a need for a set of pan-Canadian standards to ensure consistent, high-quality care for all Canadians requiring rectal cancer surgery. As such, this document seeks to support surgeons committed to treating patients with rectal cancer by highlighting the features of a facility treating rectal cancer patients, and the quality processes needed to elevate the delivery of high-quality care in the contemporary Canadian context.

There is a need for a set of pan-Canadian standards to ensure consistent, high-quality care for all Canadians requiring rectal cancer surgery.

Scope

THE SCOPE OF THIS DOCUMENT INCLUDES:

- Rectal cancer surgery, with emphasis on resources and personnel required for comprehensive rectal cancer care
- Timely access to care from a pre-, peri- and post-operative perspective
- Training and maintenance of competencies for rectal cancer surgeons
- Access to services and equipment
- Access to medical oncologists, radiation oncologists, pathologists, other physicians and allied health professionals
- Resources for patients and families
- Quality processes, including multi-disciplinary tumour board rounds
- Distinguishing tiers of complexity in patients with rectal cancer and defining appropriate centres for their management

THE SCOPE OF THIS DOCUMENT DOES NOT INCLUDE:

- Colon cancer care
- Management of care pathways by cancer type or tumour site
- Assessment of drugs and treatment options
- Facilities and resources for provision of radiation and medical oncology treatment
- Assessment of technology and equipment used to deliver care

METHODOLOGY

The standards herein were developed through consultation with an expert panel of rectal cancer surgeons from across Canada.

Literature Review and Environmental Scan

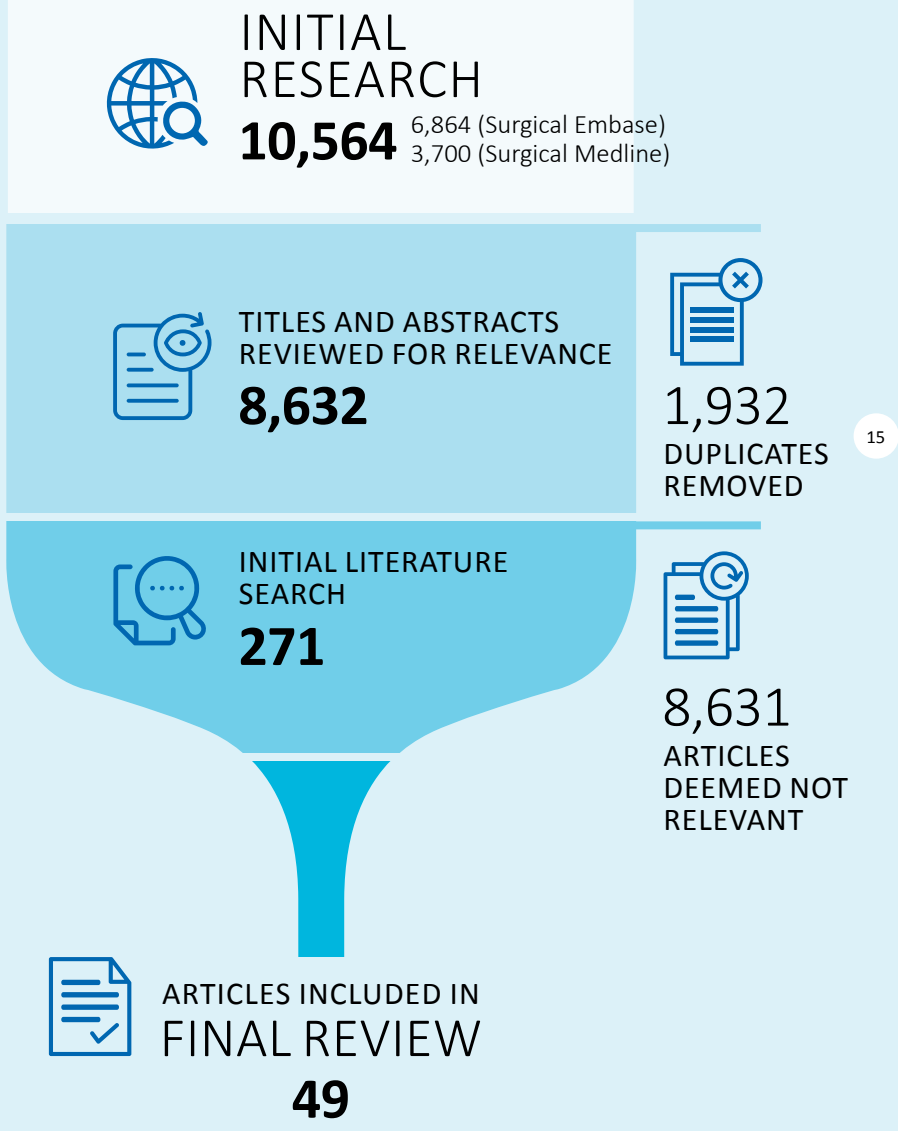
A literature search was performed using Surgical Embase and Surgical Medline, restricted to publications between 1974 to May 2017 and 1946 to June 2017, respectively. A comprehensive search strategy was developed to assess the literature to examine evidence. The search strategy incorporated medical subject headings (MeSH), Boolean operators and wild cards. Results were excluded if they were duplicate findings or were not deemed relevant after review (Figure 1).

