Operative Standards in Cancer Surgery – Defining the Critical Elements for Surgical Success

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Medical Advisory Board – Armada Health, Merck & Co.
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Objectives

• Discuss the need for surgical standards in cancer care
• Understand the development of *Operative Standards in Cancer Surgery*
• Understand the rationale that lead to the OSCS incorporation in CoC
• Discuss the benefits of synoptic operative reports for documentation of standards
What are Standards?

- A standard is a repeatable, harmonised, agreed and documented way of doing something.
- Standards contain technical specifications or other precise criteria designed to be used consistently as a rule, guideline, or definition. They help to make life simpler and increase the reliability and the effectiveness of many of the goods and services we use.
- Standards result from collective work by experts in a field and provide a consensus at the time when the standards are developed.
5651 women with early-stage breast cancer who received treatment for secondary metastases, 2007 to 2013, were evaluated for first recorded systemic therapy concordance with NCCN guidelines within the SEER–Medicare linked database.

18% received nonconcordant therapy—most common being:
- single-agent, human epidermal growth factor receptor 2 (HER2)–targeted therapy (36%)
- therapy mismatched with the estrogen receptor/HER2 status (11%)
- unapproved bevacizumab regimens (10%)
- adjuvant regimens in a metastatic setting (6%)

Younger age, hormone receptor-negative status, and HER2+ status were associated with nonconcordance ($P < .05$)

Guidelines and Patient Care

- Nonconcordance was associated with
  - Increased rates of emergency department visits (22%) and hospitalizations (21%)
  - $1765 higher average monthly Medicare costs

- Differences in adjusted mortality risk were noted by category of nonconcordance; single-agent, HER2-targeted therapy was associated with decreased mortality risk (hazard ratio [HR], 0.66; 95% confidence limit [CL], 0.57-0.76), and increased mortality risk was observed with unapproved bevacizumab use (HR, 1.40; 95% CL, 1.13-1.74).

- Most patients (82%) received treatment consistent with NCCN guidelines.

- Nonconcordant treatment was associated with higher health care utilization and costs, with mortality differences observed by the type of guideline deviation.

Components of Successful Guidelines

(1) Development is based on evidence, with the guideline formulated by key physicians in the group.

(2) The guidelines are disseminated to all affected health care professionals for critique.

(3) Implementation includes direct feedback on performance to physicians or general feedback on system performance.

(4) Accountability for performance according to the guidelines. This can consist of voluntary peer pressure to conform to evidence-based medicine, and it does not require a financial reward or penalty.

Guidelines: Impact on Processes, Outcomes

• Improvements in compliance with evidence-based guidelines or evidence-based medicine resulted in
  – Reduced health care costs
  – Reduced hospital length of stay and complications
  – Possibly improved outcomes
  – High level of patient satisfaction can be maintained

Smith TJ, Hillner BE. Ensuring quality cancer care by the use of clinical practice guidelines and critical pathways. 
Standards in Oncologic Surgical Care

• Focus has been on medical management and intraoperative standards are assumed
• Measurement of findings after surgery
  – 12 nodes in colon resection specimen
• Lack of defined standards for surgical resections
• Patient outcomes are dependent of the totality of treatment not each part
DO SURGICAL STANDARDS IMPACT OUTCOMES?
Selected standards:
(1) achieving an R0 resection
(2) having > 16 lymph nodes examined


Standards were met in:
– 36.5% of stage 0/I patients
– 41.8% of stage II/III patients

Predictors for meeting standards included age < 65, fewer comorbidities, Asian/Pacific Islander race, and treatment at academic and high-volume centers

Patients who met standards had longer OS
• stage 0/I: 104.9 versus 66.6 months;
• stage II/III: 40.6 versus 26.0 months; \( p < 0.001 \)

Meeting standards was a significant predictor for improved OS for both stage 0/I and II/III patients (HR = 0.665 and HR = 0.747, respectively, \( p < 0.001 \))

• National Cancer Data Base review to evaluate adherence to standards and impact on outcome

• Operative Standards Tested
  o Resection margin status $\rightarrow$ R0 = meet standards
  o Number of lymph nodes examined $\rightarrow$
    o $\geq 2$ LNs for cT1 and cT2/3, $>10$ LNs for pN2/3

• Adjuvant Therapy Standards Tested
  o Adjuvant therapy (chemotherapy, hormonal, and radiation) $\rightarrow$ any = meet standards

