

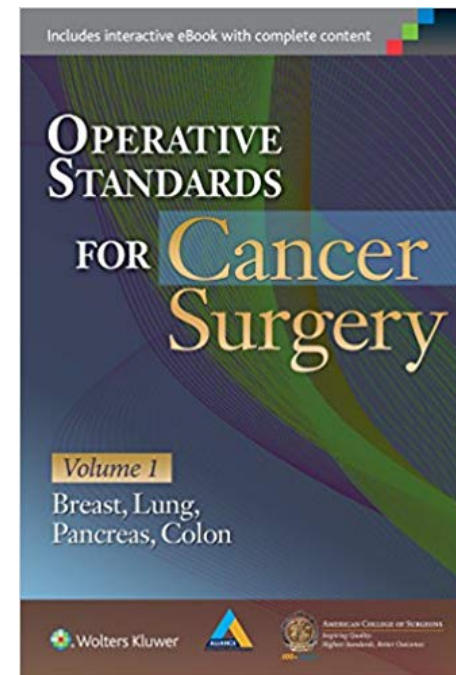


Performance and Reporting Variability in Technical Standards for Breast Cancer Operations

Sirivan Seng, MD, Jenny Chang, BA, June Yoo, BA, Sara Grossi, MD, Zachary Tran, MD, Lucyna Kryzwon, MD, Sasha Swensen, BS, Eric van Baarsel, BS, Jacqueline Chen, BA, EunJee Lee, BS, Ana Jacinto, BS, Ross Mudgway, BS and Sharon Lum, MD
Department of Surgery, Division of Surgical Oncology, Loma Linda University School of Medicine, Loma Linda, CA

INTRODUCTION

- The American College of Surgeons and the Alliance for Clinical Trials in Oncology published two volumes on The Operative Standards for Cancer Surgery in 2015 and 2018, which outline technical aspects of oncologic operations considered essential for optimal and quality surgeries.
- Standards addressing documentation of critical steps described in these manuals are currently being incorporated by the Commission on Cancer (CoC) in their revised standards for cancer center accreditation with implementation anticipated by 2020.