Expert Discussions

The standards herein were developed through consultation with an expert panel of rectal cancer surgeons from across Canada. The expert panel members reviewed literature search findings for relevance and identified key evidence to be evaluated and incorporated to support the standards, where appropriate. An in-person meeting was held to develop standard statements (40 standards were developed) and achieve consensus on standard statements to be included, followed by an electronic survey to validate and vote on the results from the in-person meeting. Based on the electronic survey, 41 standards were included in this document. A targeted review period was held to seek endorsement from the Canadian Society of Colon and Rectal Surgeons (CSCRS), which was achieved.

FIGURE 1

Flow chart of search results and article inclusion



STANDARDS AND EVIDENCE

The technical skills and knowledge to safely and competently conduct rectal surgery requires that the practitioner has completed comprehensive training in the full scope of rectal cancer surgery.

Surgeon Criteria

1.1 REQUISITE TRAINING AND COMPETENCY FOR PRACTICE

1.1.1 A rectal cancer surgeon is a general surgeon who has contemporary knowledge of the diseases of the colon, rectum and anus in adults as defined by the Objectives of Training in the specialty of General Surgery by the Royal College of Physicians and Surgeons of Canada (RCPSC) and who continues to acquire such knowledge through Continuing Medical Education (CME) and a sufficient volume of practice.[33]

1.1.2 A rectal cancer surgeon should have complete training and hold formal certification in general surgery and have significant expertise/interest in rectal cancer surgery. For those not trained in Canada, a similar regimented and accredited training program must be completed and certified.

1.1.3 A subspecialty rectal cancer surgeon, in addition to the criteria for a rectal cancer surgeon, will have complete training and hold formal certification in colorectal surgery or surgical oncology with qualification by the RCPSC. For those not trained in Canada, a similar regimented and accredited training program must be completed. For general surgeons without colorectal surgery or surgical oncology certification, expertise developed through a focused commitment to the treatment of "complex" rectal cancer may substitute for the above qualification.

1.1.4 A rectal cancer surgeon's participation in the maintenance of certification is mandatory and must be in accordance with provincial and national standards.

1.1.5 A rectal cancer surgeon should perform rectal cancer surgery as a regular part of their practice and commit regular CME time specifically to rectal cancer to maintain competency.

The technical skills and knowledge to safely and competently conduct rectal surgery require that the practitioner has completed comprehensive training in the full scope of rectal cancer surgery.[33] It is acknowledged that surgeons conducting rectal cancer surgeries often start and/or continue their practice in general surgery; however, as rectal cancer management, including both appropriate use of multimodal treatment and the technical conduct of the surgery, is constantly evolving and can be complicated, advanced skills and knowledge are required. Surgeons whose training is obtained outside of Canada should utilize the appropriate RCPSC avenue for evaluation and credentialling when possible. Certification by the RCPSC is not mandatory if all other criteria of expertise as a rectal cancer surgeon are met.

