

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

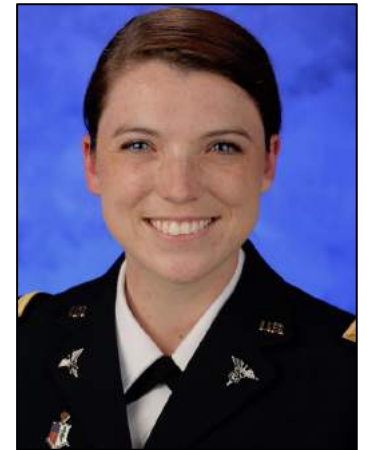
Speakers



Craig Messick, MD, FACS
MD Anderson Cancer Center
Houston, TX



Tim Vreeland, MD, FACS
Brooke Army Medical Center
San Antonio, TX



Lexy Adams, MD, MPH
Brooke Army Medical Center
San Antonio, TX



Rashna Madan, MBBS
University of Kansas Medical Center
Kansas City, KS



Mariana Berho, MD
Cleveland Clinic
Weston, FL

Standard 5.7: Total Mesorectal Excision

Craig A. Messick, MD, FACS, FASCRS



Standard 5.7: Total Mesorectal Excision

Standard	Disease Site	Procedure	Documentation
5.3	Breast	Sentinel node biopsy	Operative report
5.4	Breast	Axillary dissection	Operative report
5.5	Melanoma	Wide local excision	Operative report
5.6	Colon	Colectomy (any)	Operative report
5.7	Rectum	Mid/low resection (TME)	Pathology report (CAP)
5.8	Lung	Lung resection (any)	Pathology report (CAP)

Standard 5.7: Total Mesorectal Excision

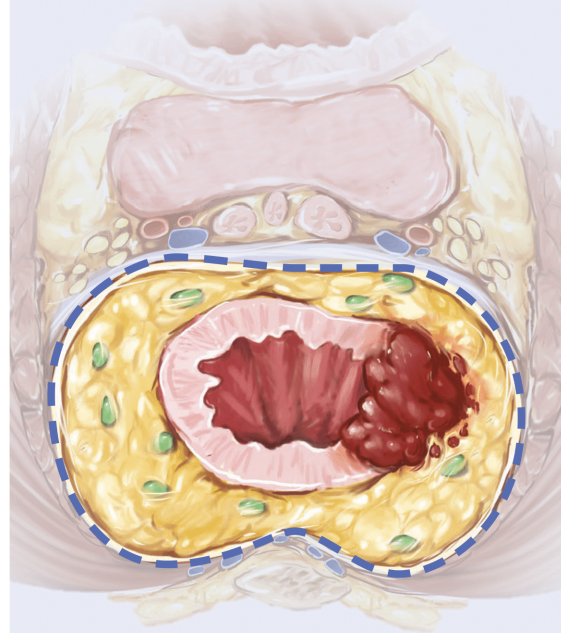
Operation

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:

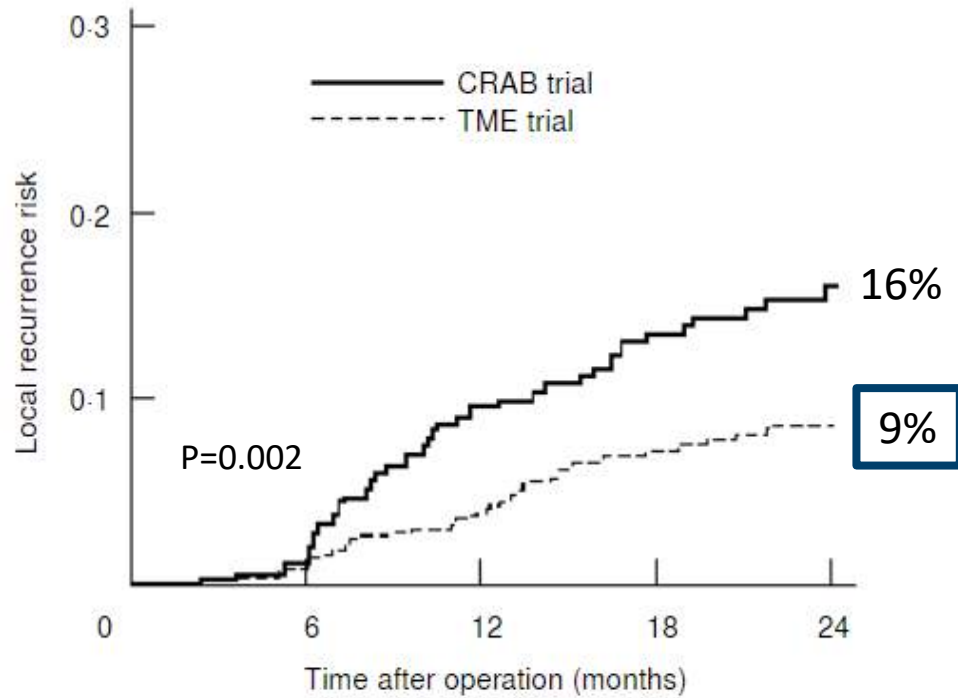
70%
Compliance

Standard 5.7: Total Mesorectal Excision

Why TME as a Standard?

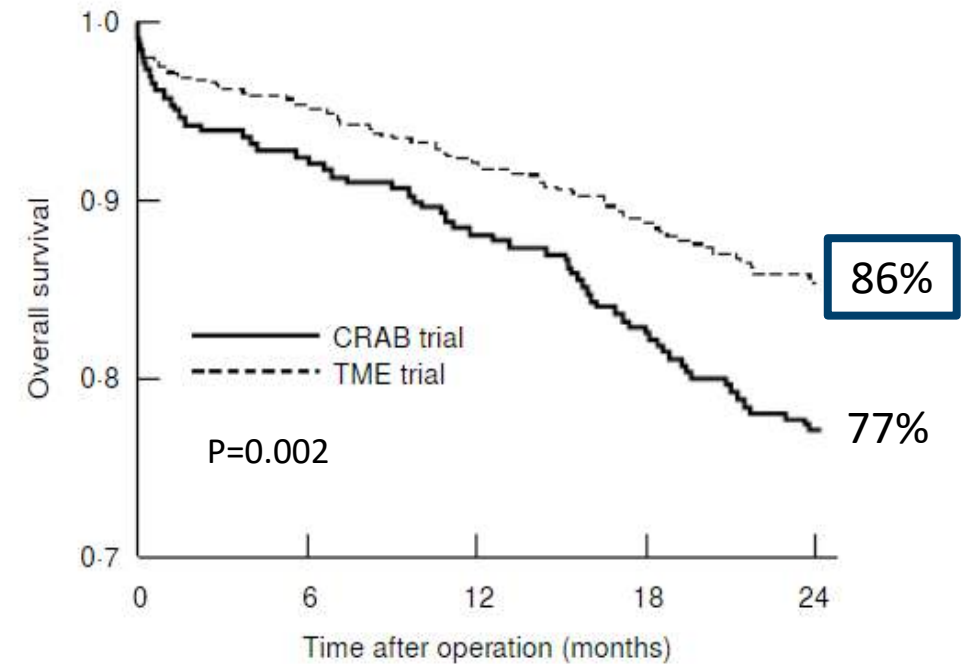
TME Improves Oncologic Outcomes

Lower recurrence



No. at risk	0	6	12	18	24
CRAB trial	269	243	213	193	180
TME trial	661	614	540	428	345

Prolonged overall survival

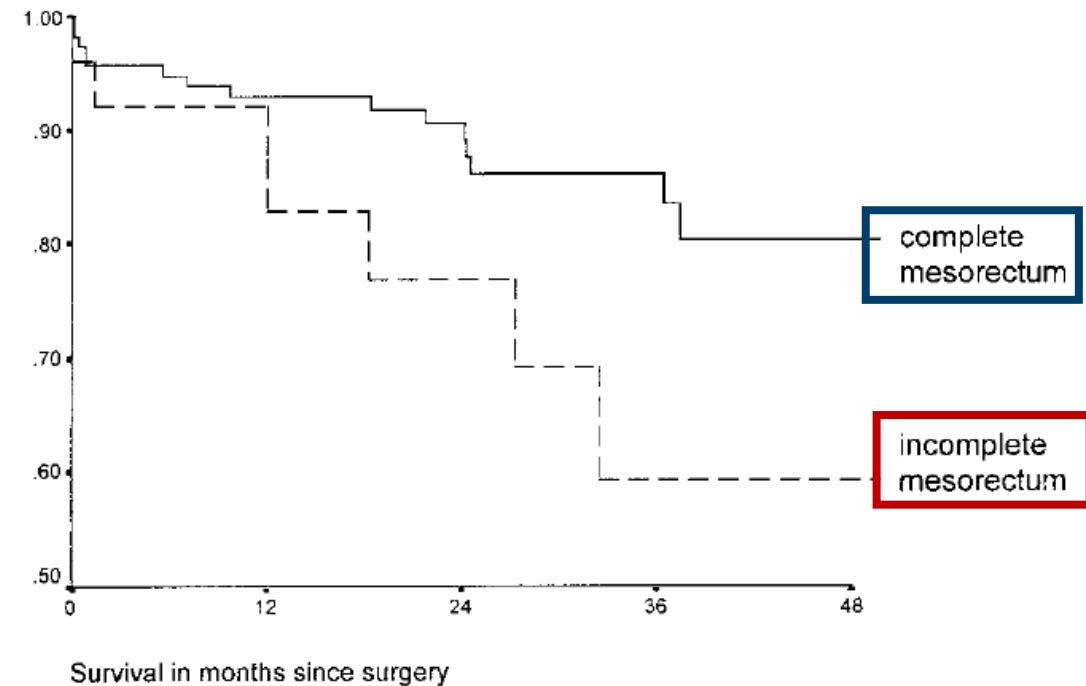


No. at risk	0	6	12	18	24
CRAB trial	269	249	237	223	207
TME trial	661	626	558	449	363

Kapiteijn E et al 2002. *J Clin Oncol*.

