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# Survey on Imaging Management and Handling of Breast Surgical Specimens by Radiologists

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**Purpose:** Imaging management of surgically removed breast biopsy specimens is a common, perhaps daily, procedure for radiologists and breast imagers. At many institutions throughout the United States, excised specimens are radiographically analyzed for verification of lesion removal. However, the exact process by which this is performed differs substantially among institutions, with wide variability of practice and lack of a uniform protocol.

**Methods:** An anonymous survey consisting of 13 multiple-choice questions was sent to 2,428 members of the Society of Breast Imaging. Results were subsequently categorized and tabulated in the Henry Ford Hospital Department of Biostatistics.

**Results:** There was a total of 354 responses to the survey, for a response rate of 14.6% (354 of 2,428). A clear majority of respondents (85%) reported the presence of department-wide standards for excisional (surgical) biopsy specimen processing. In 31% of cases, specimens were transferred two or more times between separate containers. This resulted in an increased concern for spills and leakage of biohazardous materials for 17% of the surveyed population. In addition, increased concern for sharps, or "needlestick" injuries, was also reported.

**Conclusions:** There exist within many breast imaging departments standardized methods for processing breast biopsy specimens arriving from the operating room. However, the protocols and methods of analysis differ substantially from institution to institution. These survey results demonstrate a clear desire among radiologists for a more widespread, uniform standard, taking into account the accuracy of the procedure, cost, and the health and safety of staff members within the department.

Key Words: Wire localization, mammography specimen, breast imaging survey, excisional biopsy

J Am Coll Radiol 2014; =: =- E. Copyright © 2014 American College of Radiology

### INTRODUCTION

It is estimated that >1.6 million surgical breast biopsies are performed in the United States each year. A large number of these operations involve wire localization followed by surgical excision of abnormal breast tissue for a suspicious lesion identified on preoperative imaging workup. Although the actual surgical operation may be relatively standardized, one of the most variable aspects of the entire procedure seems to be the protocol with which removed breast tissue is managed, in transit from the operating room, through radiology, to pathology for final histologic analysis.

At many institutions, surgically excised specimens are analyzed in the mammography suite by obtaining detailed specimen radiographs to determine whether the area of concern is included within the excised tissue sample. Some imaging examinations are performed to also identify clips and radiopaque markers in the tissue or to assist with margin analysis in cases of diagnosed or suspected malignancy. In some departments, radiographs are obtained with this tissue placed on a dedicated localization device, composed of an alphanumeric grid system to help pinpoint the location of the suspicious lesion. In other departments, specimen x-rays are not obtained at all or are obtained without using a grid-type device.

In addition to radiographs of the tissue specimen, some institutions that use grids for specimen x-ray further localize lesions by inserting a needle or wire through the coordinates identified on the specimen radiograph. This procedure helps maximize lesion localization for the pathologist, focusing the sectioning of tissue and helping ensure microscopic analysis of the exact area of interest.

Although some authors have raised questions regarding the necessity of specimen imaging [1], this procedure is widespread and remains common in breast imaging

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departments. At most institutions, some form of specimen radiography is required under published standards of care for the evaluation of surgically excised ductal carcinoma in situ as well as invasive breast carcinoma [2,3].

Of perhaps greater concern than the performance of specimen radiography is the issue of how such imaging is performed and the protocols used to ensure accurate diagnosis while reducing inherent risks of the procedure. In current practice throughout the country, there seems to be significant variability in how breast tissue specimens are handled. Some institutions use generic plastic containers or bags to transport and image excised tissue samples. Other departments prefer to use one of several commercially available products to manage transport and imaging of tissue [4]. There also seem to be differences in how often tissue samples are transferred from one container to another as they are processed through the various departments.

Excised biopsy samples are often obtained from patients with human immunodeficiency virus, hepatitis, and other blood-borne diseases. One significant risk to both patients and health care workers is the contamination of imaging equipment, countertops, and floors. In some cases, spillage onto the bucky of a mammography machine may lead to the next patient's placing her breast onto a contaminated surface. In other cases, health care workers may unknowingly touch contaminated surfaces or transfer biohazardous material into non-patient-care areas.

Of additional concern, excised tissue and "lumpectomy" specimens frequently have retained clips, needles, or portions of metallic wire hidden within them, thereby increasing the risk for health care worker sharps and "needlestick" injuries as they handle these specimens with nothing more than gloved hands. Such a situation represents an unseen risk to department staff members, probably not in keeping with Occupational Safety and Health Administration regulations regarding safe hospital practice [5].