It is imperative that rectal cancer surgeons regularly maintain and update their skills and knowledge and devote a significant amount of time to the practice to ensure maintenance of competency in rectal cancer surgery. As the field advances, rectal cancer surgeons need to keep up to date with contemporary standards and evolving evidence to ensure that patients

are receiving optimal care. Surgeons should maintain expertise and competence through ongoing education in Continuing Profesional Development programs, such as the Maintenance of Certification program of the RCPSC. Routine CME is considered a necessary factor to maintain best patient outcomes.

While expert technical skills are required for surgeons who are conducting rectal surgeries, appropriate systematic evaluation and patient support systems are also essential for optimal patient outcomes. Regardless of the level of training or experience of a surgeon, it is clear that best care for patients with rectal cancer may not be possible if the institution and community in which the surgeon practices do not have access to the technology, personnel and equipment required for surgical treatment. All centres treating rectal cancer patients should participate in provincial/regional networks of care to ensure that all patients are treated in an appropriate location that meets the standards herein. For patients with complex rectal cancer, it is ideal that these patients be offered treatment at referral centres, which will be defined and discussed in section 1.2 of this document.

1.2 SURGERY AND MANAGEMENT

1.2.1 All patients with rectal cancer should be evaluated by a rectal cancer surgeon early in the care process, prior to the initiation of chemotherapy and/or radiation therapy.

1.2.2 While the majority of mid- and upper rectal cancers are appropriate for treatment at any rectal cancer surgery centre, there is a recognized subgroup of "complex rectal cancer" patients who should be offered assessment and possible treatment in a referral centre for complex rectal cancer surgery. Complex rectal cancers include but are not limited to:

- The majority of rectal cancers where abdominoperineal resection is planned
- Rectal cancer where the main tumour transgresses the mesorectal or mesosigmoid radial margin, has a positive/suspicious mesorectal node, or a tumour deposit.
- Rectal cancer invading adjacent organs (T4) and thus requiring multivisceral resection
- Rectal cancer in patients with a hereditary cancer syndrome (e.g., Lynch Syndrome Hereditary Non-Polyposis Colon Cancer (HNPCC), Familial Adenomatous Polyposis)
- Recurrent rectal cancer
- Rectal cancer in a patient with synchronous pelvic malignancy (e.g., prostate, uterine, etc.)
- Rectal cancer in a patient with a prior pelvic cancer requiring surgery or radiation therapy
- Rectal cancer in a patient with previous rectal or left-sided colon surgery
- Rectal cancer that has been previously locally excised and requires subsequent completion proctectomy

1.2.3 A subgroup of rectal cancer patients with "early rectal cancer", defined as T1 lesions with favourable pathology, can be treated by transanal techniques with avoidance of radical resection. While this treatment is not equivalent to total mesorectal excision with respect to recurrence, there is no apparent cancer-specific survival compromise in these patients. Patients with early rectal cancer who are candidates for local excision should be offered assessment at a Transanal Endoscopic Surgery Centre and reviewed at a Multidisciplinary Cancer Conference (MCC) before and after treatment.[6]

1.2.4 Rectal cancer surgeries should be performed in centres that are compliant with the needs defined by this document. While a clear surgery volume threshold has not been established, the association between surgeon/hospital procedural

volume and rectal cancer outcomes suggests that the rectal cancer surgeon should have a focus on rectal cancer surgery in their practice. Furthermore, there should be sufficient hospital volume to optimize the care among allied health care providers.[6-8, 10, 16, 17, 34, 35]

1.2.5 All patients with rectal cancer should have access to an MCC. All patients should be discussed in an MCC and have the conclusions recorded as part of the patient record.[36]

1.2.6 Surgeons treating rectal cancer should have experience in and training for total mesorectal excision (TME) surgery.[37]

1.2.7 Cross-sectional imaging of patients with rectal cancer should be reviewed by an expert radiologist in consultation with a surgeon who performs rectal cancer surgery.