TME quality affects recurrence/survival

Outcome	Complete TME	Incomplete TME	P-value
Overall recurrence (%)	14.9%	28.6%	0.03
Local recurrence (%)	5.5%	11.4%	0.09
Distant recurrence (%)	12.2%	19.2%	0.11
2-year overall survival (%)	90.5%	76.9%	<0.05



Nagtegaal et al 2002. *J Clin Oncol*

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

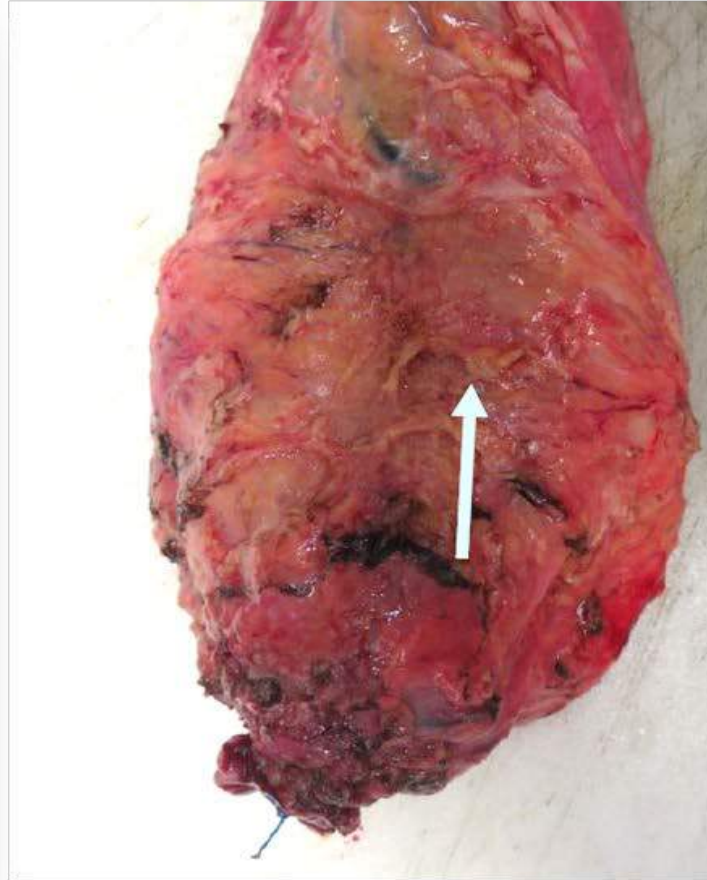
- Little bulk to mesorectum
- Defects down to muscularis propria
- Circumferential margin w/ irregular borders

Complete, near complete, and incomplete TME



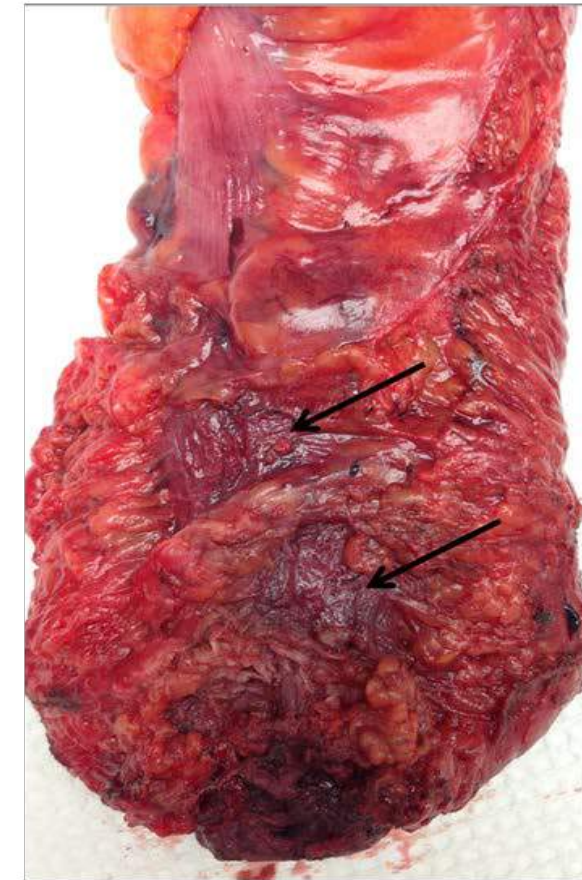
Complete
Optimal quality

- Good bulk of mesorectum, smooth surface, good clearance anteriorly, no defects in mesorectum.



Near Complete
Moderate quality

- Moderate bulk of mesorectum but some irregularity, moderate coning distally may be present.



Incomplete
Poor quality

- Irregular mesorectum with defects more than 1 cm² or incision down to the muscularis propria, little bulk of mesorectum, little clearance anteriorly.

Photo courtesy of Dr. Patricia Sylla and Dr. Mariana Berho

CAP Synoptic Pathology Reporting



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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)

- Complete
- Near complete
- Incomplete
- Cannot be determined

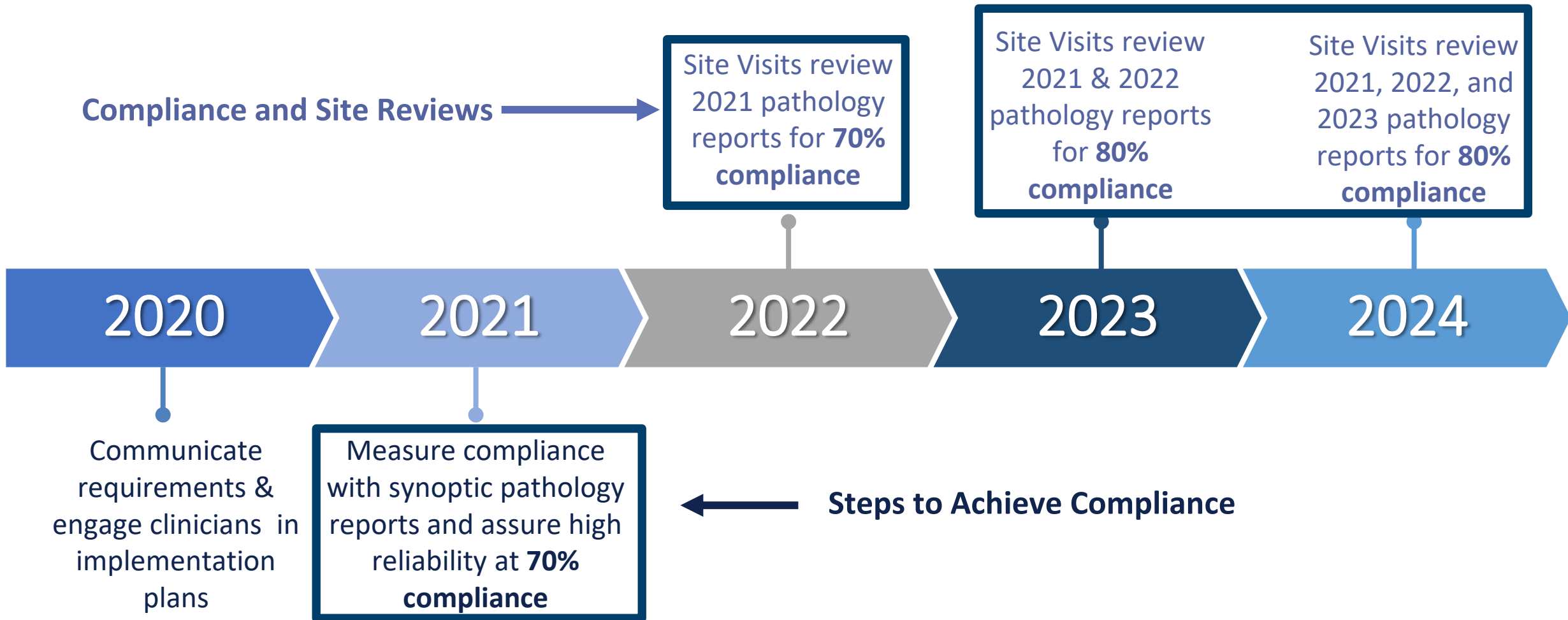
College of American Pathologists synoptic report templates available at:

<https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates>

Standard 5.7: Total Mesorectal Excision

Timeline

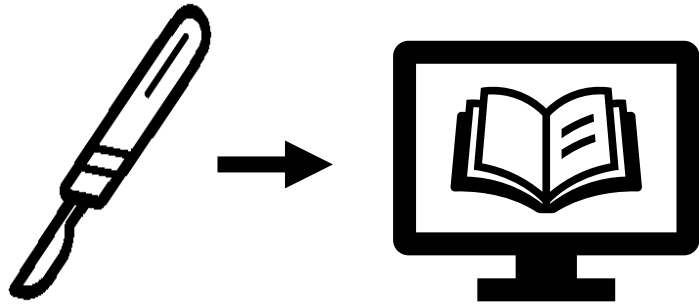
Timeline to achieve compliance



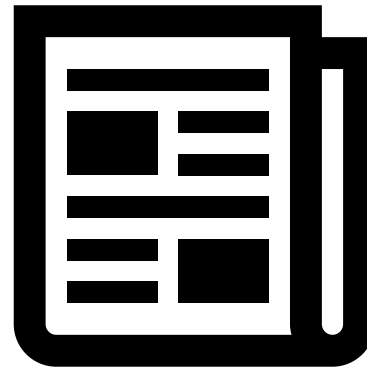
Standard 5.7: Total Mesorectal Excision

Strategies to Optimize Compliance

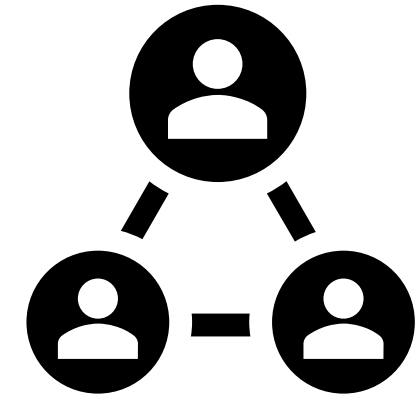
How can programs optimize compliance?



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

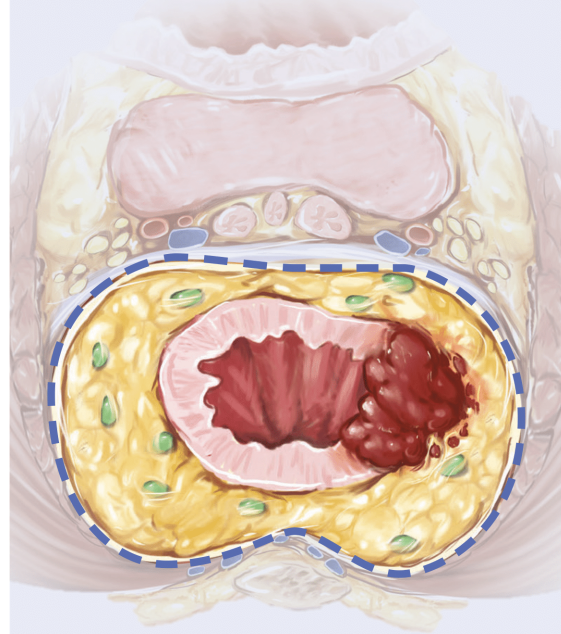
Operation

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



Standard	Disease Site	Procedure	Documentation
5.3	Breast	Sentinel node biopsy	Operative report
5.4	Breast	Axillary dissection	Operative report
5.5	Melanoma	Wide local excision	Operative report
5.6	Colon	Colectomy (any)	Operative report
5.7	Rectum	Mid/low resection (TME)	Pathology report (CAP)
5.8	Lung	Lung resection (any)	Pathology report (CAP)

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:

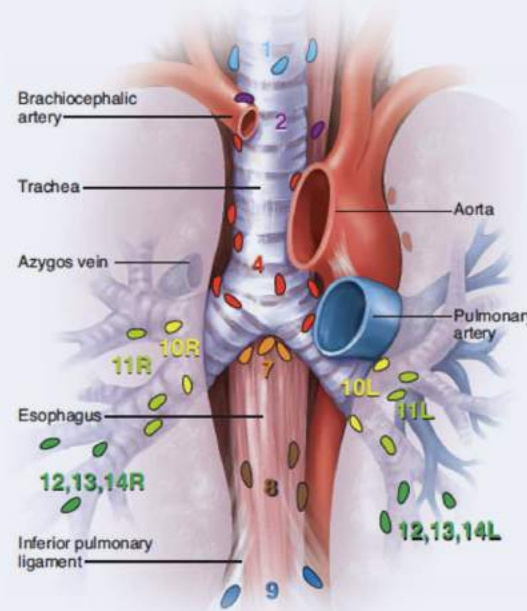


Mediastinum
(Stations 2-9)
≥3 distinct stations

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

Adapted from *Chest*, Vol. 111, Mountain CF, Dresler CM, Regional lymph node classification for lung cancer staging, Pp. 1718-1723, Copyright (1997), with permission from Elsevier.

