Best Practices for Compliance with CoC Standards 5.7 & 5.8

Thursday, June 3rd @ 8am CT
Moderator

Matthew H.G. Katz
Professor
Department of Surgical Oncology
MD Anderson Cancer Center

Chair, Cancer Surgery Standards Program
Standard 5.7: Total Mesorectal Excision

Craig A. Messick, MD, FACS, FASCRS
<table>
<thead>
<tr>
<th>Standard</th>
<th>Disease Site</th>
<th>Procedure</th>
<th>Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.3</td>
<td>Breast</td>
<td>Sentinel node biopsy</td>
<td>Operative report</td>
</tr>
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<td>5.4</td>
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<td>Rectum</td>
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<td>Lung resection (any)</td>
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</table>
**Standard 5.7: Total Mesorectal Excision**

**Operation**

Total mesorectal excision (TME) is performed for mid and low rectal tumors, resulting in **complete** or **near-complete** TME.

**Maintain the ‘Holy Plane’**

- Keep fascia propria of rectum intact, operate in plane between rectum and presacral fascia
- Ensures negative margins
- Protects neurovascular structures

**Pathology Documentation**

Quality of TME documented in synoptic report:

- Complete
- Near-Complete
- Incomplete

**When?**

2021: Implementation

2022 site visits: **70% Compliance**
Standard 5.7: Total Mesorectal Excision

Why TME as a Standard?
TME Improves Oncologic Outcomes

Lower recurrence

- Lower recurrence risk: CRAB trial vs. TME trial
- CRAB trial: 16% recurrence
- TME trial: 9% recurrence
- P-value: 0.002

Prolonged overall survival

- Overall survival: CRAB trial vs. TME trial
- CRAB trial: 86% survival
- TME trial: 77% survival
- P-value: 0.002

TME quality affects recurrence/survival

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Complete TME (%)</th>
<th>Incomplete TME (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall recurrence (%)</td>
<td>14.9</td>
<td>28.6</td>
<td>0.03</td>
</tr>
<tr>
<td>Local recurrence (%)</td>
<td>5.5</td>
<td>11.4</td>
<td>0.09</td>
</tr>
<tr>
<td>Distant recurrence (%)</td>
<td>12.2</td>
<td>19.2</td>
<td>0.11</td>
</tr>
<tr>
<td>2-year overall survival (%)</td>
<td>90.5</td>
<td>76.9</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

Standard 5.7: Total Mesorectal Excision

Documentation is Key!
Scoring of TME Quality

• TME quality **scored by pathologist** on CAP standardized synoptic report

• Score based on **worst area of specimen**, not the specimen as a whole

**Complete**
- Intact bulky mesorectum w/ smooth surface, minor irregularities
- No surface defects >5mm
- No coning towards distal specimen

**Near-complete**
- Moderate bulk to mesorectum
- Irregular mesorectal surface, + defects >5mm
- No visible muscularis propria except at insertion of levator muscles

**Incomplete**
- Little bulk to mesorectum
- Defects down to muscularis propria
- Circumferential margin w/ irregular borders
Complete, near complete, and incomplete TME

Photo courtesy of Dr. Patricia Sylla and Dr. Mariana Berho
CAP Synoptic Pathology Reporting

Summary of Changes
Version 4.1.0.0
The following data elements were modified:
Resection and biopsy case summaries separated into discrete cancer protocols
Histologic Type (WHO 2019)
Macroscopic Evaluation of Mesorectum (required for rectal cancers)
Modified Margins section

CAP Approved
Gastrointestinal • Colon and Rectum • Resection • 4.1.0.0

Macroscopic Evaluation of Mesorectum (required for rectal cancers) (Note C)

X Complete
___ Near complete
___ Incomplete
___ Cannot be determined

College of American Pathologists synoptic report templates available at:
Standard 5.7: Total Mesorectal Excision

Timeline
Timeline to achieve compliance

2020

Communicate requirements & engage clinicians in implementation plans

2021

Measure compliance with synoptic pathology reports and assure high reliability at 70% compliance

2022

Site Visits review 2021 pathology reports for 70% compliance

2023

Site Visits review 2021 & 2022 pathology reports for 80% compliance

2024

Site Visits review 2021, 2022, and 2023 pathology reports for 80% compliance
Standard 5.7: Total Mesorectal Excision

Strategies to Optimize Compliance
How can programs optimize compliance?