1.2.8 Patients with a good performance status and low-volume metastatic rectal cancer disease should be presented at an MCC with possible referral to a hepatic-pancreatic-biliary (HPB) surgeon, thoracic surgeon or radiation oncologist (for stereotactic body radiation therapy), where appropriate.

All patients with rectal cancer in Canada should be evaluated in a systematic and comprehensive way, such that care can be standardized and key decision-makers are consulted prior to treatment initiation.

Within this model, rectal cancer surgeons have an early and primary role in the diagnosis and decision-making process before other treatment options have been initiated. MRI is a key component of preoperative care for rectal cancer patients to help with staging and surgical planning, as well as identifying patients that may benefit from preoperative therapy.

While all patients should ideally be discussed at an MCC, the expert panel recognizes there are currently practical limitations to this access. In many settings, patients are selectively discussed at an MCC. However, upon request, all patients should have access to evaluation at an MCC and the recommendations of the forum shared with them to inform their treatment decisions. All MCC results should be documented in the patients' charts. Key elements for discussion should include intent of treatment (cure versus palliation), coordination and timing of adjuvant and neoadjuvant therapy, surgical approaches (resectability, sphincter preservation) and radiation treatment approaches. Additionally, all patients with metastatic disease who would otherwise be fit for curative intent treatment should be evaluated and discussed with respect to potential radical therapies.[36]

It is the opinion of the expert panel that not every general surgeon in Canada will maintain individual volume and technical expertise, or has the institutional support required to perform rectal cancer surgery at a level currently accepted as standard care. Therefore, collaboration among surgeons to determine focused local expertise for uncomplicated rectal cancer is encouraged. Furthermore, all patients with complex rectal cancer should have timely access to institutions with the surgeons, personnel and resources to provide them the best care. In a given region, good communication and collaboration among all surgeons providing care to patients with rectal cancer are necessary to ensure optimal patient outcomes at a regional level.[36]

Practice Settings

2.1 ORGANIZATIONAL CRITERIA

2.1.1 The initial treatment (surgery conducted or chemotherapy and/or radiotherapy started) for 90% of rectal cancer patients should be initiated within six to eight weeks of the date of biopsy. Appropriate referrals and investigations should be made as early as possible. It is the joint responsibility of the institution, region, surgeon and health care team to coordinate care in a timely manner, and resources should be applied appropriately to ensure time frames are met.

2.1.2 Pathology reporting time should be tracked and cases should be reported within two weeks with appropriate resourcing.

Access to care and timeliness of evaluation significantly impact a rectal cancer patient's journey.[38] The expert panel has defined appropriate time frames for care. These targets are the mutual responsibility of the surgeons, oncologists and other disciplines with direct responsibilities to the patient and the facility. Not all patients will move through the system seamlessly, particularly because of the required radiologic imaging and multidisciplinary nature of rectal cancer treatment, and these targets have accounted for reasonable delays related to these challenges. Efforts need to be focused on providing timely care so that delays in the process of evaluation and treatment do not have a negative impact on patient care and prognosis. Active monitoring of contributory wait times (e.g., pathology reporting, clinical appointments, imaging, Operating Room booking, etc.) is essential to ensure that unacceptable delays are acted upon and appropriate policies put in place to motivate responsible parties.

2.1.3 Rectal cancer surgery should be performed in a "Rectal Cancer Surgery Centre", defined as providing appropriate facilities, including the following resources:

Expert physician care

- At least one rectal cancer surgeon
- On-site pathologist (for frozen section) and access to pathologist with experience and expertise in the Quirke method of TME assessment
- Anesthesia support, including 24-hour access
- Access to radiologist with expertise in MRI and CT for rectal cancer
- Access to interventional radiology
- Access to urologist

Medical support system for major complications of abdominal surgery

- Intensive care and/or high-dependency care unit
- Access to CT scan with interventional capability
- Access to rapid response laboratory (i.e., biochemistry, cytology, hematology, transfusion and microbiology) services 24 hours a day

Perioperative planning services

- Timely access to CT, MRI, ERUS
- Timely access to radiation and medical oncology assessment and treatment
- Preoperative assessment clinic with anesthesia, nursing, ET nurse assessment