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:



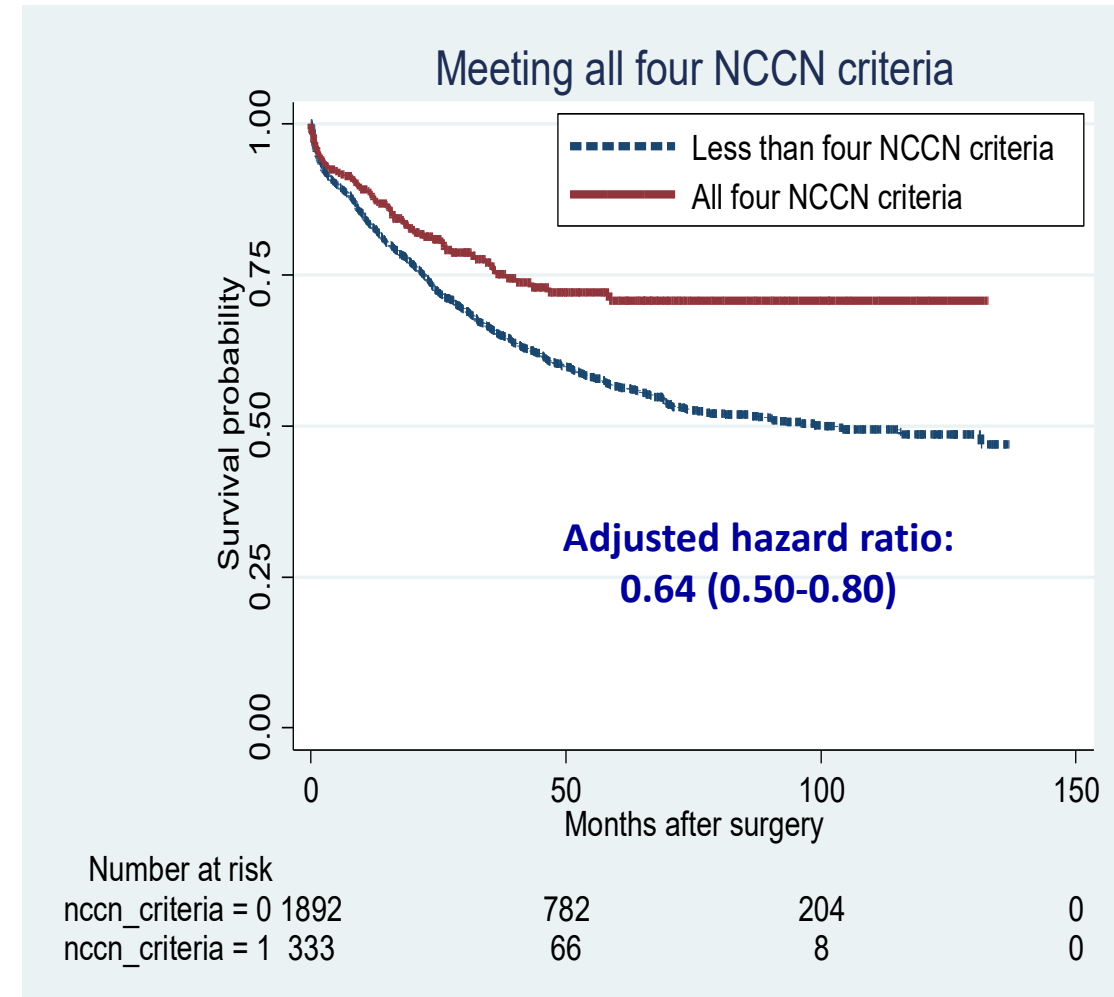
Mediastinum
(Stations 2-9)
≥3 distinct stations

Hilum
(Stations 10-14)
≥1 station

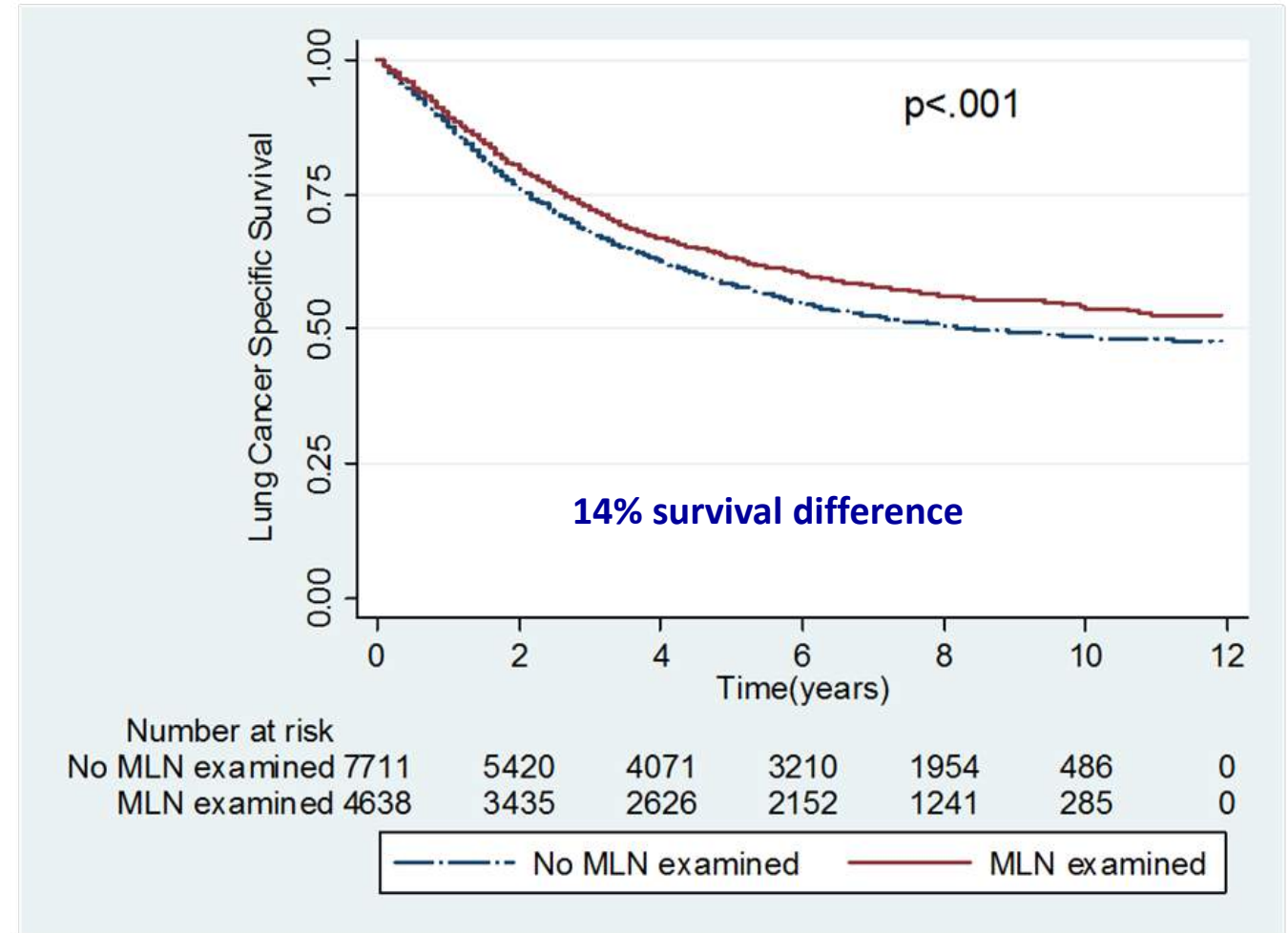
Following NCCN quality resection guidelines improves survival

NCCN Guidelines:

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



**Non-
examination of
MLNs decreases
survival**



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

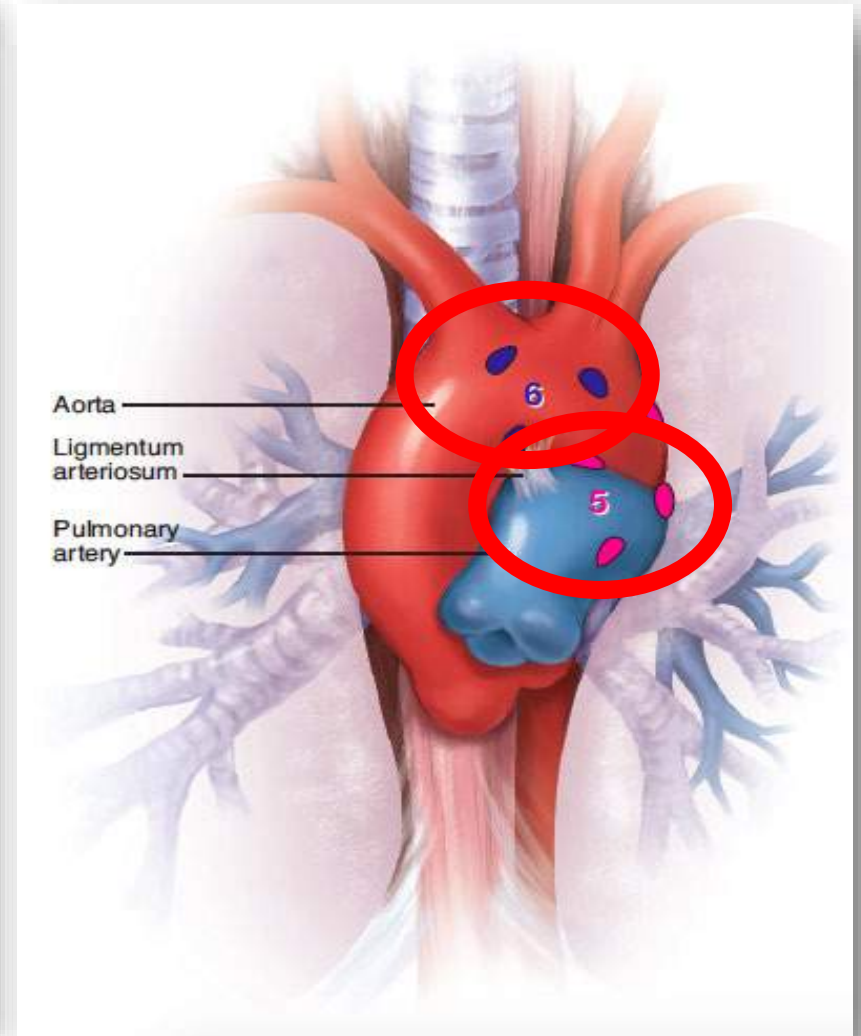
- 5 Subaortic (A-P window)
- 6 Para-aortic (ascending aorta or phrenic)

