

American College of Surgeons Commission on Cancer Standard 5.7 for Total Mesorectal Excision for Mid-to-Low Rectal Cancer

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The American College of Surgeons (ACS) created the Cancer Surgery Standards Program in July 2020 as part of a growing movement to implement national standards for cancer operations. Adherence to specific, evidence-based operative techniques with documentation of these steps heralds a significant advancement for cancer operations in the US. The ACS Commission on Cancer (CoC) has adopted 6 operative standards for accreditation. These operative standards apply to rectal, lung, breast, and colon cancer as well as melanoma, and require that both surgeons and pathologists at CoC-accredited facilities adhere to the standards in technique and documentation. The goal of these standards is to bring high-quality cancer care to patients throughout the US.

This editorial discusses Standard 5.7, which requires accurate documentation of total mesorectal excision (TME) specimens for all patients undergoing radical resection of mid- and low rectal cancers. After summarizing Standard 5.7 and its implementation timeline, we provide the rationale behind the standard. In addition, we offer best practices and resources for surgeons, pathologists, and registrars to reach compliance in 2022 and beyond.¹

COC OPERATIVE STANDARD 5.7

For all mid-to-low rectal cancers, defined as at or below the peritoneal reflection, that undergo a curative-intent resection, a complete or near-complete TME must be documented in the pathology report in synoptic format

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(Fig. 1). The College of American Pathologists (CAP) synoptic report for rectal cancer includes this designation under “Macroscopic Evaluation of Mesorectum.”² This standard applies to all patients undergoing radical, anatomic resection for rectal cancer with curative intent, and excludes patients selected for nonanatomic resections, such as transanal full-thickness approaches, endoscopic submucosal resections, or polypectomies. Patients with no residual disease after undergoing neoadjuvant chemoradiation and radical resection are excluded from Standard 5.7, because the CAP synoptic report for rectal cancer does not apply in this clinical scenario.² Although the proper operative principles of TME should apply to these patients with no residual disease, Standard 5.7 does not apply in these cases due to the standard’s alignment with the CAP synoptic reporting criteria.

MEASURES OF COMPLIANCE

Starting in 2022, site reviewers will review 7 randomly selected pathology reports for mid-to-low rectal cancer resections from the previous year, 2021. If a site has fewer than 7 patients who meet the criteria, then all applicable patient charts will be reviewed. To achieve compliance, the case must meet the following criteria:

1. TME is performed for all patients undergoing radical surgical resection of mid- and low rectal cancers, and results in a complete or near-complete mesorectal excision.
2. The quality of TME resection is documented in the pathology report in a synoptic format.

Of note, the ACS National Accreditation Program for Rectal Cancer (NAPRC) standards has developed separate standards on rectal cancer that are, by design, different to prevent significant overlap or confusion. However, the shared element between the CoC and NAPRC states the TME grade must be reported in the CAP synoptic report. The requirement of the performance of a TME is specific to CoC Operative Standard 5.7 and is not a standard required by the NAPRC for accreditation.³

Abbreviations and Acronyms	
ACS	= American College of Surgeons
CAP	= College of American Pathologists
CoC	= Commission on Cancer
NAPRC	= National Accreditation Program for Rectal Cancer
TME	= total mesorectal excision

Additionally, the NAPRC conducts independent site visits to consider accreditation at each facility, and they are separate from and focus on different elements than the CoC site visits.

TIMELINE

Compliance with Standard 5.7 is expected of all CoC-accredited programs as of January 1, 2021. Site visits in 2022 will evaluate 2021 pathology reports, with a benchmark of 70% compliance for eligible patients (ie at least 5 of 7 reviewed reports fully meeting the standard). The expected compliance will increase to 80% beginning with 2023 site visits, which will review reports from both 2021 and 2022. Going forward after 2023, cases from the previous 3 years will be reviewed for compliance with this standard, again with expected compliance of 80% (Fig. 2).

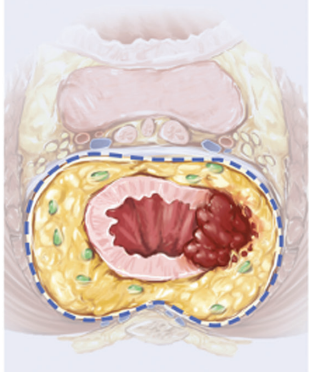
RATIONALE

TME for rectal cancer was first described in the 1980s as the preferred technique to achieve negative margins, harvest the draining lymph nodes, and preserve surrounding neurovascular structures.⁴ Two studies subsequently showed a decrease in local recurrence rates with TME compared with conventional resection. After implementation of a standardized training program for TME, the Stockholm Colorectal Cancer Study Group demonstrated a 50% increase in the rate of sphincter preservation with TME compared with data from 2 previous rectal operation trials.⁵ In addition, local recurrence rates improved (6% vs 14% and 15%), and cancer-related deaths decreased (9% vs 16% and 15%). Similarly, the Dutch Colorectal Cancer Group also showed improved local recurrence rates (9% vs 16%) in patients who received TME compared with conventional resection after receipt of neoadjuvant chemotherapy.⁶

The TME approach alone, however, is not sufficient to ensure improved outcomes, because an incomplete TME specimen is associated with higher local and distant recurrences compared with complete or near complete specimens.⁷⁻¹⁰ Patients registered in the Medical Research Council CR07 and NCIC-CTG CO16 randomized multicenter trial had higher 3-year local recurrence rates if the dissection was carried out in the muscularis propria plane

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Standard 5.7: Total Mesorectal Excision

Operation	Maintain the 'Holy Plane'	Pathology Documentation	When?
<p>Total mesorectal excision (TME) is performed for mid and low rectal tumors, resulting in complete or near-complete TME</p> <p>Keep fascia propria of rectum intact, operate in plane between rectum and presacral fascia</p> <ul style="list-style-type: none"> - Ensures negative margins - Protects neurovascular structures 		<p>Quality of TME documented in synoptic report:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Complete <input type="checkbox"/> Near-Complete <input type="checkbox"/> Incomplete 	<p>2021: Implementation</p> <p>2022 site visits: 70% Compliance</p>

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Figure 1. Elements of the Operative Standard 5.7 for rectal cancer.