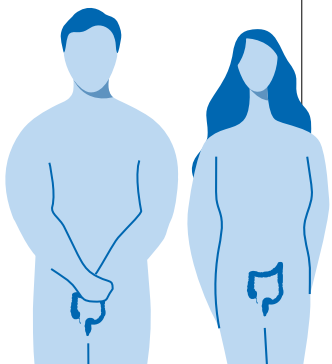
Allied health care services

- Enterostomal therapist
- Dietary and nutritional support
- Physical therapy
- Home care and social work
- Wound care service

Postoperative support services

- Access to cancer support networks
- Timely access to medical oncology and genetic counselling

2.1.4 All rectal cancer patients with "complex rectal cancer" should be assessed at a "Referral Centre for Complex Rectal Cancer Surgery". These centres should meet all criteria of a "Rectal Cancer Surgical Centre", and additionally have surgical capabilities and unique services required to address the specific needs of these complex cancer patients (e.g., requiring multivisceral resection or abdominoperineal resection, etc.). It is recognized that all provinces/regions may not be able to offer these services and interprovincial relationships need to be established. Furthermore, not every "Referral Centre for Complex Rectal Cancer Surgery" will have expertise/capacity to manage every patient with "Complex Rectal Cancer"; multiple centres (with geographic accessibility considerations) should manage some or all of these patients in collaboration, depending on the mix of expertise/capacity at each centre.



2.1.5 "Referral Centres for Complex Rectal Cancer Surgery" should meet all criteria for a "Rectal Cancer Surgery Centre", and additionally provide:

Expert physician care

- At least two subspecialty rectal cancer surgeons
- Access to pathologist with experience and expertise in the Quirke method of TME assessment
- Urologist with expertise in cystectomy/reconstruction (at sites where pelvic exenteration is performed)
- Orthopedic oncologist or neurosurgeon capable of sacrectomy, with expertise in resection of orthopedic malignancies (at sites where rectal cancers with concomitant sacrectomy/bone resection is performed)
- Plastic surgeon with experience/expertise in pelvic floor reconstruction

Medical support system for major complications of abdominal surgery

- Intensive care unit and high-dependency care unit with experience managing complex pelvic surgery patients
- Regional/provincial recognition of funding necessary to manage complicated rectal cancer patients

2.1.6 Appropriate early-stage rectal cancer patients should be assessed at a "Transanal Endoscopic Surgery Centre". This may be co-located at "Rectal Cancer Surgery Centre" or "Referral Centres for Complex Rectal Cancer Surgery" and provide additional services as follows:

Expert physician care

- At least one rectal cancer surgeon with advanced training/expertise in one of the transanal endoscopic surgery (TES) platforms
    - These platforms include, but are not limited to, Transanal Endoscopic Microsurgery (TEM), Transanal Endoscopic Operation (TEO) or Transanal Minimally Invasive Surgery (TAMIS) techniques
- Access to a pathologist with experience and expertise in evaluating local excision specimens, including documentation of all factors known to influence the need for immediate radical resection (e.g., depth of cancer invasion, lymphovascular invasion, tumour budding, margin status, etc.)

Postoperative support services

- Access and experience with rigorous follow-up not typical of rectal cancer treated by radical resection

2.1.7 Transitions between most responsible physicians must be clearly articulated and documented and transfers of care confirmed.

2.1.8 All rectal cancer centres should set targets to monitor and evaluate wait times and timely access to care.

Rectal cancer surgeries should be performed in institutions with the appropriate facilities and resources to ensure optimal patient outcomes, as outlined above.[4, 8] Expert and experienced surgeons may be capable of delivering exceptional care, but in the absence of key facilities and resources, patients could be put at risk. In these cases, it is important that institutions have relationships in place to continue to deliver care to patients to ensure they are not adversely impacted.