Inferior Mediastinal Nodes

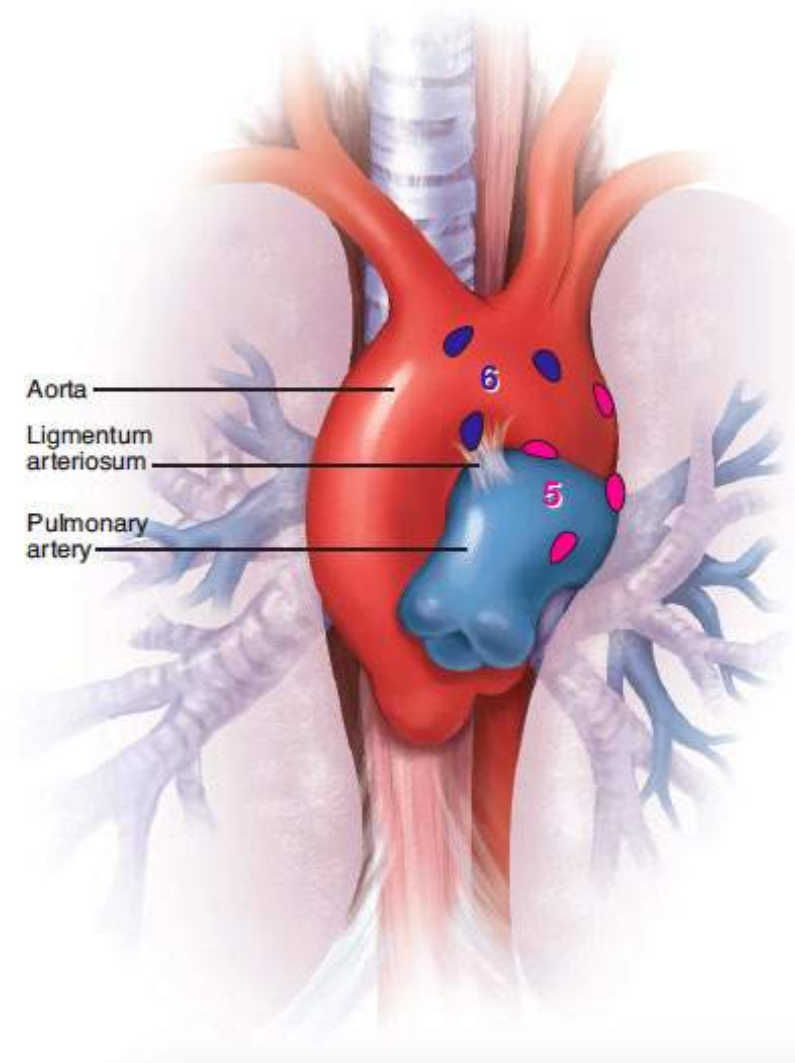
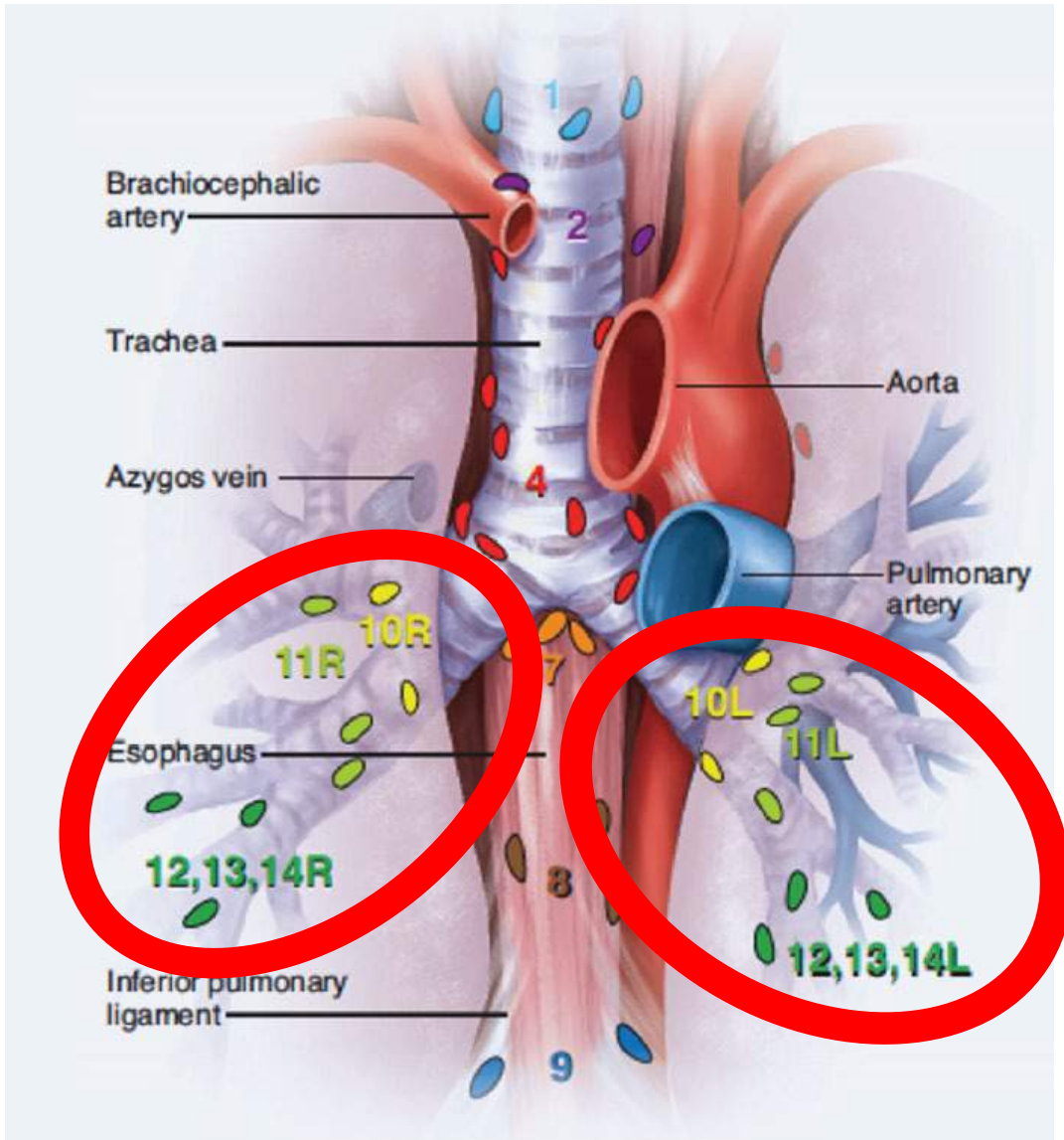
- 7 Subcarinal
- 8 Paraesophageal (below carina)
- 9 Pulmonary ligament

N₁ Nodes

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



Nelson et al. 2015



Standard 5.8: Pulmonary Resection Documentation

CoC Compliance Measures: Standard 5.8



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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



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CAP Approved

Thorax • Lung • Resection • 4.1.0.1

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(s): _____
 Cannot be determined

* Morphologically distinct tumors that are considered to represent separate primary lung cancers should have separate synoptic 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)

Lymph 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: _____

+ Extranodal 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

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: _____

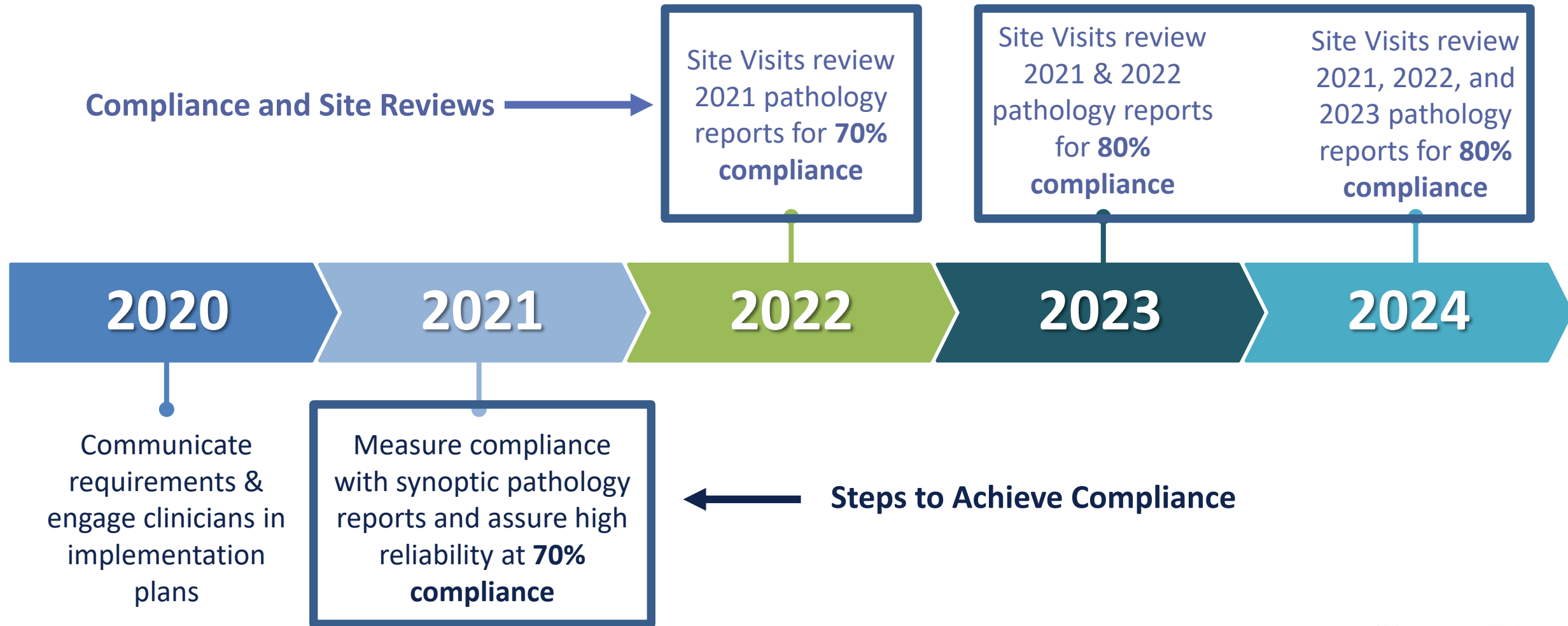
Cancer
PROGRAMS

AMERICAN COLLEGE OF SURGEONS

Standard 5.8: Pulmonary Resection

Timeline

Standards 5.7 and 5.8 Requirements



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:

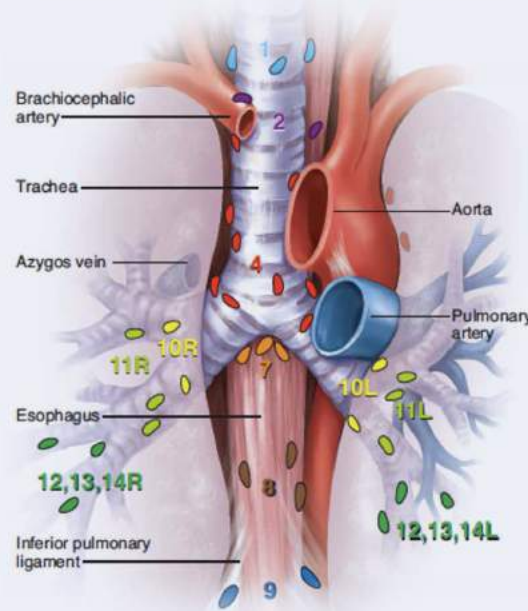


Mediastinum
(Stations 2-9)
≥3 distinct stations

Hilum
(Stations 10-14)
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Pathology Documentation

Synoptic report documents lymph nodes from:



≥ 3 mediastinal stations

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with names and/or numbers of stations

When?

2021:
Implementation

2022 site visits:

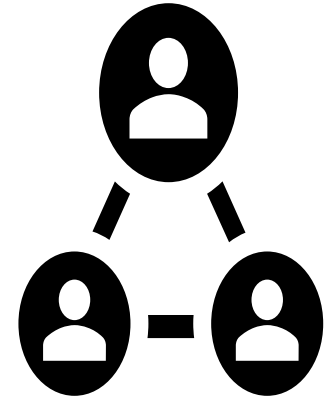
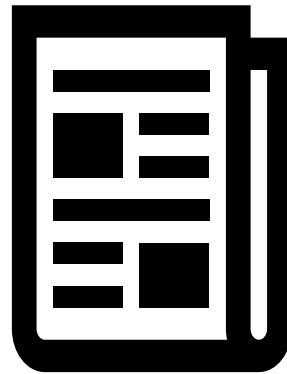
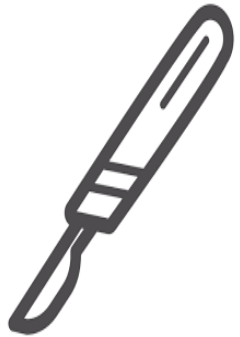
70%
Compliance

Adapted from *Chest*, Vol. 111, Mountain CF, Dresler CM, Regional lymph node classification for lung cancer staging, Pp. 1718-1723, Copyright (1997), with permission from Elsevier.

Standard 5.8: Pulmonary Resection

Strategies to Optimize Compliance

How Can Programs Optimize Compliance?

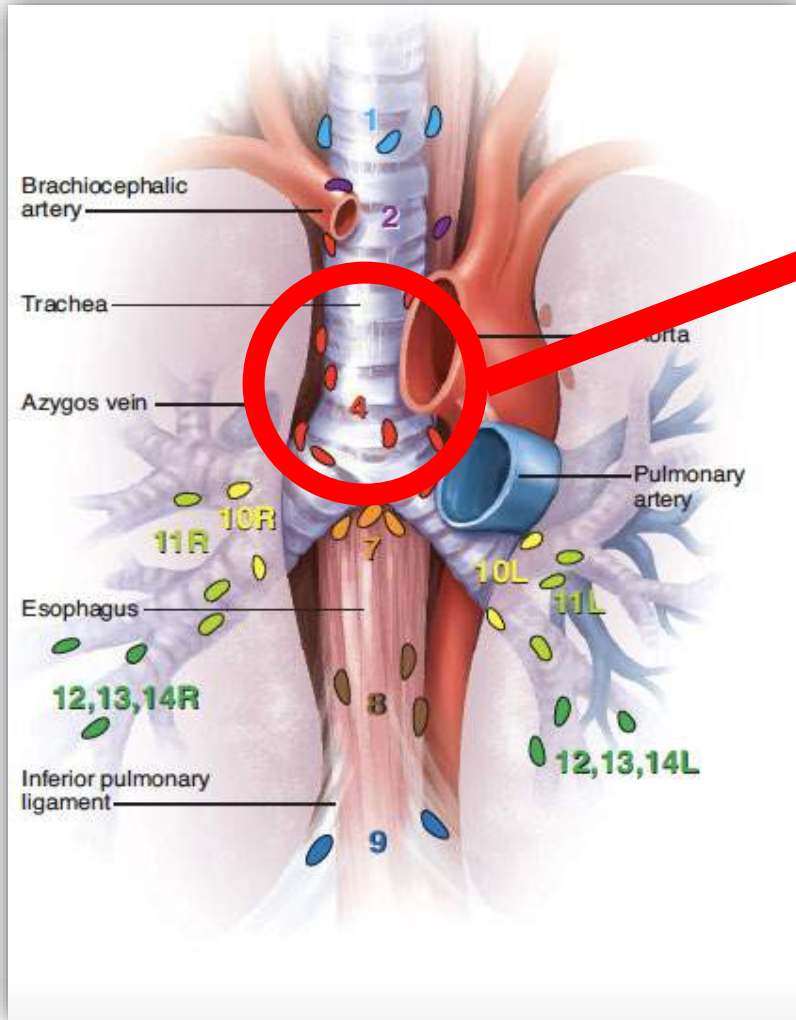


Label nodal stations **clearly and separately** during performance of pulmonary resection

Ensure institution is utilizing **standardized CAP reports** for all lung cancer procedures

Encourage communication amongst surgeons, pathologists, & registrars

Lymph Node Stations



Station 4R



Station 9R



Station 7



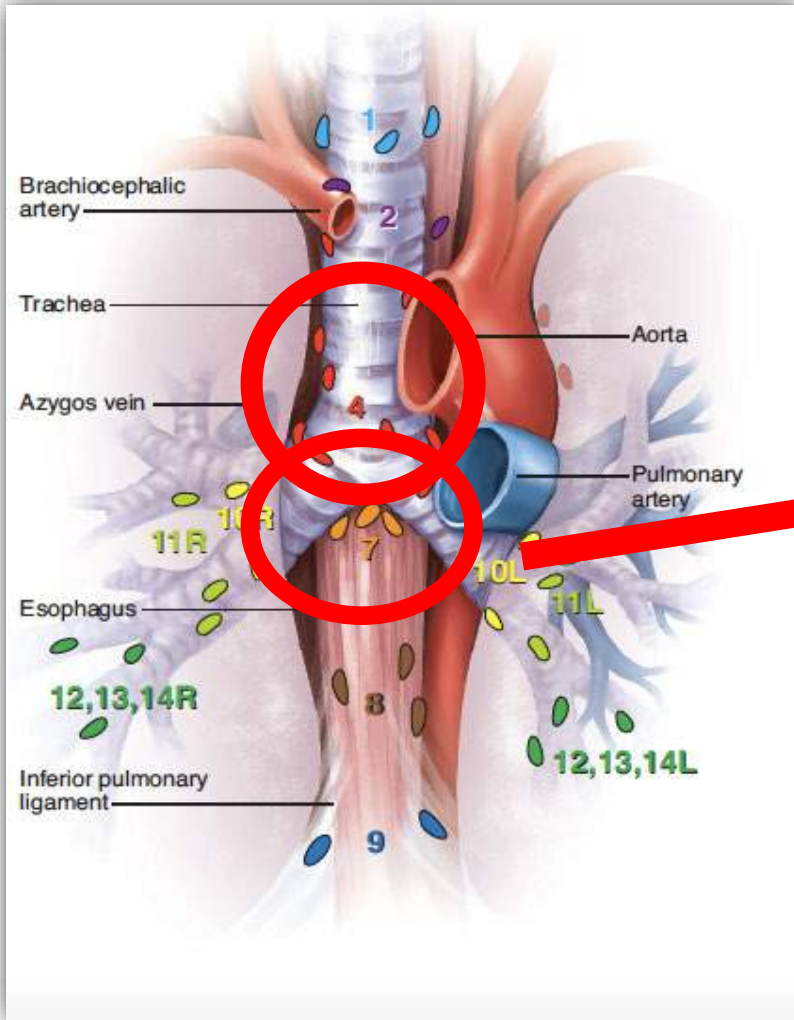
Station 11R



Nelson et al. 2015

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Lymph Node Stations



Station 4R



Station 9R



Station 7



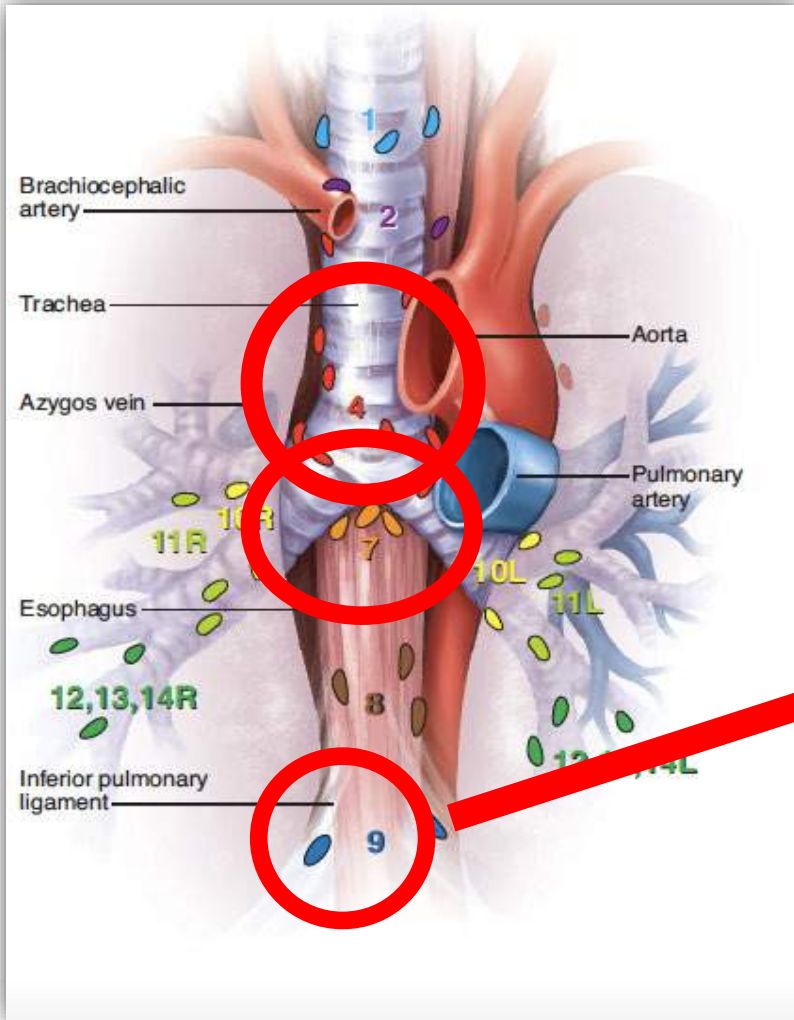
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Lymph Node Stations