- Perform TME and document indication (low-mid rectal tumor) clearly in operative notes
- Ensure institution is utilizing standardized CAP reports for all rectal cancer procedures
- Encourage communication amongst surgeons, pathologists, & registrars
Standard 5.7: Total Mesorectal Excision

**Operation**

Total mesorectal excision (TME) is performed for mid and low rectal tumors, resulting in **complete** or **near-complete** TME.

- Keep fascia propria of rectum intact, operate in plane between rectum and presacral fascia
- **Ensures negative margins**
- **Protects neurovascular structures**

**Maintain the ‘Holy Plane’**

**Pathology Documentation**

Quality of TME documented in synoptic report:

- **Complete**
- **Near-Complete**
- **Incomplete**

**When?**

- **2021:** Implementation
- **2022 site visits:** **70% Compliance**
Standard 5.8: Pulmonary Resection

Timothy Vreeland, MD, FACS
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Standard 5.8: Pulmonary Resection

**Operation**

For any primary pulmonary resection performed with curative intent (including non-anatomic parenchymal-sparing resections)

Resect nodal stations from:

- **Mediastinum** (Stations 2-9) ≥3 distinct stations
- **Hilum** (Stations 10-14) ≥1 station

**Pathology Documentation**

Synoptic report documents lymph nodes from:

- ≥3 mediastinal stations
- ≥1 hilar station

with names and/or numbers of stations

**When?**

2021: Implementation

2022 site visits: 70% Compliance


facs.org/cssp
Standard 5.8: Pulmonary Resection

Operation
For any primary pulmonary resection performed with curative intent

(including non-anatomic parenchymal-sparing resections)

Resect nodal stations from:

**Mediastinum**
(Stations 2-9)
≥3 distinct stations

**Hilum**
(Stations 10-14)
≥1 station
Examining Mediastinal Lymph Nodes Improves Survival

Following NCCN quality resection guidelines improves survival

**NCCN Guidelines:**
1. Anatomic resection
2. Negative margins
3. Examination of hilar/intrapulmonary LNs
4. Examination of ≥3 mediastinal LNs

Meeting all four NCCN criteria

- Less than four NCCN criteria
- All four NCCN criteria

Adjusted hazard ratio: 0.64 (0.50-0.80)

Number at risk
- nccn_criteria = 0: 1892
- nccn_criteria = 1: 333

Survival probability over time:
- Months after surgery
- Number at risk
  - nccn_criteria = 0: 782
  - nccn_criteria = 1: 66

*Osarogiagbon et al. 2017*
Examing Mediastinal Lymph Nodes Improves Survival

Non-examination of MLNs decreases survival

Osarogiagbon et al. 2012
Lymph Node Stations

Superior Mediastinal Nodes
- 1 Highest mediastinal
- 2 Upper paratracheal
- 3 Pre-vascular and retrotracheal
- 4 Lower paratracheal (including azygos nodes)

Aortic Nodes
- 5 Subaortic (A-P window)
- 6 Para-aortic (ascending aorta or phrenic)

Inferior Mediastinal Nodes
- 7 Subcarinal
- 8 Paraesophageal (below carina)
- 9 Pulmonary ligament

N₁ Nodes
- 10 Hilar
- 11 Interlobar
- 12 Lobar
- 13 Segmental
- 14 Subsegmental

Nelson et al. 2015
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Standard 5.8: Pulmonary Resection

Documentation
Nodal stations examined by the pathologist must be documented in any curative intent pulmonary resection in pathology reports **in synoptic format**.

Nodal stations should be named and/or numbered, and this must be documented in the pathology report.
Example of a CAP Lung Resection Synoptic Report

Surgical Pathology Cancer Case Summary

Protocol posting date: February 2020

LUNG: Resection

Select a single response unless otherwise indicated.

- Synchronous Tumors (required if morphologically distinct unrelated multiple primary tumors are present)
  - Present
  - Specify total number of primary tumors identified: 
  - Specimen ID:
  - Cannot be determined

* Morphologically distinct tumors that are considered to represent separate primary lung cancers should have separate reports.