All rectal cancer cases that are complex or advanced (as per criteria detailed in section 1.2.2) require additional expertise and resources. In these cases, patients should be referred to centres with advanced expertise, experience, resources and facilities to deal with complex rectal cancer cases. These centres should meet the criteria outlined for "Referral Centres for Complex Multivisceral Rectal Cancer Surgery" when a multivisceral resection may be required. As these patients often require surgical teams, there should be a minimum of two highly-trained subspecialty rectal cancer surgeons with appropriate expertise on staff in these centres to provide diagnostic assessment and management of advanced rectal cancer surgical issues. While there are no clinical trials or scientific studies that are able to determine when to add additional surgeons beyond a minimum of two, real-world evidence and local expert opinion should be sought to maintain a high level of quality care based on access. Clinical workload in these centres, which often goes beyond rectal cancer care, can rapidly increase the need to recruit additional surgeons. These centres should also have appropriate infrastructure, including experienced nursing and allied health care providers on patient units, operative resources to meet the needs of patients outside the hospital's immediate community, and increased collaboration with multidisciplinary teams. These factors have been shown to reduce the need for reoperation, reduce local recurrence and improve long-term survival.[8, 10, 39]

Due to the unique needs of early-stage rectal cancer patients and the specialized equipment used for the care of this population, procedures must be performed at a rectal cancer centre equipped to deliver this specialized care where both the procedure and the pathologic considerations are addressed. This can be at any rectal cancer centre that has the appropriate facilities and trained staff and may or may not be co-located at a "Referral Centre for Complex Rectal Cancer Surgery".

2.1.9 Rectal cancer surgeons should participate in regionally and provincially integrated and established networks of care to ensure appropriate care is provided as close to home as possible.

Geographic isolation, particularly within the Canadian context, can prohibit the delivery of high-quality care to vulnerable populations. Availability of a functional network of care, including ready access to telehealth and other technological solutions, can help mitigate the deficiencies and provide care closer to home. Thus, regionalization of services should take into consideration patient choice and the distance that patients are willing to travel, as these patients often need ongoing health care services.[40, 41] Innovative regional programs that leverage existing networks are important to ensure that patients get optimal care. Whether through diagnostic assessment pathways, integrated home care models or active involvement of the patient's primary care team, many existing programs can bridge these potential care gaps.

2.1.10 Infrastructure should be in place to support the participation of patients in clinical research.

Infrastructure, such as the availability of disease-specific clinical trial networks, should be in place to support and increase the participation of patients in clinical research. For treatment of rectal cancer, particular focus should be given to availability and funding of clinical trials, as this disease is under-resourced relative to its mortality and incidence.

2.2 PHYSICAL RESOURCES AND COLLABORATING SERVICES

2.2.1 MRI should be protocolled correctly for rectal cancer staging, read by an experienced GI radiologist and reported in a synoptic format within two weeks from the requisition.

2.2.2 Rectal cancer pathology, gross evaluation and processing of the specimen should be done by the Quirke method and should be reported by the College of American Pathologists (CAP) rectal cancer synoptic report within two weeks. All patients should have access to reflex-relevant immunohistochemistry/biomarker testing, including mismatch repair proteins (preferably reflex testing).[42-44]

All rectal-related MRI and pathology reports should be reported in a synoptic format within two weeks from completion, ideally using an electronic interface. Electronic synoptic reports are standardized checklists that capture information at the point of care and, once completed, can be transmitted to other health care professionals and central quality assurance data repositories.[45] Captured information can be used by surgeons to assess adherence to evidence and safety procedures and assess the delivery of high-quality care and patient outcomes.[45]

2.2.3 All rectal cancer patients who will receive a planned stoma and those who have a possibility of receiving a stoma should be referred to a qualified enterstomal nurse and/or enterstomal therapy nurse (ETN) prior to surgery for pre-op counselling, education regarding care and management of stomas, and marking.

- All rectal cancer patients who have a stoma should be provided with information about the peer and community-based supports for ostomy patients (e.g. United Ostomy Association of Canada peer support program) before surgery or prior to discharge if unplanned.[37]

2.2.4 Patients with clinical or historical factors consistent with high risk of hereditary malignancy should have access to appropriate genetic testing in accordance with established guidelines, as well as access to genetic counselling services.