Station 4R



Station 7



Station 9R



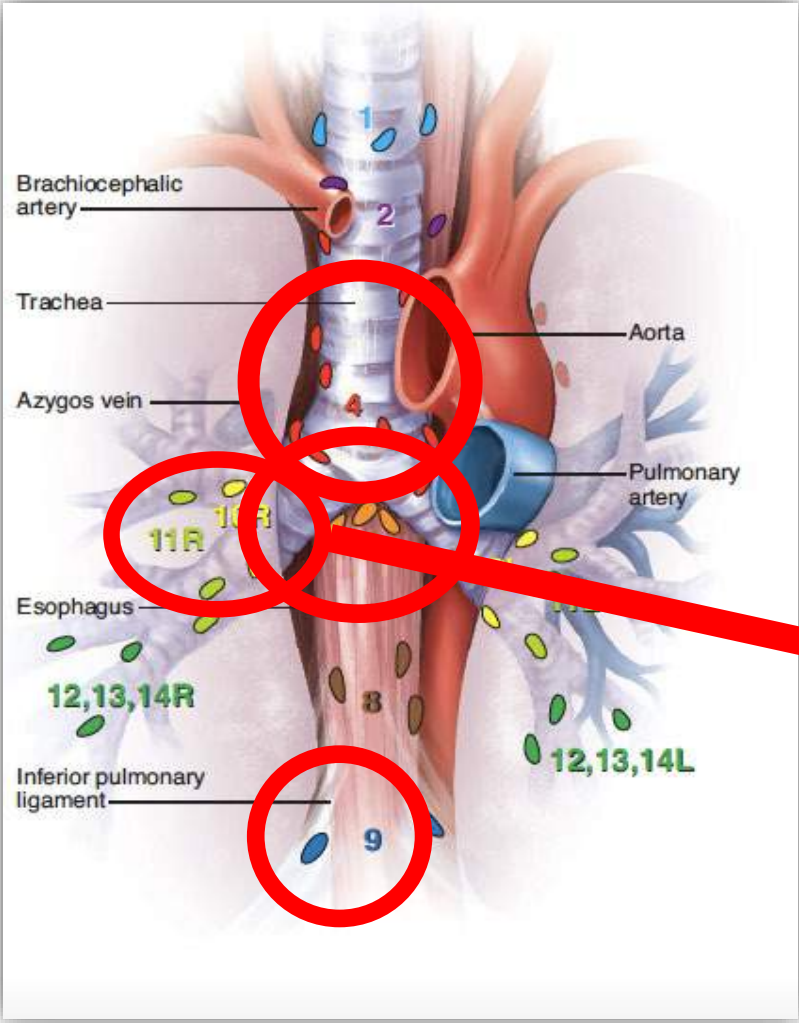
Station 11R



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Lymph Node Stations



Station 4R



Station 9R



Station 7



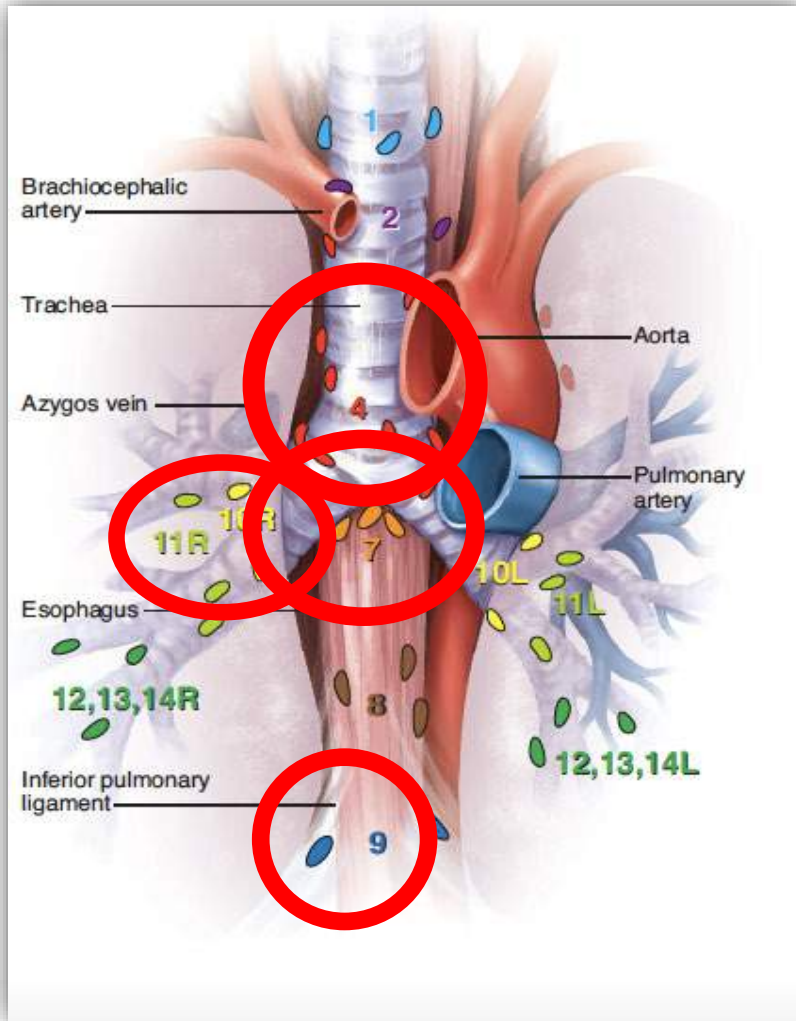
Station 11R



Nelson et al. 2015

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Lymph Node Stations



Station 4R



Station 7



Station 9R



Station 11R



Four separate specimens sent to pathology, clearly labeled.

Nelson et al. 2015

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Pre-labeled Specimen Collection Kits & Checklists Improve Communication



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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%

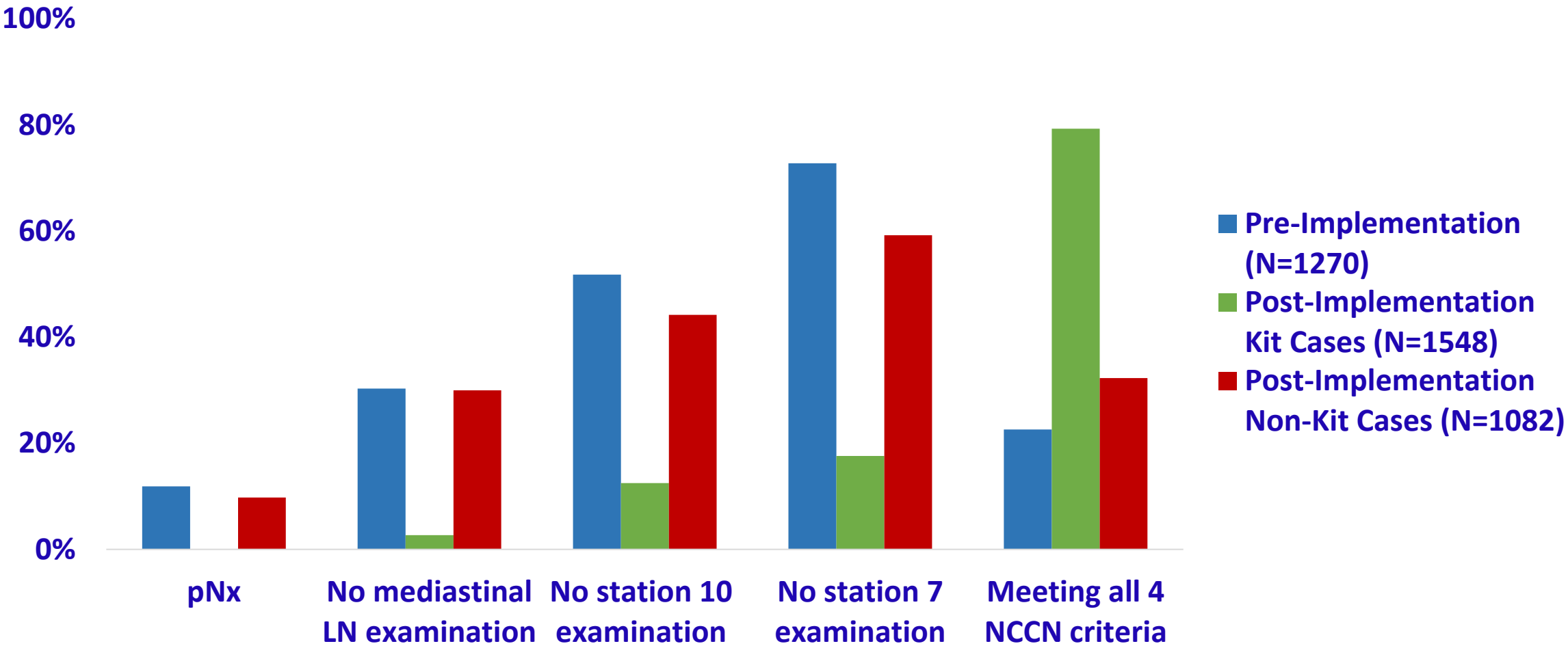


Osarogiagbon et al, 2012
Osarogiagbon et al, 2015

Standardized Collection Kits Improve Compliance With Pulmonary Nodal Staging

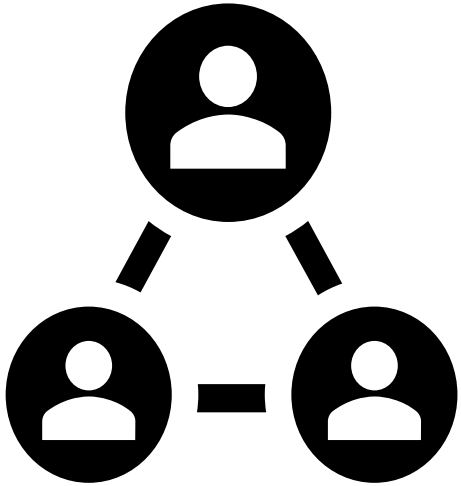


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Courtesy of Dr. Osarogiagbon

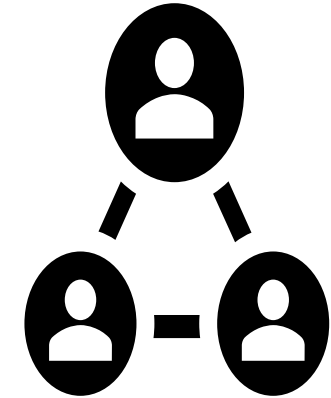
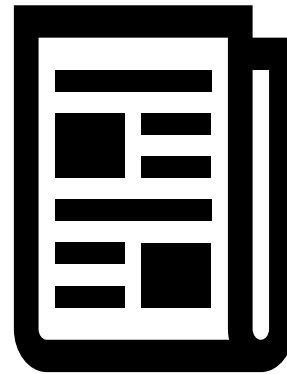
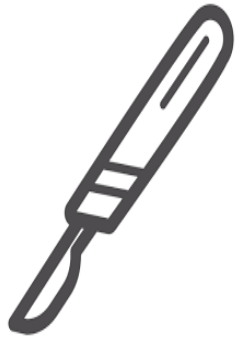
How Can Programs Optimize Compliance?