Procedure (select all that apply)
- Wedge resection
- Segmentectomy
- Lobectomy
- Completion lobectomy
- Sleeve lobectomy
- Bilobectomy
- Pneumonectomy
- Major airway resection (specify)
- Other (specify)
- Not specified

(...and other sections)

Number of Lymph Nodes Involved: ____
____ Number cannot be determined (explain): ____________________________
Specify nodal station(s) involved (applicable only if node(s) involved): __________

Number of Lymph Nodes Examined: ____
____ Number cannot be determined (explain): ____________________________
Specify nodal station(s) examined: ________________________________

Extramodal Extension (Note J)
- Not identified
- Present
- Cannot be determined

Treatment Effect (Note I)
- No known presurgical therapy
- Greater than 10% residual viable tumor
- Less than or equal to 10% residual viable tumor
- Cannot be determined
Standard 5.8: Pulmonary Resection

Timeline
Standards 5.7 and 5.8 Requirements

Compliance and Site Reviews

- Site Visits review 2021 pathology reports for 70% compliance
- Site Visits review 2021 & 2022 pathology reports for 80% compliance
- Site Visits review 2021, 2022, and 2023 pathology reports for 80% compliance

Steps to Achieve Compliance

- Communicate requirements & engage clinicians in implementation plans
- Measure compliance with synoptic pathology reports and assure high reliability at 70% compliance

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Standard 5.8: Pulmonary Resection

<table>
<thead>
<tr>
<th>Operation</th>
<th>Pathology Documentation</th>
<th>When?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For any primary pulmonary resection</strong></td>
<td>Synoptic report documents lymph nodes from:</td>
<td>2021:</td>
</tr>
<tr>
<td>performed with curative intent</td>
<td>- ≥ 3 mediastinal stations</td>
<td><strong>Implementation</strong></td>
</tr>
<tr>
<td>(including non-anatomic</td>
<td>- ≥ 1 hilar station</td>
<td></td>
</tr>
<tr>
<td>parenchymal-sparing resections)</td>
<td>with names and/or numbers of stations</td>
<td></td>
</tr>
<tr>
<td><strong>Resect nodal stations from:</strong></td>
<td></td>
<td><strong>2022 site visits:</strong></td>
</tr>
<tr>
<td>Mediastinum (Stations 2-9)</td>
<td></td>
<td>70%</td>
</tr>
<tr>
<td>≥ 3 distinct stations</td>
<td></td>
<td><strong>Compliance</strong></td>
</tr>
<tr>
<td>Hilum (Stations 10-14)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 1 station</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


facs.org/cssp
Standard 5.8: Pulmonary Resection

Strategies to Optimize Compliance
How Can Programs Optimize Compliance?

1. Label nodal stations clearly and separately during performance of pulmonary resection.
2. Ensure institution is utilizing standardized CAP reports for all lung cancer procedures.
3. Encourage communication amongst surgeons, pathologists, & registrars.
Lymph Node Stations

Station 4R

Station 7

Station 9R

Station 11R

Nelson et al. 2015

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Lymph Node Stations

Station 4R
Station 7
Station 5R
Station 11R

Nelson et al. 2015
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Lymph Node Stations

Nelson et al. 2015
Lymph Node Stations

Nelson et al. 2015
Station 4R

Station 7

Station 9R

Station 11R

Four separate specimens sent to pathology, clearly labeled.

Nelson et al. 2015

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Overall performance of mediastinal lymph node examination

*Median number of MLN examined:*

1 → 6

Concordance in surgeons’ and pathologists’ reporting

39% → 80%

Osarogiagbon et al, 2012
Osarogiagbon et al, 2015
Standardized Collection Kits Improve Compliance With Pulmonary Nodal Staging

- pNx No mediastinal LN examination
- No station 10 examination
- No station 7 examination
- Meeting all 4 NCCN criteria

Pre-Implementation (N=1270)
Post-Implementation Kit Cases (N=1548)
Post-Implementation Non-Kit Cases (N=1082)

Courtesy of Dr. Osarogiagbon
How Can Programs Optimize Compliance?

We encourage every institution to determine their own pathway to ensure the following:
- Adequate nodal sampling during surgery
- Proper pathologic evaluation
- Correct documentation of which nodal basins were resected and examined
- Correct data capture by registrars.
How Can Programs Optimize Compliance?

