CoC Operative Standards

5.3: Sentinel Node Biopsy for Breast Cancer

5.4: Axillary Lymph Node Dissection for Breast Cancer

November 17th, 2021

Presentation created by CSSP Education Committee
Webinar Logistics

• All participants are muted during the webinar

• Questions – including technical issues you may be experiencing – should be submitted through the question pane

• Questions will be answered as time permits

• Please complete the post-webinar evaluation you will receive via email
Moderator

Mediget Teshome, MD, FACS
Assistant Professor
Department of Breast Surgical Oncology
MD Anderson Cancer Center
Chair, CSSP Education Committee
Cancer Surgery Standards Program (CSSP)

- The ACS launched the CSSP in July 2020, recognizing growing evidence that adherence to specific operative techniques leads to:
  - Longer survival
  - Better surgical outcomes
  - Improved quality of life

- Expansion from standards focused on facilities/equipment to outcomes-based standards
# The CoC Operative Standards (2020)

<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>
Operative Standards in Breast Cancer

• National Cancer Database

• Standards Assessed
  • Resection margin status (R0 = meet standards)
  • Number of lymph nodes examined
    • ≥2 LNs for cT1 and cT2/3,
    • >10 LNs for pN2/3
  • Adjuvant therapy (chemotherapy, hormonal, and radiation)

• > 20% of patient care did not meet these standards

<table>
<thead>
<tr>
<th>Minimal Standards</th>
<th># of cT1 Patients (%)</th>
<th># of cT2/3 Patients (%)</th>
<th># of pN2/3 Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥2 LNs Examined</td>
<td>360316 (74.0%)</td>
<td>189208 (78.0%)</td>
<td>-</td>
</tr>
<tr>
<td>&gt;10 LNs Examined</td>
<td>-</td>
<td>-</td>
<td>91310 (78.3%)</td>
</tr>
</tbody>
</table>

Zhao et al JSO 2019: 120:148-159
Breast Cancer Standards and Survival

<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>0.872</td>
<td>0.745</td>
<td>&lt;0.001a</td>
</tr>
<tr>
<td>10-Year Overall Survival</td>
<td>0.718</td>
<td>0.548</td>
<td></td>
</tr>
</tbody>
</table>

Zhao et al JSO 2019: 120:148-159
Standard 5.3:

Sentinel Node Biopsy for Breast Cancer
Sentinel Lymph Node (SLN) Biopsy as an Operative Standard

• SLN Biopsy improves staging and oncologic outcomes

• Preferred axillary staging procedure over an axillary dissection in appropriate clinically node-negative patients offering decreased risk of lymphedema and operative morbidity

• Standard approach to care and likely already practiced at most institutions performing breast cancer surgery
Critical Elements Standard 5.3 Sentinel Lymph Node Biopsy

- Identification of All Sentinel Nodes
- Technique for Injecting Localizing Tracer or Dye
- Pre-incision Evaluation of Drainage Pattern
- Node Removal Technique to Limit Seroma Formation
Identification of All Sentinel Lymph Nodes Improves Staging Accuracy

- NSABP B-32
- Median SLN yield: 2
- Interquartile range: 1-4
- Identification of increased numbers of SLN is associated with decreased false negative rate

<table>
<thead>
<tr>
<th>Patients, n</th>
<th>False negative, number of patients (%)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>766</td>
<td>75 (9.8)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of specimens removed during SLN resection</th>
<th>Patients, n</th>
<th>False negative, number of patients (%)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>209</td>
<td>37 (17.7)</td>
<td>&lt;0.001‡</td>
</tr>
<tr>
<td>Two</td>
<td>210</td>
<td>21 (10.0)</td>
<td>&lt;0.0001‡</td>
</tr>
<tr>
<td>Three</td>
<td>173</td>
<td>12 (6.9)</td>
<td>..</td>
</tr>
<tr>
<td>Four</td>
<td>73</td>
<td>4 (5.5)</td>
<td>..</td>
</tr>
<tr>
<td>Five or more</td>
<td>101</td>
<td>1 (1.0)</td>
<td>..</td>
</tr>
</tbody>
</table>

Table 4: False-negative rate of SLN resection according to selected factors in patients in group 1 with positive nodes

Krag DN et al., Lancet Oncol 2007; 8: 881–88
1) All sentinel nodes for breast cancer are identified using tracers or palpation, removed, and subjected to pathologic analysis

2) Operative reports for sentinel node biopsies for breast cancer document the required elements in synoptic format
Diligent Search for Sentinel Nodes

Search to identify and remove all colored, radioactive, and/or suspicious nodes in addition to any non-colored nodes at the end of a colored lymphatic
CoC Compliance Measures: Standard 5.3

1) All sentinel nodes for breast cancer are identified using tracers or palpation, removed, and subjected to pathologic analysis.