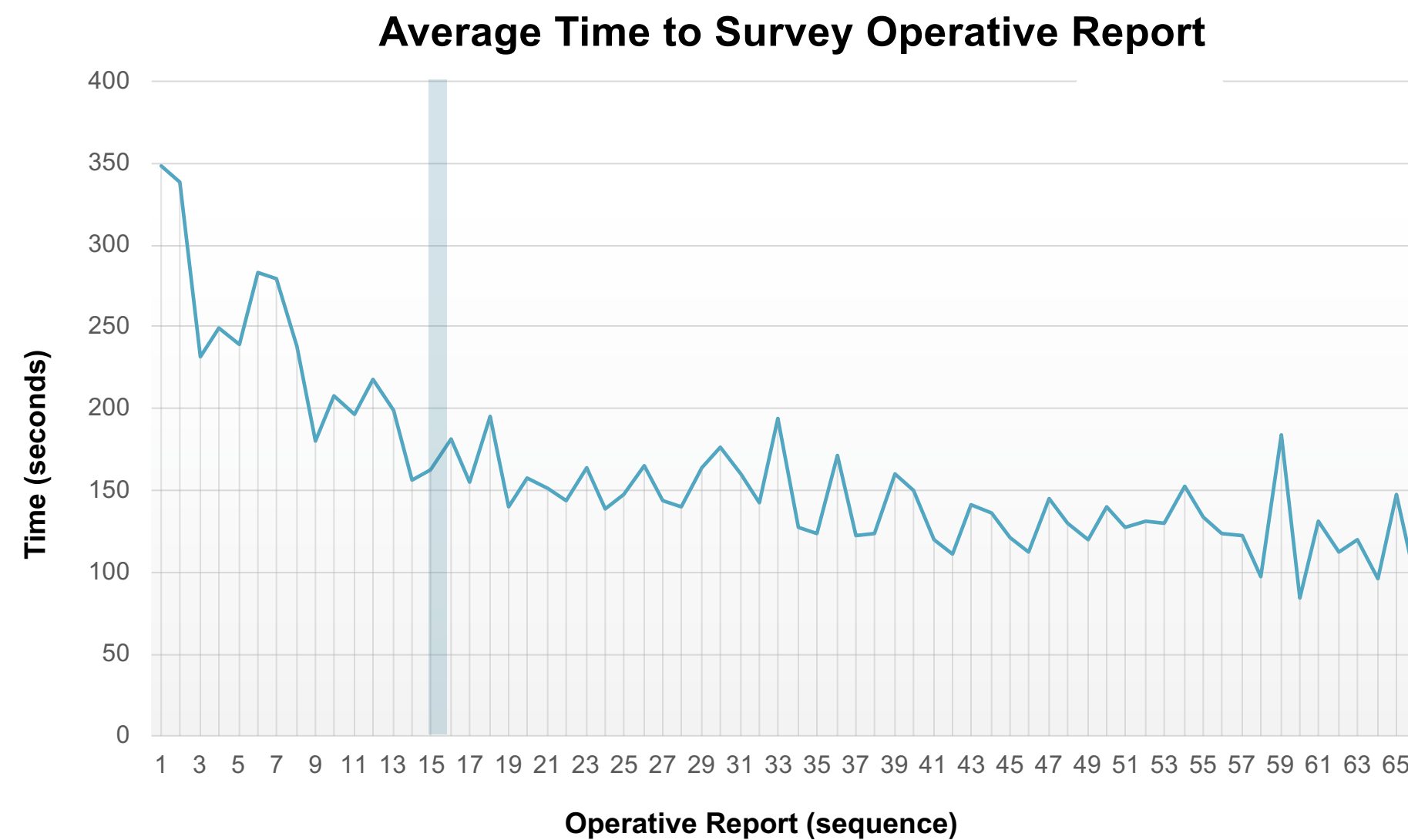


Oncologic Elements of Operative Record – Breast

Clinical Staging				
Operative Intent	Primary excision	Re-excision	Prophylactic	
Procedure Summary				
Partial Mastectomy				
Method of localization	Needle	Radioactive seed	Ultrasonography	Palpation
Skin excision with specimen	Yes	No		
Depth of resection	___ cm to fascia	Fascia resected		
Margin status checked with pathologist	Yes	No		
Margin status if checked	Positive	Negative		
Specimen radiography	Yes	No		
Clip detected	Yes	No		
Sentinel Lymph Node Biopsy				
Tracer	Radioactive tracer	Blue dye	Dual tracer	
Nodes palpable	Yes	No		
Radioactive counts of node	___			
Background counts	___			
Intraoperative assessment	None	Frozen section	Imprint cytology	

METHODS

- The objective of this study was to assess the current status of documentation of essential elements in operative reports for breast cancer surgery.
- Operative reports for partial mastectomy (PM) with sentinel lymph node biopsy (SLNB) performed at Loma Linda University Medical Center, a CoC accredited institution, from January 2013 to May 2018 were analyzed.
- Reviewers assessed operative record compliance with the Operative Standards list of Oncologic Elements of Operative Record - Breast. The non-redundant Mastery of Breast Surgery (MBS) intra-operative quality measure was evaluated for comparison.
- Each reviewer was provided with a training module, which included a sample operative record, to simulate basic training of surveyors.



Operative Standards for Cancer Surgery: Breast – Partial Mastectomy

n = 660	Average % Reported	% Reported Range	% Overall Agreement	kappa (95% CI) ¹
Operative Intent	97.4%	77.3-100.0 ²	87.5%	0.84 (0.79, 0.89)
Method of Localization	86.8%	81.8-95.5 ³	71.3%	0.67 (0.60, 0.75)
Skin Excised Along with the Specimen	29.6%	3.0-75.8 ²	62.4%	0.53 (0.47, 0.59)
Depth of Resection	13.8%	3.0-30.3 ²	81.1%	0.75 (0.68, 0.81)
Margins Checked with a Pathologist	25.0%	1.5-66.7 ²	64.9%	0.53 (0.47, 0.59)
Margin Status if Checked	7.4%	1.5-10.6 ²	86.3%	0.82 (0.76, 0.87)
Radiography Used	73.8%	68.2-80.3 ³	84.0%	0.80 (0.75, 0.85)
Clip Detection Upon Removal	48.4%	19.7-84.9 ²	61.9%	0.49 (0.43, 0.55)