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



Single Site Review: Determining a Baseline

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

Single Site Review: Determining a Baseline

Chart Review: Investigate adherence to each contributing element

Standard 5.7	Standard 5.8
Standard applies?	
Appropriate surgical technique detailed in operative report?	
Complete or near complete TME performed	3 MLN + 1 HLN resected
Synoptic pathology report used?	
TME quality reported?	Lymph node stations reported?
Meets standard completely?	

Single Site Review: Baseline Results

Standard Elements	Standard 5.7	Standard 5.8
Standard applies?	N = 12	N = 48
Appropriate surgical technique?	12 / 12	18 / 48 <i>(30/48 inadequate MLNS, 2/48 no HLN sampled)</i>
Synoptic pathology report used?	10 / 12	46 / 48
Pathology report includes:	<i>TME quality:</i> 8 / 12	<i>Lymph node stations:</i> 47 / 48
Meets standard completely?	6 / 12	17 / 48

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)**

**18/48 with adequate MLNS
(0/6 with pre-op EBUS)
46/48 included HLN**

Single Site Review: Addressing the Deficits

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:

Standard 5.7
(Rectal)

50%



100%

4/4 cases

Standard 5.8
(Lung)

35%



100%

3/3 cases

- 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

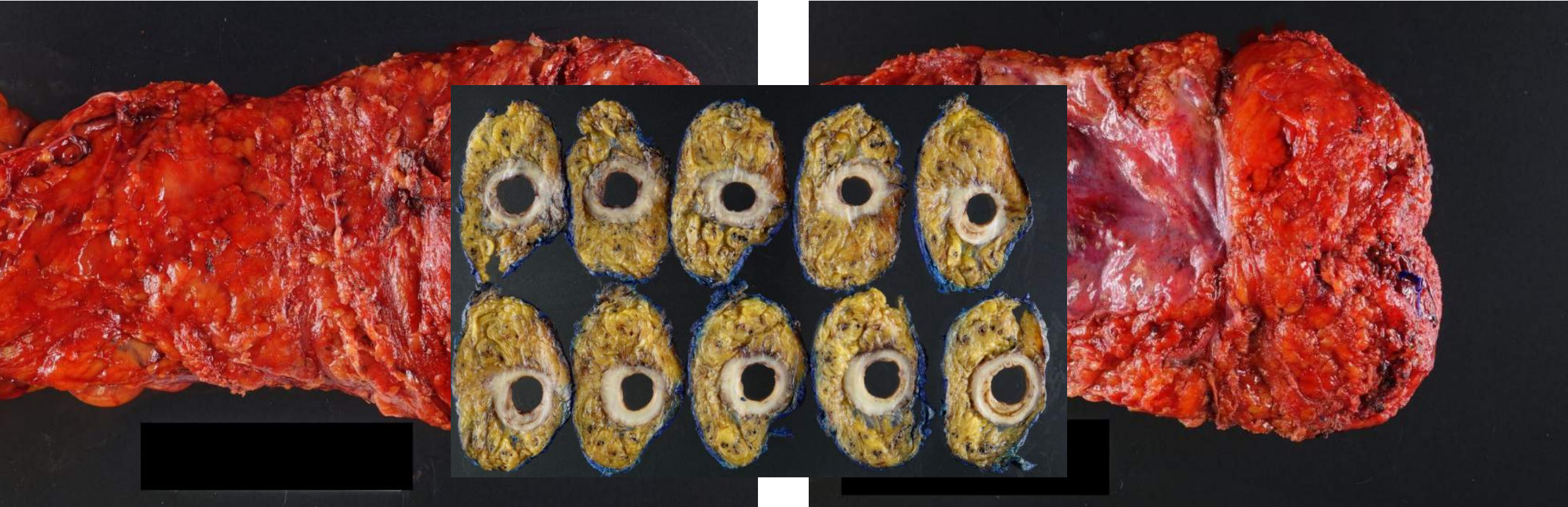
Pathological examination

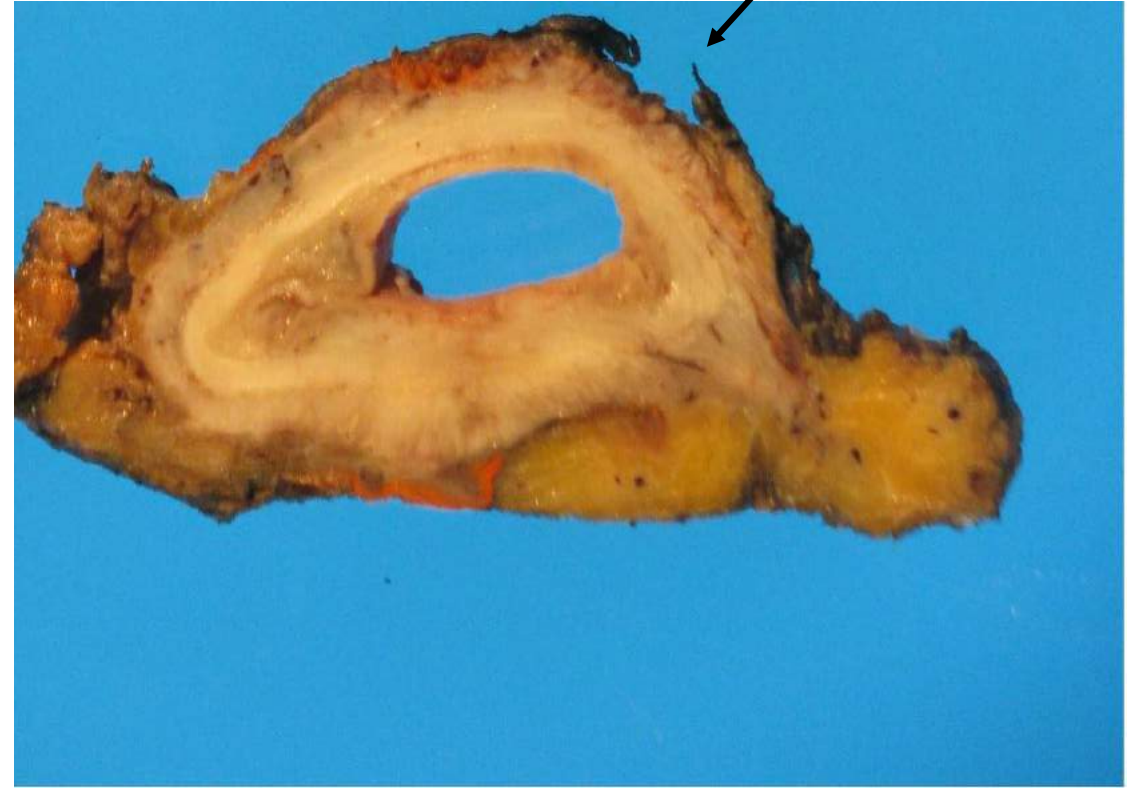
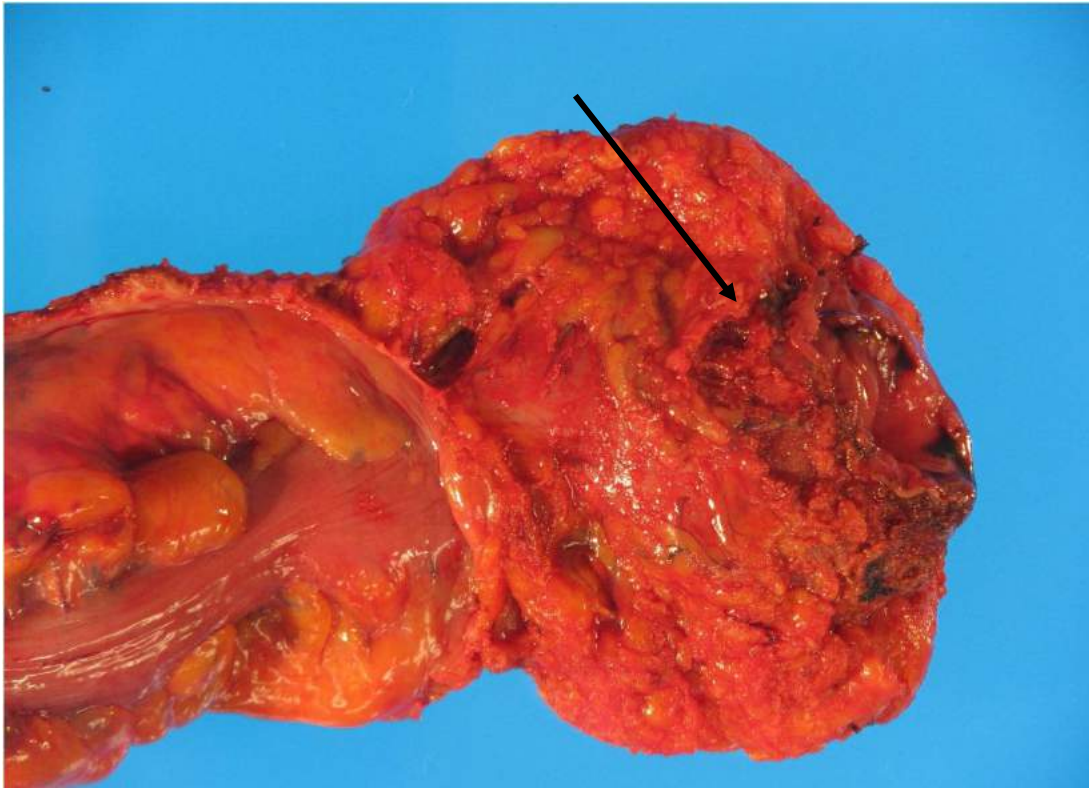
Mariana Berho, MD