2) Operative reports for sentinel node biopsies for breast cancer document the required elements in synoptic format.
## Standard 5.3: Synoptic Operative Report Requirements

<table>
<thead>
<tr>
<th>Element</th>
<th>Response Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation performed with curative intent</td>
<td>Yes or No</td>
</tr>
<tr>
<td>Tracer(s) used to identify sentinel nodes in the upfront surgery setting <em>(select all that apply)</em></td>
<td>Dye, Radioactive tracer, Superparamagnetic iron oxide, Other <em>(with explanation)</em>, and/or N/A</td>
</tr>
<tr>
<td>Tracer(s) used to identify sentinel nodes in the neoadjuvant setting <em>(select all that apply)</em></td>
<td>Dye, Radioactive tracer, Superparamagnetic iron oxide, Other <em>(with explanation)</em>, and/or N/A</td>
</tr>
<tr>
<td>All nodes (colored or non-colored) present at the end of a dye-filled lymphatic channel were removed</td>
<td>Yes, No <em>(with explanation)</em>, or N/A</td>
</tr>
<tr>
<td>All significantly radioactive nodes were removed</td>
<td>Yes, No <em>(with explanation)</em>, or N/A</td>
</tr>
<tr>
<td>All palpably suspicious nodes were removed</td>
<td>Yes, No <em>(with explanation)</em>, or N/A</td>
</tr>
<tr>
<td>Biopsy-proven positive nodes marked with clips prior to chemotherapy were identified and removed</td>
<td>Yes, No <em>(with explanation)</em>, or N/A</td>
</tr>
</tbody>
</table>
Case Identification Guidelines: Standard 5.3

• Programs can audit for compliance using the following steps:
  ✓ Using the Cancer Registry database - Pull cases within the scope of the standard with the following criteria:
    o Patient identifiers (MRN, Accession year [2021 and >], Class of case)
    o Surgeon identifiers (NPI, physician code, etc.)
    o Primary site (Breast, C50.0 – C50.9), histology per the Standard
    o Date of sentinel lymph node biopsy field does not equal blank
    o Sentinel lymph nodes examined = 01–90, 98
    o Scope of regional lymph node surgery codes: 2, 6, or 7
Case Identification Guidelines: Standard 5.3

- Using the EMR - Review the Operative Report to determine the following:
  - Curative or palliative intent
  - Sentinel lymph nodes were removed
  - A synoptic format is used in the operative report and includes the current required data elements and responses according to Standard 5.3

- Using the EMR - Review the Pathology Report for each case to confirm:
  - Pathologic analysis of sentinel lymph nodes that have been removed
Standard 5.4:

Axillary Lymph Node Dissection for Breast Cancer
Axillary Lymph Node Dissection (ALND) as an Operative Standard

• High quality axillary dissection improves staging and oncologic outcomes in appropriate patients

• Axillary lymphadenectomy for indicated cases is accepted as standard approach to care and is likely already the practice pattern at most institutions performing breast cancer surgery
Critical Elements Standard 5.4
Axillary Lymphadenectomy

- Identification of anatomical structures levels I/II
- Management of level III nodes
- Management of Rotter nodes
- Removal of sufficient number of nodes
- Preservation of nerves
  - Long thoracic, thoracodorsal, and others
  - 2nd/3rd intercostobrachial nerves
- Drain placement
ALND Levels I/II: Anatomic Boundaries

- Level I: 60-70% of axillary lymph nodes
- Level II: 20-30% of axillary lymph nodes
- Level I/II dissection should be complete
- Anatomic triangle
  - Axillary vein
  - Latissimus dorsi muscle
  - Chest wall (Serratus anterior muscle)

Berg et al. Cancer 1955, 8: 776
ALND: Level III Management

• Level III: < 20% of axillary lymph nodes

• Level III nodes should not routinely be removed

• Level III dissection
  • Consider if level III is clinically involved or suspicious at time of surgery for local-regional control
  • Limited data support level III dissection

ALND: Nerve Preservation

• Attempt to preserve motor and sensory nerves unless encased by tumor
  • Motor nerves
    • Thoracodorsal, long thoracic, and other
    • Injury → muscle atrophy and motor deficits
  • Sensory Nerves
    • Intercostobrachial nerves (2\textsuperscript{nd} / 3\textsuperscript{rd})
    • Injury → paresthesia and decreased quality of life

Warrier S. The Breast. 2014;23:310-316
CoC Compliance Measures: Standard 5.4

1) Axillary lymph node dissections for breast cancer include removal of level I and II lymph nodes within an anatomic triangle comprised of the axillary vein, chest wall (serratus anterior), and latissimus dorsi, with preservation of the main nerves in the axilla.

