Allina Health
VIRGINIA PIPER CANCER INSTITUTE

Oncology Clinical Service Line
System-wide Consensus Guidelines: **Evaluation and Management of Breast Lumpectomy and Mastectomy Specimens by Surgeons and Pathologists**

These guidelines apply to clinical interventions that have well-documented outcomes, but whose outcomes are not clearly desirable for all patients

Reference #: SYS-PC-OCSL-CG-012

Origination Date: April 2012
Next Review Date:
Effective Date:
Approved Dates:
Approval By:

System-wide Ownership Group: Allina Health Breast Program Committee

System-wide Information Resource: Manager of Clinical Programs

Hospital Division Quality Council: August 2018

Stakeholder Groups
Virginia Piper Cancer Institute

SCOPE:

Sites, Facilities, Business Units	**Departments, Divisions, Operational Areas**	**People applicable to**
Abbott Northwestern Hospital, Buffalo Hospital, Cambridge Medical Center, District One Hospital, Mercy Hospital, Mercy Hospital – Unity Campus, New Ulm Medical Center, River Falls Area	Breast Surgeons, Pathology, Operating Room Staff, Radiologists	Physicians, Advanced Practice providers

Hospital, Regina Hospital, St. Francis Medical Center, United Hospital		

PICO (TS) Framework

Population: Breast cancer patients undergoing lumpectomy or mastectomy cancer surgeries.

Intervention: Appropriate handling of surgically removed breast specimens, by surgeons and pathologists.

Comparison: N/A

Outcomes:

1. Surgeons will orient all lumpectomy cancer specimens with intraoperative inks, and orientate mastectomy specimens with a stitch at 12 o'clock
2. All new surgeons practicing at Allina Health will be given Allina Breast Program Committee guidelines, and will be expected to adhere to breast orientation and handling procedures.
   All breast specimens will be appropriately handled by pathologists and surgeons, according to ASCO/CAP guidelines (in terms of cold ischemic and specimen processing times).

Timing: During and following all breast surgeries

Setting: Inpatient/hospital

CLINICAL PRACTICE GUIDELINES:

1. The surgeon will orient the lumpectomy margins using the standard inking scheme (see below). The inks will be secured using acetic acid or vinegar.

a. Surgeon / OR staff must record time specimen removed from patient on requisition slip.

2. The surgeon will orient mastectomy specimens with a stitch at 12 o'clock.

a. Surgeon / OR staff must record time specimen removed from patient on requisition slip

3. Specimens will be sent immediately to pathology for evaluation of margins (for known cancers) and for handling of specimens according to ASCO/CAP guidelines (see below). If pathologist is unavailable at surgical site, see #5 below.

4. Pathologist will grossly assess margin status of known cancers. Frozen sections may be obtained at pathologist's and surgeon's discretion. Pathologists will report to surgeons any close margins requiring immediate re-excision.

a. Pathologist will record time specimen placed into formalin on requisition slip.

- **5. If pathologist is not available at surgery site**, surgeon must bisect specimen through tumor after securing inks on specimen (surgeon must ink all margins on lumpectomy specimens, and anterior and posterior margins of mastectomy prior to sectioning), and place specimen into 10% neutral buffered formalin (specimen must be placed in 10 fold greater amount of formalin than volume of specimen).

a. Surgeon / OR staff must record time specimen placed into formalin on requisition slip.

6. ASCO/CAP recommendations apply to all surgical breast specimens, including benign and malignant breast tissues, since it may be not known at the time of surgery if an excision of breast tissue harbors a previously unknown breast cancer (exception: reduction mastectomy specimens).

Procedure for inking lumpectomy specimens:

1. Dry specimen with gauze
2. Apply inks as follows*:
   Anterior – Orange
   Posterior – Black
   Medial – Green
   Lateral – Yellow
   Superior – Blue
   Inferior – Red
3. Seal ink with white vinegar (apply with squirt bottle to all surfaces) and blot dry. Make certain ink is completely dry before sectioning.
4. Section through tumor and place in adequate formalin to fix specimen (10% neutral buffered formalin, 10 fold greater amount of formalin than volume of specimen).
5. Specimen must be sectioned and placed in formalin within 1 hour of removal from patient.
6. Surgeon / OR staff is responsible for providing times when specimen was removed from patient and placed into formalin on accession slip or in Epic.

Procedure for inking mastectomy specimens

1. Dry specimen with gauze
2. Apply inks as follows:
   Deep **-** black
   Anterior superior - blue
   Anterior inferior - red

3. Seal ink with white vinegar (apply with squirt bottle to all surfaces) and blot dry. Make certain ink is completely dry before sectioning.
4. Section through tumor (from posterior aspect), and place in adequate formalin to fix specimen (10% neutral buffered formalin, 10 fold greater amount of formalin than volume of specimen).
5. Gauze should be placed between sections of breast mastectomy specimens to allow for adequate formalin infiltration into tissue and fixation.
6. Specimen must be sectioned and placed in formalin within 1 hour of removal from patient.
7. Surgeon / OR staff is responsible for providing times when specimen was removed from patient and placed into formalin on accession slip or in Epic.