All patients with suspected hereditary malignancies should be referred for appropriate genetic testing and/or reflex testing to ensure appropriate

treatment and follow-up care. Access to genetic counselling services for these patients is also important and the referral should be made in a timely manner.

2.2.5 All cancer centres should have well-maintained and adequately resourced equipment and facilities.

2.2.6 Capital expenditures must be available to provide contemporary equipment and be re-evaluated when there are changes in the workforce and evolving standards of care.

Ensuring regular maintenance of equipment and adequate resourcing is important to deliver exceptional patient care. Upfront budgeting and resourcing should be taken into consideration in planning.[46, 47] As needs are constantly evolving, it is vital to monitor and evaluate in order to respond to changing needs.

2.3 HUMAN RESOURCES

2.3.1 The MCC should consist of health professionals with expertise/interest in GI cancers, including but not limited to:

- Rectal cancer surgeons
- Medical oncologists
- Radiation oncologists
- Pathologists
- Radiologists

Surgeons treating rectal cancer must participate in multidisciplinary conferences via telemedia, virtually or in person.

2.3.2 All rectal cancer patients should be offered screening for and management of distress shortly after diagnosis and at key transition points (e.g., initiation of neoadjuvant therapy, preoperatively, adjuvant therapy, end of treatment).[37]

Critical to successful patient care is the team involved in managing the care. Rectal cancer surgeons recognize that while their role as the surgeon is one of leadership, knowledge and technical excellence, the entire care team contributes to prevention of mortality and morbidity and rescue from adverse events. "Failure to rescue" in the broader sense is an institutional failing as much as a physician one.[48] Although the rectal cancer surgeon has an integral role, collaboration with other specialties, consultants and clinical nurse specialists is key to providing high-quality surgical care. Human resource planning should be comprehensive and systematic; thought has to be put into the composition of the team (i.e. full-time equivalence, etc.) with clear emphasis that this is a team sport.

Attendance at MCC is mandatory, with one representative from each specialty. Collaboration and knowledge-sharing are essential for those involved in patient care. Collaboration between and within specialties has been shown to enhance patient outcomes and significantly reduce the time from diagnosis to treatment.[49-51] It is critical that radiologists, medical oncologists, radiation oncologists and surgeons formulate a unified, evidenced based management plan for patients. Timely communication within multidisciplinary teams is necessary to ensure compliance with agreed-upon patient pathways, including personalized case management and compliance with definitive treatment.[10, 48]

A systematic and comprehensive plan should be in place to ensure that all rectal cancer patients are regularly screened for signs of distress. This will help to measure the patient journey and ensure that they are coping well with their diagnosis and treatment. Patients showing signs of distress should receive timely, appropriate support.

2.4 TREATMENT AT ONCOLOGY CENTRES AND RELATIONSHIP WITH AFFILIATED CENTRES

2.4.1 All rectal cancer centres should have a relationship with a cancer centre with access to consultation from medical and radiation oncologists. There should be a mechanism in place to provide urgent consultation and treatment for in-patients.

For services not immediately available in the institution, knowledge and/or formal relationships with centres that can provide these services in the region are important. Barriers in geography or available beds should not impede the necessary consultation or treatment. Although a rectal cancer centre should be equipped with adequate resources to manage the full range of rectal cancer surgical care, if this is not the case, a formal working relationship or association with a regional cancer centre should be in place.[34, 38] This includes affiliation with a regional cancer centre that has access to radiation therapy equipment, and where consultation with medical and radiation oncologists is also readily available.

Quality Processes

3.1 DATA COLLECTION AND CONTINUOUS QUALITY IMPROVEMENT

3.1.1 Institutions and regions that have regional cancer centres need to support quality processes such that financial barriers are not a limitation to participation.