2) Operative reports for axillary lymph node dissections for breast cancer document the required elements in synoptic format.
## Standard 5.4: Synoptic Operative Report Requirements

<table>
<thead>
<tr>
<th>Element</th>
<th>Response Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation performed with curative intent</td>
<td>Yes or No</td>
</tr>
<tr>
<td>Resection was performed within the boundaries of the axillary vein, chest wall (serratus anterior), and latissimus dorsi</td>
<td>Yes or No <em>(with explanation)</em></td>
</tr>
<tr>
<td>Nerves identified and preserved during dissection <em>(select all that apply)</em></td>
<td>Long thoracic nerve, Thoracodorsal nerve, Branches of the intercostobrachial nerves, Other <em>(with explanation)</em></td>
</tr>
<tr>
<td>Level III nodes were removed</td>
<td>Yes <em>(with explanation)</em> or No</td>
</tr>
</tbody>
</table>
Case Identification Guidelines: Standard 5.4

• Programs can audit for compliance using the following steps:

✓ Using the Cancer Registry database - Pull cases within the scope of the standard with the following criteria:
  o Patient identifiers (MRN, Accession year [2021 and >], Class of case)
  o Surgeon identifiers (NPI, physician code, etc.)
  o Primary site (Breast, C50.0–C50.9), histology per the Standard
  o Date of regional lymph node dissection does not equal blank
  o Regional lymph nodes examined = 01–90, 96–98
  o Scope of regional lymph node surgery codes 3–7 from STORE
Case Identification Guidelines: Standard 5.4

✓ Using the EMR - Review the Operative Report to determine the following:
  - Curative or palliative intent
  - Axillary dissection is completed
  - A synoptic format is used in the operative report and includes the current required data elements and responses according to Standard 5.4
Best Practices to Optimize Compliance with Standards 5.3 & 5.4
Best Practices to Optimize Compliance

• Evaluate current practices (Internal Audit)
  • Identify cases
  • Evaluate for required elements
• Identify and discuss areas to improve
  • Discussion at CoC meetings
  • Audit results
  • CoC Operative Standards
• Interventions
  • System specific
• Case Example
Best Practices to Optimize Compliance: Case Study: Evaluate Current Practice

- For Profit, Community-Based Hospital System
- 2 general surgeons; 2 surgical oncologists
- Reviewed single quarter in late 2020
- 34 axillary cases identified
  - SLNB 30
  - ALND 4
Best Practices to Optimize Compliance - Case Study: Evaluate Current Practice

• Compliance rate....
Best Practices to Optimize Compliance - Case Study: Evaluate Current Practice

• Compliance rate….
Best Practices to Optimize Compliance: Case Study: Identify Areas to Improve

- None reported curative intent
- When curative intent excluded
  - SLNB 50%
  - ALND 25%

- Areas to improve
  - Narrative
  - Dictations
  - Technique
  - Documentation
  - Knowledge gaps
Best Practices to Optimize Compliance - Case Study: Interventions

- Discussion at Cancer Committee meetings, Tumor Boards
  - Internal audit results
  - Identify Stakeholders
    - Surgeons, Pathologists, Registrars, Administration, IT, etc
- CSSP
  - Operative Standards
  - Timeline (To be discussed later)
  - Value of synoptic reporting (To be discussed later)
  - Toolkit
Best Practices to Optimize Compliance: Case Study: Planned Interventions

- Education of team members (particularly surgeons)
  - CoC Operative Standards → requirements
  - Technique → required elements
  - Documentation → required elements

- Create Solutions
  - Utilizing EMR and synoptic reporting
    - Capabilities
    - Options available (To be discussed later)
    - Resources (To be discussed later)

- Create a timeline for increasing compliance
  - Active surveillance
  - Quarterly review
Synoptic Operative Reporting for Standards 5.3 & 5.4
What is the value of Synoptic Operative Reporting?

• Improve accuracy of documentation
• Improve efficiency of data entry and data abstraction
• Reinforce education (can emphasize the critical elements of oncologic operations)
• Reduce variability in care
• Overall improve quality of cancer care
Practical Applications

• TNM staging information can be missing in >50% of records.

• Within a single encounter, TNM staging may differ in different notes.