The primary objective of this research project was to assess the prevalence and variety of breast specimen processing techniques among Society of Breast Imaging (SBI) members and their departments. To the best of our knowledge, no prior attempt has been made to evaluate the variability of this process and the necessity for a common protocol. This project is considered a first step in identifying the various practices used by different institutions so that future standards may be established.

### METHODS

After institutional review board approval was obtained, an anonymous online survey was developed using the Gold edition of SurveyMonkey.com (SurveyMonkey, Palo Alto, California). This consisted of 13 multiplechoice and fill-in questions. The survey was e-mailed in February 2013 to 2,428 members of the SBI with the permission and assistance of the SBI. Results were analyzed in the Henry Ford Hospital Department of Biostatistics. All data are categorical and are summarized using counts and percentages. No group comparisons were performed.

### RESULTS

Of the 2,428 surveys e-mailed, a total of 354 SBI radiologists responded. The results are shown in Table 1. Because some questions allowed multiple answers and not all respondents answered every question, the total number for each question may not equal 354.

Our findings show that 15.3% of the respondents either do not have, or do not know about, departmental standards for the processing of breast tissue specimens. However, 94.6% of respondents were of the opinion that such a standardized method would be helpful. In the broader context, 82.4% of respondents felt that breast imaging radiologists play an important role in helping localize specific lesions for pathologists.

With regard to health care workers' safety, 17% of survey respondents reported knowledge of instances in which spillage of tissue or bodily fluids occurred while processing tissue specimens. In 75% of these cases, blood or fluids leaked onto mammography machines, presumably used for patient care. In 9 cases, specimen fluids came in contact with health care staff members. Equally troubling, 4.3% of those surveyed had direct or indirect knowledge of needlestick injuries that occurred during localization procedures or while handling specimens. It remains to be seen whether these injuries are related to the number of times a specimen is transferred from one container to another or otherwise manipulated with a gloved hand.

In 60% of survey responses, radiologists indicated that typical tissue specimens are transferred 2 or more times or an unknown number of times during processing of excised material in transit from surgery, through radiology, to pathology and final storage.

#### DISCUSSION

From the survey results, the majority of breast imaging departments seem to have standardized methods for processing breast tissue specimens and find this to be important in the care of patients. Beyond this acknowledgment, however, there seems to be variation in the manner and degree of radiologist involvement regarding the localization of lesions within excised breast specimens.

Approximately half of the surveyed radiologists play a role in postsurgical localization, with either needle or wire placement or with alphanumeric coordinate reporting. A minority of respondents have either personally witnessed or have heard of needlestick-type injuries while processing breast specimens. For institutions that do not use needle or wire localization, concern for worker safety may be a contributing factor as to why this technique is not used. Seventeen percent of

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Table 1. Survey results (n = $354$ )		
Question	n	%
1. Does your department have a standardized method of processing breast tissue (lumpectomy) specimens?	353	
Yes	299	84.7
NO Don't Know	25	7.1 8.2
2. Does everyone in the department follow the same general process for handling of breast tissue specimens?	354	0.2
Yes	307	86.7
No	24	6.8
Don't Know	23	6.5
3. What method(s) does your department utilize to help further localize a particular lesion within a breast tissue specimen (prior to sending to pathology for histologic analysis)?	309	
Nothing further	168	54.4
Report alphanumeric coordinates	66	21.4
Place a needle (or wire) through the lesion	97	31.4
Other	66	21.4
4. What container(s) does your department use in analyzing the tissue specimen? (may specify more than one)	272	
Grid-View <sup>®</sup> ("clam shell") device	60	22.1
Irans-Spec <sup>®</sup> (Dubin) device	33	12.1
	55	4.4 20.2
Generic plastic container	143	20.2 52.6
Other	78	28.7
5. Do you find devices with an alphanumeric grid to be helpful in localizing a lesion within the larger tissue specimen?	351	
Yes	140	39.9
No	57	16.2
Don't utilize these devices	154	43.9
6. Within your department, have you witnessed instances of spillage of blood (fluids) while processing breast tissue specimens?	351	
Yes	36	10.3
No	291	82.9
Heard of, but haven't personally witnessed	24	6.8
7. If yes to question 6: what surfaces have blood (fluids) leaked on to?	301	25.9
Counters	19	35.8
Mammography machine (bucky)	40	75.5
Staff members	9	17.0
Other	9	17.0
8. Within your department, have you witnessed instances of needle-stick (or sharps) injuries to staff members while they were processing breast tissue specimens?	349	
Yes	4	1.1
No	334	95.7
Heard of, but haven't personally witnessed	11	3.2
9. Are you aware the cost of the breast tissue specimen containers utilized in your department?	348	10.0
Yes	48	13.8
10 How many times is the breast tissue specimen transferred between containers (or other devices) from the time it	354	00.2
leaves the operating room to the final storage container in the pathology department?		
1	142	40.1
2	40	11.3
3	7	2.0
4 E ex mere	2	0.6
5 or more	162	0.3 45.8
11. Do you believe that correct processing of breast tissue specimen is important to the overall care of the patient?	353	45.0
Yes	341	96.6
No	2	0.6
Don't know	10	2.8
12. Do you believe that your department should have a standardized method to process breast tissue specimens so that they are all handled the same way?	352	
Yes	333	94.6
No	4	1.1
Don't know	15	4.3
13. Do you believe that the breast imaging radiologist plays an important role in helping to localize a specific lesion for the pathologist, within a (larger) breast tissue specimen?	352	
Yes	290	82.4
No Dan't know	39	11.1
Don t know	23	6.5