- Label nodal stations clearly and separately during performance of pulmonary resection
- Ensure institution is utilizing standardized CAP reports for all lung cancer procedures
- Encourage communication amongst surgeons, pathologists, & registrars
Case Study

Lexy Adams, MD, MPH
Objectives:
• To establish our institution’s current adherence to Standards 5.7 and 5.8
• To identify deficits and to develop a site-specific plan to address them

Methods:
• Cases identified through surgical scheduling system
  • Another option: cancer registrar
• All operative and pathology reports reviewed for:
  • Mid to low rectal adenocarcinoma
  • Curative lung cancer resections
• Review team – residents, with staff surgeon supervision
**Chart Review:** Investigate adherence to each contributing element

<table>
<thead>
<tr>
<th>Standard 5.7</th>
<th>Standard 5.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard applies?</td>
<td>Standard applies?</td>
</tr>
<tr>
<td>Appropriate surgical technique detailed in operative report?</td>
<td>Appropriate surgical technique detailed in operative report?</td>
</tr>
<tr>
<td>Complete or near complete TME performed</td>
<td>3 MLN + 1 HLN resected</td>
</tr>
<tr>
<td>Synoptic pathology report used?</td>
<td>Synoptic pathology report used?</td>
</tr>
<tr>
<td>TME quality reported?</td>
<td>Lymph node stations reported?</td>
</tr>
<tr>
<td>Meets standard completely?</td>
<td>Meets standard completely?</td>
</tr>
<tr>
<td>Standard Elements</td>
<td>Standard 5.7</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Standard applies?</td>
<td>N = 12</td>
</tr>
<tr>
<td>Appropriate surgical technique?</td>
<td>12 / 12</td>
</tr>
<tr>
<td></td>
<td>(30/48 inadequate MLNS, 2/48 no HLN sampled)</td>
</tr>
<tr>
<td>Synoptic pathology report used?</td>
<td>10 / 12</td>
</tr>
<tr>
<td>Pathology report includes:</td>
<td>TME quality:</td>
</tr>
<tr>
<td></td>
<td>8 / 12</td>
</tr>
<tr>
<td>Meets standard completely?</td>
<td>6 / 12</td>
</tr>
</tbody>
</table>

**Overall Compliance:**

50% 35%
Areas to Improve:

**Standard 5.7 (Rectal)**
- Surgeon → Specify low/mid/high rectal tumors (3/12)
  Performance of TME stated in operative report (8/12)
- Pathology → Use of synoptic report to report TME quality (6/12)

**Standard 5.8 (Lung)**
- Surgeon → Routinely take 3 MLN + 1 HLN, regardless of pre-operative EBUS
  If nodes are inaccessible, explicitly document so
- Pathology → Use of synoptic report with individual stations listed (47/48)
Interventions:

- Discussion with Cancer Committee
  - Educational materials and video shared
  - Review of surgeon & pathology expectations
  - Chart review results reviewed, detailing areas requiring improvement

- Department leadership discussion & review of standards
  - Granular review of data helped clarify:
    - Definitions of MLN stations
    - Required 3 MLN + 1 HLN sampling despite pre-operative EBUS
    - Need for improved documentation for difficult dissections and inaccessible nodes
Single Site Review: Addressing the Deficits

Outcomes for first half of 2021:

Overall Compliance:

<table>
<thead>
<tr>
<th>Standard 5.7</th>
<th>50%</th>
<th>100%</th>
<th>4/4 cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Rectal)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Standard 5.8</th>
<th>35%</th>
<th>100%</th>
<th>3/3 cases</th>
</tr>
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<tr>
<td>(Lung)</td>
<td></td>
<td></td>
<td></td>
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</table>
Beginning Your Site Review

1. Identify applicable cases
   - Use cancer registry or surgical schedule

2. List all contributing elements required to meet standard
   - Ex: surgical technique components, surgical documentation, specimen labeling, synoptic pathology report, report elements needed

3. Simplify the chart review
   - Operative & pathology reports only – trainees can help!

4. Identify & address the deficits
   - Identify appropriate stakeholders, discuss within departments, share previously published videos & education materials, develop specimen labeling checklist, etc.
   - Re-evaluate your progress!
Standard 5.7: Total Mesorectal Excision

Pathological examination

Mariana Berho, MD
The plane of surgery correlates with the integrity of the mesorectum

