


# Operative Standards Protocols: Why Are They Important?

Tina J Hieken MD FACS, Vice Chair, ACS Cancer Programs Cancer Surgery Standards Program  
Professor of Surgery  
Mayo Clinic  
Rochester, MN USA



1

---

---

---

---

---

---

---

---

## Disclosures

Unrelated research funding:

- Genentech, SkylineDX BV

2

---

---

---

---

---

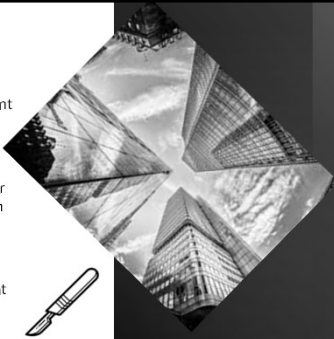
---

---

---

## Oncology Standards

- Focus has been on medical management and institutional care processes
- Operative standards are assumed (although highly variable)
- Measurement of outcome metrics after surgery (e.g. number of lymph nodes in a resection specimen)
- Prior lack of defined **standards** for the actual **cancer operation**
- Typically, surgery is the only component of care that can be curative!



3

---

---

---

---

---

---

---

---

### Operative Standards for Cancer Surgery Manuals



- Describe critical steps of the major cancer operations for key disease sites
- Promote surgical uniformity for clinical trials (and pt care)
- Highlight evidence-based best practices in surgical oncology
- Establish surgical checklists
- Gap analysis for future research
- Inform protocol standards

4

---

---

---

---

---

---

---

---

---

---

### Critical Elements

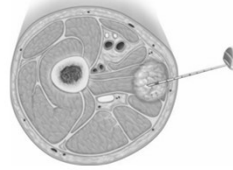
Critical steps defined by experts and stakeholders to have the most significant influence on patient outcomes

#### PRETREATMENT BIOPSY OF SOFT TISSUE MASSES OF THE EXTREMITY AND TRUNK

**Recommendation:** Pathologic subtyping of soft tissue masses suspicious for sarcoma of the extremity and trunk should be performed to facilitate planning of appropriate multimodality therapy. Histologic sampling of the tumor should generally be obtained via core needle biopsy, but an incisional biopsy should be obtained if adequate tissue cannot be acquired safely in this manner. *The biopsy tract and incision should be oriented so that the entire tract (including scar, if applicable) can be excised en bloc with the tumor at the time of definitive resection.*

**Type of data:** Retrospective reports, case series, or case control studies

**Strength of recommendation:** Strong recommendation, moderate-quality evidence



5

---

---

---

---

---

---

---

---

---

---

### Impact of Standards on Outcomes in Oncology

• Improvements in compliance with evidence-based guidelines may

- ✓ Reduce health care costs
- ✓ Reduce hospital length of stay and complications
- ✓ Improve long-term outcomes
- ✓ Increase patient satisfaction

Smith TJ, Hillner BE. Ensuring quality cancer care by the use of clinical practice guidelines and critical pathways. *J Clin Oncol* 2001 Jun 1;19(11):2886-97

6

---

---

---

---

---

---

---

---

---

---

### Adherence to standards improves survival in breast cancer

- Standards Assessed (NCDB review)
  - 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
- OS > with standards-concordant care

	pN2/3		
	Standards+	Standards-	p-Value
5-Year Overall Survival	0.696	0.567	<0.001*
10-Year Overall Survival	0.469	0.347	
Median Overall Survival	109 mos	73 mos	

Zhao et al JSO 2019: 120:148-159

7

---

---

---

---

---

---


---

---

---

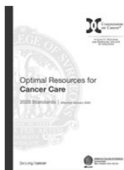
---

### Evidence-Based Standards in Clinical Practice



CoC Accreditation Committee Work Groups + Disease Site Experts from the OSCS Manuals translated 6 critical elements into 6 CoC Surgical Standards

- 2018 – Draft
- 2019 – Public Commentary + Revision
- 2020 – Focus Groups (identified need for education on synoptic reporting)



8

---

---

---

---

---


---







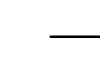
---

---

---

---



- Cancer Surgery Standards Program launched in 2020 to support implementation of operative standards (including the CoC standards)
- Cancer Surgery Protocols developed for education & documentation

9

---

---

---

---

---

---

---

---

---

---

**Cancer Surgery Standards Program**

- **Mission**
  - To improve the quality of surgical care for persons with cancer
- **Goals**
  - Develop standards for the technical conduct of oncologic surgery
  - Disseminate resources and tools that support implementation of and adherence to those standards
  - Improve communication regarding cancer surgery to facilitate appropriate (downstream) multidisciplinary care
  - Educate and train surgeons, trainees, staff

AFO

---

---

---

---

---

---

---

---

10

**Narrative versus Synoptic Reporting**

<p><b>Narrative</b></p> <ul style="list-style-type: none"> <li>• May be constructed using pre-determined data fields and pre-determined responses</li> <li>• Constructed by dictation, free text, smart text, etc.</li> <li>• May use standardized terminology</li> <li>• Presented in a <b>prose</b> format</li> <li>• Prone to <b>omission</b> of necessary data and <b>inconsistencies</b> in language and formatting</li> <li>• May allow for discrete data capture</li> </ul>	<p><b>Synoptic</b></p> <ul style="list-style-type: none"> <li>• <b>Always</b> constructed using pre-determined data fields and pre-determined responses</li> <li>• Typically created using a <b>tool</b></li> <li>• <b>Always</b> uses standardized terminology</li> <li>• Presented in <b>checklist</b> format</li> <li>• <b>Always</b> allows for discrete data capture           <ul style="list-style-type: none"> <li>• Information is formatted so it can be collected, stored, and is easily retrievable for data repositories and analysis</li> <li>• Can automatically populate data from the EHR</li> </ul> </li> </ul>
--	---

Hieken et al., Technical Standards for Cancer Surgery: Improving Patient Care through Synoptic Operative Reporting. Ann Surg Oncol 2022.  
Hieken et al., Surgeons Adding Value – Are Synoptic Operative Reports a Step Forward in Cancer Care? Ann Surg Oncol 2022.