Operative Standards for Cancer Surgery: Breast – Sentinel Lymph Node Biopsy

n = 660	Average % Reported	% Reported Range	% Overall Agreement	kappa (95% CI) ¹
Tracer Used	97.1%	90.9-100.0 ³	96.0%	0.95 (0.92, 0.98)
Type of Tracer	97.3%	90.0-100.0 ³	34.2%	0.23 (0.21, 0.26)
Radioactive Counts	15.0%	0-80.3 ²	77.5%	0.76 (0.72, 0.81)
Background Counts	4.6%	0-15.2 ²	92.5%	0.92 (0.88, 0.97)
Intraoperative Assessment	30.6%	3.0-75.8 ²	54.3%	0.43 (0.36, 0.50)

Mastery of Breast Surgery

n = 660	Average % Reported	% Reported Range	% Overall Agreement	kappa (95% CI) ¹
Specimen Orientation	87.0%	74.2-95.5 ³	87.9%	0.84 (0.79, 0.89)

Critical elements and specimen orientation were compared by Pearson's Chi-squared analysis. Interrater reliability was assessed by Randolph's free-marginal multirater kappa.
¹Randolph's free-marginal multirater kappa
²Pearson's Chi-squared for range p<0.01
³Pearson's Chi-squared for range p<NS

Patient Demographics

Race/Ethnicity	N = 66	Overall %
Non-Hispanic White	46	69.7%
Non-Hispanic Black	5	7.6%
Hispanic	11	16.7%
Asian/Pacific Islander	4	6.1%

Pathologic Characteristics

		N = 66	Overall %
Tumor	pT _{is}	3	4.5%
	pT ₁	44	66.7%
	pT ₂	14	21.2%
	pT ₃	1	1.5%
	pT ₄	1	1.5%
Node	pN ₀	49	74.2%
	pN ₁	16	24.2%
	pN _x	1	1.5%

Histologic Characteristics

		N = 66	Overall %
Ductal Carcinoma in situ	3	4.5%	
Invasive Ductal Carcinoma	57	86.3%	
Invasive Lobular Carcinoma	6	9.1%	

Biomarker Status

		N = 66	Overall %
ER	Negative	9	13.6%
	Positive	53	80.3%
	Not Available	4	6.1%
PR	Negative	13	19.7%
	Positive	49	74.2%
	Not Available	4	6.1%
HER-2	Negative	48	72.7%
	Positive	10	15.2%
	Not Available	8	12.1%

RESULTS

- During the study period, 66 cases of PM with SLNB had complete operative reports available for review in electronic format. A total of five attending physicians performed operations with one surgeon performing 50% of cases.
- Operative reports were completed by the attending surgeon in 63.6% of cases and resident in 36.5%. Ten reviewers (ranging in experience from third year general surgery clerkship medical students to third post-graduate year general surgery residents) evaluated all 66 cases for 14 critical elements (13 Oncologic Elements of PM and SLNB and one MBS measure).
- No operative records were identified where all critical elements were reported for PM with SLNB or for PM alone. Two operative reports were identified where all critical elements were reported for SLNB.
- The average time required to survey the operative report was 2 minutes (min) 41 seconds (sec). After the first 15 cases, the average survey time per case decreased from 3 min 55 sec to 2 min 19 sec (p<0.0001).
- Combined reporting performance and interrater reliability were variable across elements, and were highest for reported use of SLNB tracer (97.1% and κ= 0.95, respectively) and lowest for inclusion of intraoperative assessment of SLNB (30.6%, κ=0.43).
- MBS specimen orientation had both high proportion reported (87%) and interrater reliability (κ=0.84).

CONCLUSIONS

- Limitations included selection bias inherent to retrospective studies along with variation in educational backgrounds of observers.
- Adherence to essential elements of breast cancer operations listed in the Operative Standards manual was found to be variably reported by surgeons performing PM with SLNB in the current study.
- Regardless of whether differential compliance in reporting is tied to discrepancies in surgeon documentation or reviewer abstraction of critical elements, clarification of synoptic choices may help to improve reporting consistency.
- Rapidly evolving standards in technique or technology will require continuous appraisal of any mandated reporting elements for breast cancer surgery.

REFERENCES

- Katz, M. Operative Standards for Cancer Surgery: Volume I: Breast, Lung, Pancreas, Colon. 2015.
- Katz, M. Operative Standards for Cancer Surgery: Volume II: Esophagus, Melanoma, Rectum, Stomach, Thyroid. 2018.