• Registrars and other staff must sort through and interpret these narratives to glean the necessary information and then manually enter the data into a registry, leading to issues with quality and cost.
## Synoptic vs. 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><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 EMR (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>Reduction Critical Error (% of op notes)</td>
<td>1</td>
<td>110</td>
<td>Mean Difference</td>
<td>32.13%</td>
</tr>
<tr>
<td>Reduction 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>

Implementation Timeline for Standards 5.3–5.6

- **2020**: Introduction of operative standards
- **2021**: Plan for implementation, educate/train surgeons & registrars
- **2022**: Document final plan for implementation and conduct audits
- **2023**: Site Visits review documentation of final plans for compliance
- **2024**: Site Visits review 2023 operative reports for 70% compliance
- **2025**: Site Visits review 2023 & 2024 operative reports for 80% compliance

**Steps to Achieve Compliance**

- Begin compliance with Standards 5.3-5.6
Current Options for Synoptic Operative Reporting

Create Your Own Basic Synoptic Templates

License Third-Party Vendor Tools

Use Fillable PDF Forms
Current Options for Synoptic Operative Reporting

Create Your Own Basic Synoptic Templates

- Use required elements and responses from the CoC 2020 Standards manual
- Can be done using smart phrases/smart tools to supplement a traditional narrative operative report
- Can be integrated into an existing smartform or synoptic report within EMR
- Reporting format must be uniform across all surgeons at the facility
Current Options for Synoptic Operative Reporting

License Third-Party Vendor Tools

- Includes all data elements and responses from comprehensive CSSP synoptic operative reporting templates, including elements required for CoC accreditation
- Fully developed tool supported by vendor
- Current vendor list available on ACS website: [Commercial Options](#)
Use Fillable PDF Forms

- Includes only the required elements and responses from the CoC 2020 Standards manual
- Downloads as blank PDF from the Standards Resource Library
- Supplements a traditional narrative operative report
- Stop-gap measure to allow programs to ensure compliance with synoptic formatting requirements
How Can Programs Optimize Compliance?

Ensure institution is utilizing **synoptic operative reports** for all breast cancer procedures.

**Document** details of SLN biopsy or axillary dissection **clearly** in operative notes.

Encourage open communication between surgeons and registrars to promote compliance.
Panel Discussion/Q&A

Lauren Postlewait, MD
Shruti Zaveri, MD, MPH
Nadine Walker, MS, CTR
Chantal Reyna, MD, FACS
Kelly Hunt, MD, FACS
# Standard 5.3: Sentinel Node Biopsy for Breast Cancer

## Operation

All nodal staging operations performed with curative intent for patients with breast cancers of epithelial origin

## Documentation

### Required elements/responses in synoptic format

- Curative intent
- Tracer(s) used
- Upfront or neoadjuvant setting
- Removal of all sentinel nodes
- Removal of all clipped nodes *(if applicable)*

## Timeline

- **2022:** Document final plan for implementation
- **2023:** Begin compliance
- **2024:** Site visits assess 2023 reports for 70% Compliance
## Commission on Cancer Operative Standards 2020

### Standard 5.4: Axillary Lymph Node Dissection for Breast Cancer

<table>
<thead>
<tr>
<th>Operation</th>
<th>Documentation</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>All axillary lymph node dissections performed with curative intent for patients with breast cancers of epithelial origin</td>
<td><strong>Required elements/responses in synoptic format</strong></td>
<td><strong>2022:</strong> Document final plan for implementation</td>
</tr>
<tr>
<td></td>
<td>• Curative intent</td>
<td><strong>2023:</strong> Begin compliance</td>
</tr>
<tr>
<td></td>
<td>• Resection boundaries</td>
<td><strong>2024:</strong> Site visits assess 2023 reports for 70% Compliance</td>
</tr>
<tr>
<td></td>
<td>• Preservation of vasculature</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Level III node removal <em>(if applicable)</em></td>
<td></td>
</tr>
</tbody>
</table>

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Operative Standards Toolkit

All resources can be found on the Operative Standards Toolkit, organized by topic.
Questions? cssp@facs.org

Resources

ACS Cancer Surgery Standards Program (CSSP)
www.facs.org/cssp

Operative Standards Toolkit

Operative Standards for Cancer Surgery (OSCS) Manuals
https://www.facs.org/quality-programs/cancer/acs-crp/oscs

Optimal Resources for Cancer Care (2020 Standards)
https://www.facs.org/quality-programs/cancer/coc/standards/2020

CoC Operative Standards
Special thanks

**Moderator:**
Mediget Teshome, MD, FACS

**Panelists:**
Kelly Hunt, MD, FACS  
Lauren Postlewait, MD  
Chantal Reyna, MD, FACS  
Nadine Walker, MS, CTR  
Shruti Zaveri, MD, MPH

**CSSP Leadership & Staff:**
CSSP Chair: Matthew H.G. Katz, MD FACS  
CSSP Vice-Chair: Kelly K. Hunt, MD, FACS  
CSSP Senior Manager: Amanda Francescatti, MS  
CSSP Administrator: Linda Zheng

**CoC Leadership:**
CoC Chair: Timothy W. Mullett, MD, FACS

**CSSP Education Committee**

**ACS Cancer Programs Staff:**
Heidi Nelson, MD, FACS: Medical Director, Cancer Programs  
Asa Carter: Senior Manager, Education & Training  
Chantel Ellis: Administrator, Education & Training  
Andrea Scrementi: Meetings and Events Administrator

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