---

---

---

---

---

---

---

---

11

**Advantages of Synoptic Reports**

- Improve **accuracy** of documentation
- Improve **efficiency of entry**
- Improve **efficiency of data abstraction/measurement of compliance**
- Reinforce education: for example, can emphasize the **“critical elements”** of oncologic operations
- **Reduce variability** in care
- Improve **quality of cancer care**

---

---

---

---

---

---

---

---

12

## Slide 10

---

**AF0** We updated the goals recently so I added our new goals. Here is what you had:

Develop evidence-based standards for the technical conduct of oncologic surgery (review and updated as needed)

Create and disseminate tools that support implementation and adherence to standards, including synoptic operative report templates and (electronic) protocols for cancer surgery

Educate surgeons on best practices for the technical conduct of oncologic surgery

Amanda Francescatti, 2024-02-20T14:32:56.017

**Operative Standards Evolution**

The diagram illustrates the evolution of operative standards. On the left, there is a book titled "OPERATIVE STANDARDS FOR Cancer Surgery" (Volume 7: Breast, Lung, Pancreas, Colon) published by Wolters Kluwer. In the middle, there is a document titled "Optimal Resources for Cancer Care" from the College of Surgeons, dated 2020. An arrow points to the right, where a digital platform titled "Synoptic Operative Report + Knowledge Platform" is shown, specifically for "Primary Colon Cancer" with the protocol for cancer surgery documentation from ACS/CSPP.

13

---

---

---

---

---

---

---

---

---

---

**The CoC Operative Standards**

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)

14

---

---

---

---

---

---

---

---

---

---

**CoC Standard 5.5 - Wide Local Excision Melanoma**

The diagram shows a cross-section of skin with a melanoma lesion. A wide local excision is performed, removing the lesion and a margin of normal skin. A ruler is shown measuring the width of the excision. A microscope is used to examine the margins. The diagram illustrates the removal of the lesion and the surrounding skin, and the measurement of the excision width.

Element	Response Options
Operation performed with curative intent	Yes; No.
Original Breslow thickness of the lesion	Melanoma in situ (MIS); ... mm (to the tenth of a millimeter).
Clinical margin width (measured from the edge of the lesion or the prior excision scar)	0.5 cm; 1 cm; 2 cm; Other: ... cm due to cosmetic/anatomic concerns. Other (with explanation).
Depth of excision	Full-thickness skin/ subcutaneous tissue down to fascia (melanoma); Only skin and superficial subcutaneous fat (melanoma in situ); Other (with explanation).

15

---

---

---

---

---

---

---

---

---

---

### Slide 13

---

**AF0** Maybe here you could say that the protocols are undergoing a revamp and will include the evidence and synoptic reports?

Amanda Francescatti, 2024-02-20T16:39:36.552

### Slide 15

---

**AF0** These pictures came from the RAS webinar slides. We could instead use the image from the OSCS manual but I like how it shows the progression.

Amanda Francescatti, 2024-02-20T16:04:19.731

### CoC Standard 5.5 - Wide Local Excision Melanoma

**Measures of Compliance**

① Wide local excisions for melanoma include the skin and all underlying subcutaneous tissue down to the fascia (for invasive melanoma) or the skin and the superficial subcutaneous fat (for in situ disease). Clinical margin width is selected based on original Breslow thickness:

- 1 cm for invasive melanomas less than 1 mm thick.
- 1 to 2 cm for invasive melanomas 1 to 2 mm thick.
- 2 cm for invasive melanomas greater than 2 mm thick.
- At least 5 mm for melanoma in situ.

② Operative reports for wide local excisions of primary cutaneous melanomas document the required elements in synoptic format.

*If both requirements are met, the case is compliant.*

Element	Response Options
Operation performed with curative intent	Yes; No.
Original Breslow thickness of the lesion	Melanoma in situ (MIS); ... mm (to the tenth of a millimeter).
Clinical margin width (measured from the edge of the lesion or the prior excision scar)	0.5 cm; 1 cm; 2 cm; Other: ... cm due to cosmetic/anatomic concerns; Other (with explanation).
Depth of excision	Full-thickness skin/ subcutaneous tissue down to fascia (melanoma); Only skin and superficial subcutaneous fat (melanoma in situ); Other (with explanation).

---

---

---

---

---

---

---

---

---

---

16

### Synoptic Operative Reporting

- 4 EMR-integrated SORs allowing for data sharing across groups, automated data abstraction, and improved quality
- 3 Universal implementation of structured SORs
- 2 Comprehensive set of SOR content developed covering all disease sites represented in surgical oncology
- 1 First phase of synoptic operative report (SOR) development and implementation via local or third-party vendor solutions

---

---

---

---

---

---

---

---

---

---

17

RF0

### Key Takeaways

- Compliance with surgical standards for cancer operations can improve outcomes for patients with cancer
- Synoptic reporting can document adherence to standards
- Synoptic reporting can improve communication across the multidisciplinary team
- Iterative process

---

---

---

---

---

---

---

---

---

---

18



## Slide 18

---

**AFO** Not sure about these... I'm sure you have other/better ideas!!!  
Amanda Francescatti, 2024-02-20T16:40:40.477

**Thank you**

Do not add a question slide  
Questions will be addressed during the Q and A period  
at the end of the session.

---

---

---

---

---

---

---

---