Figure 2. Timeline of site visits and expected compliance for Standard 5.7.

(ie incomplete TME) compared with the appropriate mesorectal plane (13% vs 4%, $p = 0.003$).⁹ In a Dutch multicenter quality review of pathology reports, incomplete TME was associated with higher local and distant recurrence compared with complete TME (36.1% vs 20.3%, $p = 0.02$). This study highlighted the importance of routine documentation of TME grading in the pathology report, as well as its clinical relevance and prognostic value.⁸

Determination of adequacy of the TME specimen

The ideal TME specimen is classified as a complete and has an intact, smooth mesorectal envelope, displays no distal coning, it has no visible defects >5 mm, and muscularis propria is not visible. A near complete mesorectal excision has moderate bulk, may have an irregular surface with >5 mm defects, but no exposed muscularis propria, and only up to moderate coning. Incomplete mesorectal excisions have poor bulk, defects to the muscularis propria, and circumferentially irregular borders. A specimen is scored based on its worst area.^{11,12}

Operative technique

TME not only improves oncologic outcomes by ensuring complete tumor resection with its adjacent draining lymph nodes but also leverages tissue planes to decrease the difficulty in dissection, while avoiding critical neurovascular structures and the ureters. Ideally, the posterior plane is identified first at the level of the sacral promontory, which leads into the loose areolar tissue plane posterior to the fascia propria of the rectum and anterior to Waldeyer's (or presacral) fascia along the sacrum. Dissection between the visceral mesorectal fascia and parietal presacral fascia is first performed posteriorly and then laterally, with division of the middle rectal vessels and careful identification and

protection of the hypogastric nerve trunks. The dissection is then continued anteriorly, posterior to Denonvilliers' fascia (in men) with care to avoid the autonomic nerve bundles located anterolaterally, uterus, or seminal vesicles.¹³ Maintaining this plane of dissection helps to avoid nerve injury, which result in retrograde ejaculation or impaired bladder function. Although this is the safest dissection plane, Denonvilliers' fascia should be included in specimens with anterior tumors and threatened circumferential resection margins. Ideally this dissection is carried down to a margin 5 cm distal to the tumor when performing a tumor-specific mesorectal excision (TsME), but a 1- to 2-cm distal margin is acceptable if a TME is completed.¹⁴

Implications for national oncologic outcomes

Increasing evidence demonstrates that adherence to oncologic operative standards leads to higher-quality care and improved oncologic outcomes for other primary sites such as breast, lung, and gastric cancers, yet national adherence to these standards remains low.¹⁵⁻¹⁷ In the case of rectal cancer, TME is accepted as the standard of care for mid-to-low rectal cancers across multiple professional societies: the American Society of Colon and Rectal Surgeons, the Society of Surgical Oncology, the National Comprehensive Cancer Network, the ACS NAPRC, and other international societies. Although rates of TME completeness have not been reported in the US, international publications have suggested high rates of incomplete TME, up to 32% of resections, and low reporting compliance despite professional society recommendations.^{18,19} Although improving patient outcomes remains the focus, an added benefit of widespread implementation of Standard 5.7 will be the ability to conduct research about TME at a national level with standardized metrics and outcomes.

BEST PRACTICES FOR COMPLIANCE

Although compliance with this standard is assessed through the pathology report, it is incumbent on the surgeon to perform the resection using proper technique and to document appropriately. Surgeons should first document whether the rectal resection is done with or without curative intent in the operative report. Similarly, surgeons should document the location of the rectal cancer (low/mid/high). The division of these locations, as noted on the CAP synoptic report, is in relation to the anterior peritoneal reflection, with mid/low tumors defined as those at or entirely below the peritoneal reflection. The importance of the surgeon documenting tumor location is underscored by its inclusion in the NAPRC synoptic operative report with options of low, mid, or high.³ Although using this type of operative report for rectal cancer is not currently required by the CoC, it is highly recommended as a best practice. Standard 5.7 does not explicitly require the surgeon to document tumor location or curative intent, but doing so will allow registrars to correctly identify cases to which the standard applies. Without this documentation by the surgeon, a case may have the standard misapplied with resultant lack of compliance.

Additional information about technical aspects of TME and meeting Standard 5.7 can be found as part of the Operative Standards Toolkit and in Volume 2 of the *Operative Standards for Cancer Surgery*.¹³ These resources include a video detailing the requirements and strategies to optimize compliance.²⁰

CONCLUSIONS

Although there have been many advances in the therapy and oncologic outcomes for rectal cancer, this is the first national metric that standardizes the operative technique and pathology documentation for rectal cancer operations in the US. Performance of a complete and near-complete TME for mid-to-low rectal cancer is known to decrease recurrence and improve survival outcomes. Adoption and compliance of this operative standard at CoC-accredited programs will contribute to improved oncologic outcomes for patients with rectal cancer.

Author Contributions

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Critical revision: Adams, Vreeland, Teshome, Francescatti, Zheng, Hunt, Katz, Messick

Final approval of manuscript: Adams, Vreeland, Teshome, Francescatti, Zheng, Hunt, Katz, Messick

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