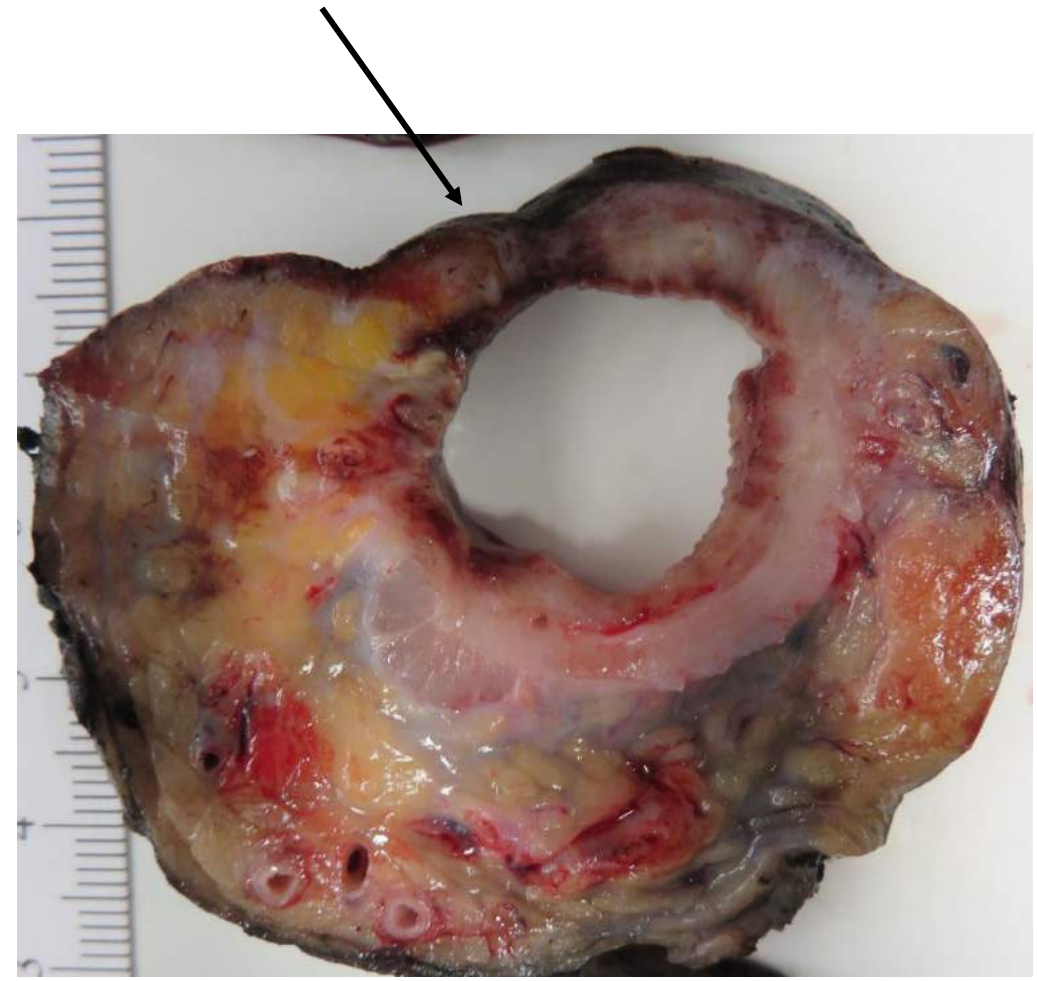
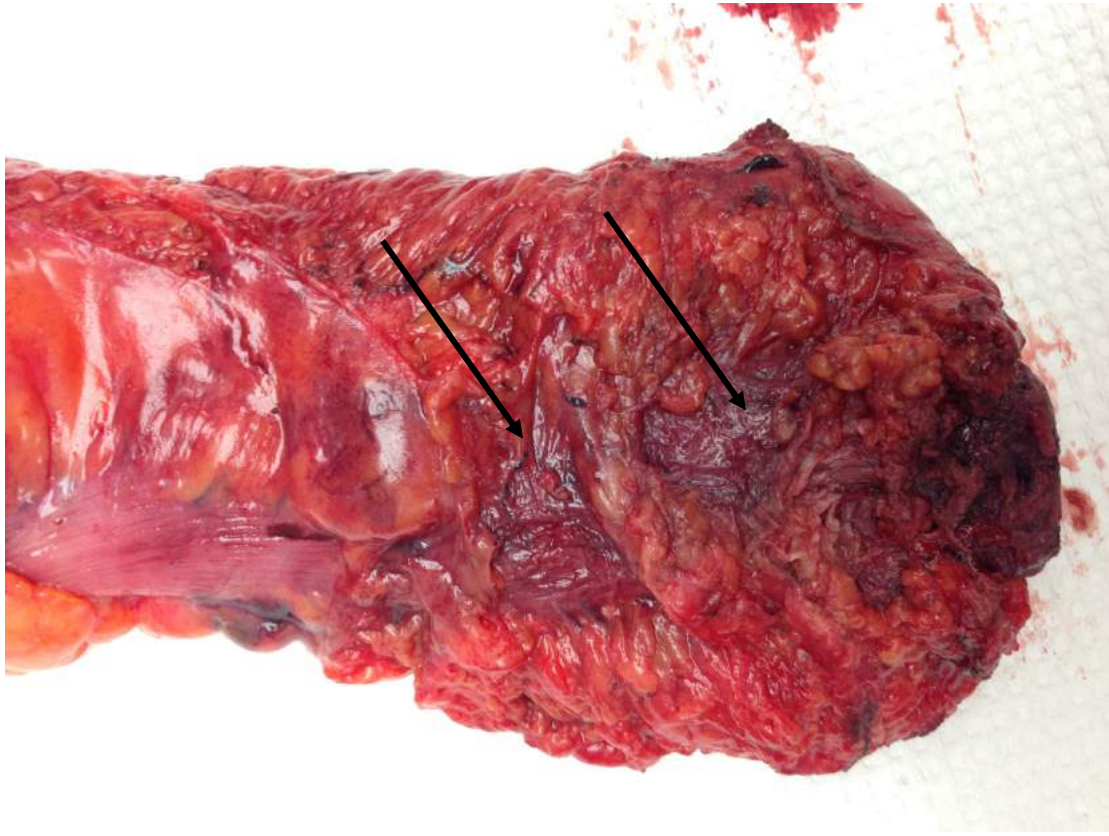
The plane of surgery correlates with the integrity of the mesorectum

- Mesorectal: Complete mesorectum
- Intramesorectal: Near complete mesorectum
- Muscularis propria: Incomplete mesorectum

Complete Mesorectum







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



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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

<https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates>

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

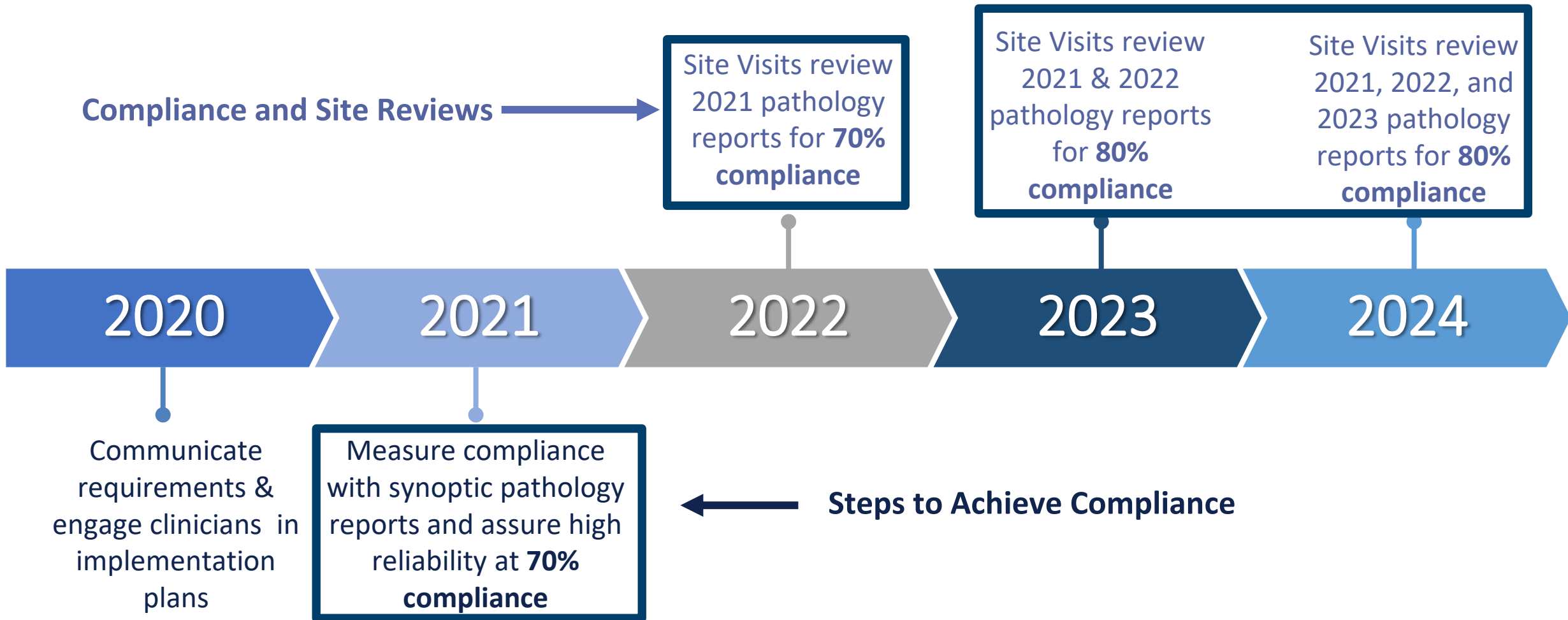
Macroscopic Evaluation of Mesorectum (required for rectal cancers) (Note C)

- Complete
- Near complete
- Incomplete
- Cannot be determined

Standard 5.7: Total Mesorectal Excision

Timeline

Timeline to achieve compliance



Standard 5.8: Pulmonary Resection

Pathologic Evaluation

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Surgeon

Specifically designated mediastinal/N2 and hilar/N1 nodal stations in separate specimen containers



Report in synoptic format



Registrar

Pathologist

N1 nodal stations dissected from main resection specimen



College of American Pathologists (CAP) synoptic format for Pathology Reports

- CoC Standard 5.1:
 - 90% of eligible cancer reports - synoptic reporting format - CAP cancer protocols...



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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

<https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates>



Lymph Node reporting - CAP synoptic format

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

Lymph 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