## Overall Adherence Rates to Standards

<table>
<thead>
<tr>
<th>Minimal Standards</th>
<th>Number of cT1 Patients (%)</th>
<th># of cT2/3 Patients (%)</th>
<th># of pN2/3 Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All</td>
<td>+/+</td>
<td>+/-</td>
</tr>
<tr>
<td>Negative Margins</td>
<td>470037</td>
<td>350383</td>
<td>48780</td>
</tr>
<tr>
<td></td>
<td>(96.8%)</td>
<td>(96.8%)</td>
<td>(96.6%)</td>
</tr>
<tr>
<td>Any Adjuvant Therapy</td>
<td>447348</td>
<td>337445</td>
<td>46412</td>
</tr>
<tr>
<td></td>
<td>(92.7%)</td>
<td>(93.9%)</td>
<td>(92.5%)</td>
</tr>
<tr>
<td>Hormonal Therapy</td>
<td>347945</td>
<td>303221</td>
<td>37846</td>
</tr>
<tr>
<td></td>
<td>(73.5%)</td>
<td>(85.8%)</td>
<td>(77.2%)</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>177840</td>
<td>102236</td>
<td>24044</td>
</tr>
<tr>
<td></td>
<td>(37.2%)</td>
<td>(28.7%)</td>
<td>(48.3%)</td>
</tr>
<tr>
<td>Radiation Therapy</td>
<td>314781</td>
<td>241133</td>
<td>31888</td>
</tr>
<tr>
<td></td>
<td>(64.5%)</td>
<td>(66.3%)</td>
<td>(62.9%)</td>
</tr>
<tr>
<td>≥2 LNs Examined</td>
<td>360316</td>
<td>268955</td>
<td>37027</td>
</tr>
<tr>
<td></td>
<td>(74.0%)</td>
<td>(74.1%)</td>
<td>(73.1%)</td>
</tr>
<tr>
<td>&gt;10 LNs Examined</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Breast Cancer cT1 cohort

- 480,140 patients → 318,853 (65.0%) met minimal standards
- 5-/10-year probability of overall survival significantly longer for those who met standards


<table>
<thead>
<tr>
<th></th>
<th>+ Standards</th>
<th>-- Standards</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-Year Overall Survival</td>
<td>0.956</td>
<td>0.943</td>
<td>&lt;0.001a</td>
</tr>
<tr>
<td>10-Year Overall Survival</td>
<td>0.880</td>
<td>0.858</td>
<td></td>
</tr>
</tbody>
</table>

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Breast Cancer cT2 cohort

- 238,934 patients → 164,593 (67.3%) met minimal standards
- 5-/10-year probability of overall survival significantly longer for those who met standards

Zhao B et al. Adherence to surgical and oncologic standards improves survival in breast cancer patients. 
Breast Cancer pN2/3 cohort

- 114,674 patients → 77,626 (67.7%) met minimal standards
- 5-/10-year probability and median overall survival significantly longer for those who met standards

Cancer Care Standards Development Committee

- Promote surgical uniformity for clinical trials
- Inform protocol standards
- Recommend evidence-based best practices in surgical oncology
- Establish surgical checklists
- Serve as gap analysis for research
Surgical Standards in Practice

• Establish and disseminate evidence based minimum operative standards
• Surveillance on adherence to surgical standards
• Elucidate reasons why standards are not met, and educate/rectify
Cancer Care Standards Development Committee

• Volume 1 published 2015
• Volume 2 published 2018
• OSCS Volume III (adrenal, hepatobiliary, peritoneal malignancies, neuroendocrine, sarcoma, urothelial) publication expected 2021
• OSCS Volume IV (pediatrics) 2021
• Breast, melanoma, rectal, colon and lung operative standards incorporated into Commission on Cancer standards
Operative Standards for Cancer Surgery

- Breaks down the major cancer operations for each disease site into critical steps.
- **Critical elements** were perceived by teams of experts and stakeholders to have the most significant influence on outcomes.
- Teams determined how each step should be performed based on a review of available literature and expert opinion.
- Teams identified **key questions** (areas of controversy) for each site related to the technical aspects of how the operations should be performed. Could be used as the basis for future clinical trials.
Endobronchial Ultrasonography/Endoscopic Ultrasonography

CRITICAL ELEMENTS

- Identification of Lymph Nodes Suspicious for Cancer Metastasis
- Node Station Assessment Utilizing Endobronchial Ultrasonography/Endoscopic Ultrasonography

1. IDENTIFICATION OF LYMPH NODES SUSPICIOUS FOR CANCER METASTASIS

**Recommendation:** The standard endobronchial ultrasonography (EBUS) classification system of the sonographic features of lymph nodes is useful to determine whether lymph nodes are malignant or benign.