3.1.2 Regional authorities should collect relevant quality marker data for audit and feedback intervention in collaboration with rectal cancer surgeons, and coordinate with national efforts.[5, 52, 53]

3.1.3 There should be implementation of a national, data-driven approach to deliver best practice care. Routine data collection on process and outcomes should be systematically and prospectively captured and benchmarked against national and international standards. This includes systematic classification of adverse events, regular review of morbidity and mortality rounds, and periodic review of data to allow for self-evaluation and to promote continuous cyclical improvement (through audit and feedback). Best practice approaches should be utilized and shared to ensure high-quality care. Funding, capturing and coordinating this process is the responsibility of health authorities in order to provide appropriate supports and governance to institutions to achieve best practices.[53, 54]

3.1.4 Patient education should be conducted in accordance with the institutional/provincial education standards for adults affected by cancer.[37]

3.1.5 It is the joint responsibility of the regional cancer centres and rectal cancer surgeons to actively monitor patient complications and for human resources to have quality processes in place to support quality improvement. Every regional cancer centre needs to have a system in place to identify adverse events and outcomes early in the patient's journey and rescue the patients to avoid further, more serious events.

3.1.6 Institutions should support adequate collection and measurement of patient experience data (e.g., patient-reported outcomes, wait times).

3.1.7 There is an expectation that techniques and processes of care will change over time. Adoption should be done in a systematic manner to support standardized implementation with a need for credentialling where significant changes in technologies and approaches are introduced. When adopting new technologies and techniques, active tracking of adverse events and outcomes should be completed.

3.1.8 National, provincial and institutional organizations should identify patients at high risk for negative outcomes, in particular those from vulnerable populations, and develop appropriate pathways and monitor compliance with them.[54]

3.1.9 At the completion of active treatment, patients should have structured, systematic and comprehensive surveillance and access to survivorship resources.

Although difficult to precisely define, quality improvement is often measured by components of structure, outcomes and processes.

One way for rectal cancer surgeons to evaluate their practices is to compare themselves with evidence-based national guidelines.[55] Data about quality care, process and outcome measures can provide meaningful information regarding surgical outcomes and quality.[53] Regular monitoring of data can help predict surgical morbidity and mortality. Over time, routine collection of data will improve data quality and lead to better patient care. However, outcomes not only depend upon surgeon and hospital volume, but also can depend on surgical technique, patient factors (e.g., comorbidities) and multidisciplinary treatment decisions.[39] Data collection at various points of the patient journey and benchmarking against national and international standards/targets can support the delivery of high-quality patient-centred care.

The goal of data collection, evaluation and monitoring is to help improve surgical and hospital performance in a non-punitive manner and to steer away from a "blame and shame" approach. When adopting new techniques or technologies, risk to patients needs to be balanced against the amount and significance of the innovation. Review and regular audit of data and monitoring of complications in a standardized way have been shown to improve outcomes. Institution-level data should be fed back into the system to improve quality and minimize interprovincial barriers, as well as to local participants providing rectal cancer surgical services to help improve quality. Monitoring outcome data can help clinicians identify which processes they have followed, or not, that have directly impacted patient outcomes.

In Canada, an eight-centre pilot program was designed to improve clinical outcomes for patients by implementing quality initiatives for rectal cancer across the country. Supported by the Canadian Partnership Against Cancer and led by Dr. Erin Kennedy, this program demonstrated improved adherence to standards over the duration of the two-year project (see http://www.rcacprojects.ca/?page_id=15). Ongoing data collection with iterative feedback to treating clinicians is an important quality assurance tool in rectal cancer care.

Recognizing that there is considerable variation in the evaluation of quality of care, the uniform use of well-defined quality of care indicators to measure and monitor performance holds the promise of improving outcomes in patients who undergo rectal surgeries.

FUTURE DIRECTIONS

This document is intended to serve as an informational and decision-making resource to elevate and standardize the delivery of rectal cancer surgery in Canada.

Following publication, future work will include wide dissemination and identification of strategies to catalyze systematic and comprehensive adoption to help narrow the gap and address current deficiencies and variability in care.

Efforts are underway to develop an evaluation framework to measure uptake and to explore the role of CSCRS and Accreditation Canada as a mechanism to promote and offer accreditation processes to enforce the recommended standards.

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This document provides high-level guidance on the foundational resources and requirements that need to be in place to improve cancer surgical care and outcomes. It will serve as a decision-making resource to support the delivery of consistent, high-quality care to all Canadians requiring rectal surgery.

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