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respondents have knowledge of spillage of bodily fluids within their departments.

In analyzing results, there seems to be no standard device used for imaging and localization of surgical biopsy specimens received from the operating room. A significant percentage of respondents (72.8%) used either generic plastic containers or pieces of film. Several proprietary containers were cited most frequently by respondents, including the Grid-View, Trans-Spec, and PathProof devices. The majority of surveyed radiologists did not know the cost of these containers.

From the survey responses, it seems clear that a standardized protocol for imaging breast tissue specimens has yet to be universally accepted. Nevertheless, it would seem that the ideal device, fitting the needs of most breast imaging departments, would be one that allows imaging of excised tissue on an alphanumeric grid, as well as allowing safe placement of a needle (or wire) for further localization, should this be desired. The ideal device should be made of rigid plastic, to prevent needlestick injuries or puncture by sharp objects contained in the specimen. The device should also be watertight to prevent leakage of potentially biohazardous fluids onto machines, countertops, and floors. Finally, the ideal device would be a single container that could be used throughout the entire process, reducing handling of tissue between imaging devices and transport containers, and providing the most cost-effective solution for the department.

One of the limitations of this study was the low overall response rate. Overall, only 14.6% of the surveyed radiologists submitted responses. Furthermore, not every respondent answered every question. Responses to individual questions ranged from 76.8% to 100%. Despite the low response rate, this study is the first to look into the various practices used by different institutions in the handling and management of breast tissue specimens. The results clearly demonstrated significant variability due to the lack of a universal standardized practice.

Although further research is needed to demonstrate the single best practice, there seems to be consensus among breast imagers regarding the importance of proper tissue specimen management to the overall care of patients. There also seems to be a desire among radiologists for a standardized process to evaluate surgically excised breast tissue specimens. The preferred method should take into account cost, accuracy, and patient and worker safety.

### TAKE-HOME POINTS

- From the survey results, the majority of breast imaging departments appear to have standardized methods for processing breast tissue specimens and find this to be important in the care of patients. Beyond this acknowledgment, however, there seems to be variation in the manner and degree of radiologist involvement regarding the localization of lesions within excised breast specimens.
- Approximately half of surveyed radiologists play a role in postsurgical localization, with needle or wire placement or alphanumeric coordinate reporting. A minority of respondents have either personally witnessed or have heard of needlestick-type injuries while processing breast specimens. For institutions that do not use needle or wire localization, concern for worker safety may be a contributing factor in why this technique is not used. Seventeen percent of respondents have knowledge of spillage of bodily fluids within their departments.
- Although further research is needed to demonstrate the single best practice, there appears to be consensus among breast imagers regarding the importance of proper tissue specimen management to the overall care of patients. There also appears to be a desire among radiologists for a standardized process to evaluate surgically excised breast tissue specimens.

### REFERENCES

- Bimston DN, Bebb GG, Wagman LD. Is specimen mammography beneficial? Arch Surg 2000;135:1083-9.
- American College of Radiology. ACR—ACS—CAP—SSO practice guideline for the management of ductal carcinoma in-situ of the breast (DCIS). Available at: http://www.acr.org/~/media/ACR/Documents/PGTS/ guidelines/DCIS.pdf. Accessed July 29, 2013.
- American College of Radiology. ACR–ACS–CAP–SSO practice guideline for breast conservation therapy in the management of invasive breast carcinoma. Available at: http://www.acr.org/~/media/ACR/Documents/ PGTS/guidelines/Invasive\_Breast\_Carcinoma.pdf. Accessed July 29, 2013.
- 4. Monda LA. Breast specimen imaging. Radiol Technol 2005;77:121-37.
- Occupation Safety and Health Administration. Bloodborne pathogens. Available at: https://www.osha.gov/pls/oshaweb/owadisp.show\_document? p\_id=10051&p\_table=STANDARDS. Accessed March 5, 2014.