* In some cases, single-use sterile inks may be used, which advocate a different inking scheme. Use of these inks is acceptable, providing that the surgeon / OR staff records the inking scheme on the surgical pathology requisition slip (a sticker denoting the inking scheme is included in these kits, and should be directly placed on the requisition slip).

SUPPORTING EVIDENCE:

The College of American Pathologists (CAP) and the American Society of Clinical Oncology (ASCO) issued a joint updated guideline in 2013 (to the 2010 guideline (2)) aimed at improving the accuracy of immunohistochemistry (IHC) testing for the expression status of hormone receptors (estrogen (ER) and progesterone receptors (PgR) and the IHC or fluorescent in situ hybridization (FISH) of HER2 in breast cancers (1). This is result of scientific studies that have demonstrated inaccurate hormone receptor analysis and HER2 evaluation due to variances in handling of breast tissue. Studies have shown that pre-analytic variables such as cold ischemic time (time following when specimen is removed from patient until specimen is placed into formalin) and inadequate formalin fixation of tissue results in degradation of cells resulting in inability to test for certain biomarkers which are used to identify tumors for which targeted breast cancer therapies. Based on these guidelines, **breast tissue must be sectioned and placed into 10% neutral buffered formalin (NBF) within 1 hour of removal from patient. And, the tissue must be fixed in formalin for a minimum of 6 hours, not to exceed 72 hours.**

Intra-operative and pathologic examination of breast specimens has been standardized for Allina Hospitals & Clinics that are served by Hospital Pathology Associates (HPA). These include orientation of lumpectomy specimens by the surgeon intra-operatively by using a standardized multi-colored inking scheme (blue=superior, red=inferior, green=medial, yellow=lateral, orange=anterior, black=deep), and orientation of mastectomy specimens by the surgeon with a stitch at 12 o'clock. In some cases, single-use sterile inks may be used, which advocate a different inking scheme*. Use of these

inks is acceptable, providing that the surgeon / OR staff records the inking scheme on the surgical pathology requisition slip (a sticker denoting the inking scheme is included in these kits, and should be directly placed on the requisition slip). Precise orientation of breast specimens allows for accurate assessment of margin status, which is crucial in determining if further excision is needed.

A standardized protocol developed by HPA for sectioning the lumpectomy and mastectomy specimens for gross assessment of margins is utilized on all specimens. Specimens are cut at approximately 0.5 cm sections along the long axis of the specimen. Sectioning of specimens at 0.5 cm intervals allows for adequate fixation of the tissue, decreasing the degradation of important biomarkers.

Following gross evaluation, the specimens are placed in 10% neutral buffered formalin within 60 minutes from removal from the patient, and are fixed in formalin for a minimum of 6 hours, not to exceed 72 hours, according to American Society of Clinical Oncology (ASCO) and College of American Pathology (CAP) guidelines.

ADDENDUM:

Associated Metrics:

% lumpectomy, mastectomy cancer specimens inked by surgeon.

Who will be measured for guideline adherence?

- Surgeons at all sites performing breast surgeries

What will be measured?

- % of breast specimens handled appropriately according to ASCO/CAP guidelines.
- % of lumpectomy cancer specimens inked intraoperatively by surgeon (measure as needed, most likely with new surgeons)
- % of mastectomy specimens oriented by a suture at 12 o'clock (measure as needed, most likely with new surgeons)

Where is the data located?

- The breast handling information is available in the breast biomarker synoptic reports.
- The lumpectomy inking information can be obtained from pathology reports.
- The mastectomy orientation information will have to be obtained from reading pathology reports.

How will adherence be monitored?

- Monitored by Breast Program Committee

When will adherence data be collected?

- TBD by availability of data

REFERENCES:

1. Wolff AC, Hammond EH et al: Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Update. J Clin Oncol November 1, 2013 vol. 31 no. 31 3997-4013

2. Hammond E et al: American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for Immunohistochemical Testing of Estrogen and Progesterone Receptors in Breast Cancer. *Arch Pathol Lab Med* 2010; 134:e48–e72.

3. Goldhirsch A et al: Thresholds for therapies: highlights of the St Gallen International Expert Consensus on the Primary Therapy of Early Breast Cancer 2009. *Ann Oncol* 2009; 20:1319-1329.

4. Goldstein, NS. Standardized predictive receptor immunohistochemical assays: the view forward from our past. *Am J Clin Pathol* 2010; 133:681-83.

5. Hicks D, Tubbs RR: Assessment of the HER2 status in breast cancer by fluorescence in situ hybridization: a technical review with interpretive guidelines. *Hum Pathol* 2005; 36(3):250-61.

6. Hammond ME et al:American Society of Clinical Oncology/College of American Pathologists guideline recommendations for immunohistochemical testing of estrogen and progesterone receptors in breast cancer*. J Clin Oncol* 28*:*2784–2795*.*

7. Nkoy FL et al: Variable specimen handling affects hormone receptor test results in women with breast cancer: A large multihospital retrospective study. *Arch Path Lab Med* 134*:*606–612*.*

Alternate Search Terms:

Related Guidelines/Documents

Name	Content ID	Business Unit where Originated