**Type of Data:** Retrospective

**Strength of Recommendation:** Weak

Rationale

Round lymph nodes whose short-axis diameter is larger than 1 cm, that have distinct margins and heterogeneous echogenicity, and that have coagulation necrosis sign but not central hilar structures are suspicious for malignancy and must be biopsied (Fig. 6-1).

During EBUS-guided transbronchial needle aspiration (EBUS-TBNA) or endoscopic ultrasonography (EUS)–guided fine needle aspiration (EUS-FNA), all mediastinal and hilar lymph nodes should be assessed, characterized, and documented systematically.

Lymph nodes should be identified according to the International Association for the Study of Lung Cancer lymph node map. EBUS-TBNA and EUS-FNA should proceed from N3 nodes to N2 nodes and then to N1 nodes to prevent needle contamination and avoid accidental disease overstaging.
What is a Key Question?

Technical aspects:

Safety of the needle
Choice of anesthetic
Use of suction aspiration
Specimen handling
In patients with stage I non–small cell lung cancer, what factors determine if segmentectomy should be abandoned for lobectomy?
Sentinel Lymph Node Biopsy

• Critical Elements
  • Identification of All Sentinel Nodes
  • Technique for Injecting Localizing Tracer or Dye
  • Preincision Evaluation of Drainage Pattern
  • Node Removal Technique to Limit Seroma Formation
Pancreas Cancer

- Common bile duct
- PV (Papilla Vateri)
- Hepatic artery
- Ligated GDA
- Vein graft
- Splenic artery
- Ligated coronary vein
- Splenic vein
- SMV (Superior Mesenteric Vein)
- Ligated gastroepiploic vein
- SMA (Superior Mesenteric Artery)
- Pancreas
- SMV
- Traditional plane of dissection
- Plane of anterior RAMPS
- Adrenal gland
- Plane of posterior RAMPS
- Kidney
- Spleen
- Short gastric ve
- Panetal peritone
- Anterior renal fasci
- Posterior renal fasci

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Rates of Adherence to Standards

- Margin negative resection and any adjuvant therapy rates >90% for all groups
- Adequate number of LNs examined <80%
- For cT1 and cT2/3 groups ~25% of patients had <2 LNs examined
- For pN2/3 group ~12% of patients had <10 LNs examined

Why do we need them?

Adherence to standards improves outcomes for patients
Adherence to Standards and Survival

- Difference in OS was small in cT1 patients, but more pronounced in cT2 and pN2/3 patients
  - pN2/3 patients who met standards had median OS advantage of 36.4 months

<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>
<tr>
<td>5.4</td>
<td>Breast</td>
<td>Axillary dissection</td>
<td>Operative report</td>
</tr>
<tr>
<td>5.5</td>
<td>Melanoma</td>
<td>Wide local excision</td>
<td>Operative report</td>
</tr>
<tr>
<td>5.6</td>
<td>Colon</td>
<td>Colectomy (any)</td>
<td>Operative report</td>
</tr>
<tr>
<td>5.7</td>
<td>Rectum</td>
<td>Mid/low resection (TME)</td>
<td>Pathology report (CAP)</td>
</tr>
<tr>
<td>5.8</td>
<td>Lung</td>
<td>Lung resection (any)</td>
<td>Pathology report (CAP)</td>
</tr>
</tbody>
</table>
Why are we discussing the 2020 CoC standards?

• Potential compliance GAP with new operative standards

• Rates of compliance with the operative standards are estimated at 50-60%

• New CoC standards were introduced in 2020

• Unclear if gap is for technical or documentation component
Understanding the Gap

• Lack of clarity?
  • Purpose
  • Value
  • Supporting evidence

• Need more education about the standards?
  • Technical aspects
  • Documentation details
The ACS launched the CSSP in June 2020, recognizing growing evidence that adherence to specific operative techniques leads to:

- Improved survival
- Better surgical outcomes
- Improved quality of life

Shift from standards based in facilities/equipment to outcomes-based standards.
Synoptic Operative Reports
“There is an ulcerated tumour 4 cm in diameter arising in the anterior wall of the rectum. Grossly, the resection margins appear uninvolved. Microscopic appearance: well-differentiated adenocarcinoma, broaching the muscularis propria and extending into the subserosal fat in multiple locations. In several locations there is extensive tumour necrosis and pooled mucin. The distal resection margin is approximately 2 cm, the proximal resection margin is approximately 15 cm, the radial margin is 0.5 cm at the closest approach. Of 20 lymph nodes examined, 2 appear to be involved by adenocarcinoma.”