- Mesorectal: Complete mesorectum
- Intramesorectal: Near complete mesorectum
- Muscularis propria: Incomplete mesorectum
Complete Mesorectum
• TME quality **scored by pathologist** on CAP standardized synoptic report

• Score based on **worst area of specimen**, not the specimen as a whole

---

**Complete**

- Intact bulky mesorectum w/ smooth surface, minor irregularities
- No surface defects >5mm
- No coning towards distal specimen

---

**Near-complete**

- Moderate bulk to mesorectum
- Irregular mesorectal surface, + defects >5mm
- No visible muscularis propria except at insertion of levator muscles

---

**Incomplete**

- Little bulk to mesorectum
- Defects down to muscularis propria
- Circumferential margin w/ irregular borders
Protocol for the Examination of Resection Specimens From Patients With Primary Carcinoma of the Colon and Rectum

Version: Colon and Rectum Resection 4.1.0.0    Protocol Posting Date: February 2020
CAP Laboratory Accreditation Program Protocol Required Use Date: November 2020
Includes pTNM requirements from the 8th Edition, AJCC Staging Manual

Summary of Changes

Version 4.1.0.0
The following data elements were modified:
Resection and biopsy case summaries separated into discrete cancer protocols
Histologic Type (WHO 2019)
Macroscopic Evaluation of Mesorectum (required for rectal cancers)
Modified Margins section
Macroscopic Evaluation of Mesorectum (required for rectal cancers) (Note C)

___ Complete
___ Near complete
___ Incomplete
___ Cannot be determined
Standard 5.7: Total Mesorectal Excision

Timeline
Timeline to achieve compliance

**Steps to Achieve Compliance**

2020
- Communicate requirements & engage clinicians in implementation plans

2021
- Measure compliance with synoptic pathology reports and assure high reliability at 70% compliance
- Site Visits review 2021 pathology reports for 70% compliance

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- Site Visits review 2021, 2022, and 2023 pathology reports for 80% compliance

2024
- Site Visits review 2021, 2022, and 2023 pathology reports for 80% compliance
Standard 5.8: Pulmonary Resection

Pathologic Evaluation

Rashna Madan, MBBS
Specifically designated mediastinal/N2 and hilar/N1 nodal stations in separate specimen containers

N1 nodal stations dissected from main resection specimen

Report in synoptic format

Registrar
CoC Standard 5.1:

• 90% of eligible cancer reports - synoptic reporting format - CAP cancer protocols…
Protocol for the Examination of Resection Specimens From Patients With Primary Non-Small Cell Carcinoma, Small Cell Carcinoma, or Carcinoid Tumor of the Lung

Version: Lung 4.1.0.1  Protocol Posting Date: February 2020
CAP Laboratory Accreditation Program Protocol Required Use Date: November 2020

Includes pTNM requirements from the 8th Edition, AJCC Staging Manual

Lymph Node reporting - CAP synoptic format

• Conditional data element:
  • If lymph nodes are present, required to report:
    • Number
    • Specify stations

Lymp Node Examination (required only if lymph nodes present in the specimen)

Number of Lymph Nodes Involved: ____
  ____ Number cannot be determined (explain): ______________________
  Specify nodal station(s) involved (applicable only if node(s) involved): ______________

Number of Lymph Nodes Examined: ____
  ____ Number cannot be determined (explain): ______________________
  Specify nodal station(s) examined: ______________
N1 nodes received as part of Main Resection specimen

- Nodes dissected out by the Pathology team
  - Peribronchial or intraparenchymal in location
- Count towards the Standard 5.8 requirement

- Surgeons should perform hilar nodal dissection
Fat only specimen

• Fat pad submitted from a station but no nodes identified on pathologic evaluation.

• Does not meet the requirement for Standard 5.8
Nodes from Mediastinoscopy (prior)

- Nodes from mediastinoscopy can be utilized to meet requirements of Standard 5.8 if:
  - Documented in the same pathology report as the curative resection

- However endobronchial ultrasound (EBUS) needle biopsies of lymph nodes do not count towards Standard 5.8
Pathologic nodal staging

- Standard 5.8 is a quality metric
- pN staging can be performed provided lymph nodes can be assessed even if the criteria for Standard 5.8 are not met:
  - Failure to meet the criteria does not imply pNX
Q&A