T stage: T3
Radial margin: 0.5 cm
Grade: Well differentiated
Distal margin: 2 cm
Nodes: 2 of 20 lymph nodes involved
Stage: pT3N1 (adjuvant therapy indicated)
5.1 College of American Pathologists Synoptic Reporting

Definition and Requirements

Ninety percent of the eligible cancer pathology reports are structured using synoptic reporting format as defined by the College of American Pathologists (CAP) cancer protocols, including containing all core data elements within the synoptic format.

The synoptic format is defined as a structured format that includes all of the following:

- All core elements must be reported (whether applicable or not)
- All core elements must be reported in a “diagnostic parameter pair” format, in other words, data element followed by its response (answer)
- Each diagnostic parameter pair must be listed on a separate line or in a tabular format to achieve visual separation (refer to CAP Cancer Protocols for exceptions to this rule)
- All core elements must be listed together in synoptic format in one location in the pathology report

Documentation

Reviewed On-Site

- The site visit reviewer reviews the standardized synoptic pathology reports for eligible patients.

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

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

Measure of Compliance

During the accreditation cycle, the cancer program fulfills the compliance criteria:

1. Ninety percent of the eligible cancer pathology reports are structured using synoptic reporting format as defined by the College of American Pathologist (CAP) cancer protocols, including containing all core data elements within the synoptic format.
## Comparison of data elements recorded between free text and synoptic reports

<table>
<thead>
<tr>
<th>Data Element Recorded</th>
<th>Free Text (n=50)</th>
<th>Synoptic Report (n=50)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relationship to the anterior peritoneal reflection</td>
<td>45 (90%)</td>
<td>50 (100%)</td>
<td>0.0218</td>
</tr>
<tr>
<td>Intactness of mesorectum</td>
<td>38 (76%)</td>
<td>50 (100%)</td>
<td>0.0002</td>
</tr>
<tr>
<td>Distance of tumor to the non-peritonealized CRM</td>
<td>38 (76%)</td>
<td>50 (100%)</td>
<td>0.0002</td>
</tr>
</tbody>
</table>

King S et al. Structed pathology reporting improves the macroscopic assessment of rectal tumour resection specimens. *Pathology* 2016;48:349-352
## Synoptic v. Narrative Reports

<table>
<thead>
<tr>
<th>Outcome or Subgroup</th>
<th># Studies</th>
<th>N</th>
<th>Statistical Method</th>
<th>Effect Estimate – Synoptic v. Narrative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inter-rater Reliability</td>
<td>4</td>
<td>943</td>
<td>Mean Difference (95% CI)</td>
<td>0.35 [0.09, 0.62]</td>
</tr>
<tr>
<td><strong>Efficiency</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to complete (min)</td>
<td>6</td>
<td>891</td>
<td>Mean Difference (95% CI)</td>
<td>-0.86 m [-1.17, -0.55]</td>
</tr>
<tr>
<td>Time to verified report in chart/EPR (hours)</td>
<td>1</td>
<td>336</td>
<td>Mean Difference</td>
<td>-373.53 h</td>
</tr>
<tr>
<td><strong>Quality</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accuracy</td>
<td>1</td>
<td>208</td>
<td>Mean Difference (95% CI)</td>
<td>40.60% [38.54, 42.66]</td>
</tr>
<tr>
<td>Critical Error (% of op notes)</td>
<td>1</td>
<td>110</td>
<td>Mean Difference</td>
<td>32.13%</td>
</tr>
<tr>
<td>Error Rate (% of op notes)</td>
<td>1</td>
<td>110</td>
<td>Mean Difference</td>
<td>75.26%</td>
</tr>
<tr>
<td>Validity</td>
<td>1</td>
<td>208</td>
<td>Mean Difference (95% CI)</td>
<td>3.40% [2.02, 4.78]</td>
</tr>
<tr>
<td>Cost ($/note)</td>
<td>2</td>
<td>72</td>
<td>Mean Difference</td>
<td>-$8.27</td>
</tr>
</tbody>
</table>

• Improve **accuracy** of documentation
• Improve **efficiency of entry**
• Improve **efficiency of data abstraction/measurement of compliance**
• **Reduce variability** in care
• Improve **quality of cancer care**
• Emphasize the “**critical elements**” of oncologic operation
Mission: To **improve the quality of care** for persons with cancer

**Goals:**

- **Educate surgeons** on key technical aspects of oncologic procedures
- **Create tools** to support implementation and adherence to the standards
- **Synoptic operative report templates**
- *Integrated documentation in EMRs*
Critical Elements

- Identification of Anatomical Structures for Level I and II Axillary Dissection
- Removal of Level III Nodes
- Removal of Rotter Nodes
- Removal of Sufficient Number of Lymph Nodes for Axillary Staging
- Identification and Preservation of the Long Thoracic, Thoracodorsal, and Medial Pectoral Nerves
- Identification and Preservation of the Second and Third Intercostobrachial Nerves
- Drain Placement
<table>
<thead>
<tr>
<th>Element</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resection was performed within the boundaries of the axillary vein, chest wall (serratus anterior), and latissimus dorsi.</td>
<td>Yes; No.</td>
</tr>
<tr>
<td>The long thoracic and thoracodorsal nerves were spared during dissection.</td>
<td>Yes; No; Not identified.</td>
</tr>
<tr>
<td>Attempts were made to spare the intercostobrachial nerves during dissection if possible.</td>
<td>Yes; No.</td>
</tr>
<tr>
<td>If one or more level III nodes is/are removed, then document why.</td>
<td>Yes; No. If yes, then why.</td>
</tr>
</tbody>
</table>
Colon Resection

• Critical Elements

  • Abdominal Exploration
  • Extent of Bowel Mobilization and Resection
  • Proximal Vascular Ligation and Regional Lymphadenectomy
  • Multivisceral Resection
  • Removal of Lymphadenopathy Beyond the Primary Distribution
### Standard 5.6 - Colon Resection

#### Synoptic Operative Report Requirements

<table>
<thead>
<tr>
<th>Element</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor location</td>
<td>Right colon; hepatic flexure; transverse colon; splenic flexure; descending colon; sigmoid colon</td>
</tr>
<tr>
<td>Extent of lymphovascular resection</td>
<td></td>
</tr>
<tr>
<td><strong>Tumor location</strong></td>
<td><strong>Proximal vascular ligation</strong></td>
</tr>
<tr>
<td>Right colon (cecum and ascending colon)</td>
<td>Ileocolic artery and vein and, if present, right colic artery and vein</td>
</tr>
<tr>
<td>Hepatic flexure</td>
<td>Ileocolic artery and vein and, if present, right colic artery and vein and middle colic artery and vein</td>
</tr>
<tr>
<td>Transverse colon</td>
<td>Middle colic artery and vein</td>
</tr>
<tr>
<td>Splenic flexure</td>
<td>Middle colic artery and vein and ascending left colic artery and vein</td>
</tr>
<tr>
<td>Descending colon</td>
<td>Inferior mesenteric artery and vein to include ascending left colic artery and vein</td>
</tr>
<tr>
<td>Sigmoid colon</td>
<td>Inferior mesenteric artery and vein</td>
</tr>
<tr>
<td>If anatomic guidance other than listed above, document why</td>
<td>If yes, why.</td>
</tr>
<tr>
<td>If patient is excluded, then document why</td>
<td>If yes, why.</td>
</tr>
</tbody>
</table>
Total Mesorectal Excision

Critical Elements

• Location of tumor
• Scope of the procedure
• Adequate resection planes for clear margins
Total Mesorectal Excision (TME)
Total Mesorectal Excision (TME)

A complete mesorectal dissection should yield:

- Intact mesorectal envelope with smooth border
- No visible defects >5mm depth
- No coning effect of the distal specimen
- No visible muscularis propria
Incomplete TME yields worse oncologic outcomes

<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>

Conclusions

• Adherence to surgical standards can improve outcomes for patients with cancer
• The *Operative Standards in Cancer Surgery* are evidence-based standards that impact survival and quality of life
• Synoptic operative reports can improve documentation of standards and allow for assessment and quality improvement
Thank you for your attention