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## **ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF ULTRASOUND-GUIDED PERCUTANEOUS BREAST INTERVENTIONAL PROCEDURES**

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### **PREAMBLE**

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care<sup>1</sup>. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

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<sup>1</sup> *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, \_\_\_ N.W.2d \_\_\_ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

## I. INTRODUCTION

Breast interventional procedures may be diagnostic, such as tissue sampling, or therapeutic, such as abscess drainage, or both diagnostic and therapeutic, such as cyst aspiration. They include, but are not limited to, cyst aspiration, abscess drainage, presurgical needle localization, fine-needle aspiration (FNA) biopsy, and core-needle biopsy (CNB). The advantages of image-guided CNB over surgical biopsy are numerous, with similar accuracy and fewer complications [1-3].

Ultrasound is one of several imaging techniques that may be used to guide interventional procedures. Other breast imaging modalities used for guidance include mammography (conventional and stereotactic) and magnetic resonance imaging (MRI). When a lesion can be visualized sonographically, ultrasound guidance is often preferred because of operator experience or preference, patient comfort, efficiency, economy, absence of ionizing radiation, and sampling accuracy (real-time visualization of the needle or other instrument within the lesion).

## II. GENERAL PRINCIPLES

Minimally invasive biopsy is the standard of care for diagnosing most breast lesions.

Advantages of percutaneous procedures include the following:

- A. Reduced morbidity, with better cosmetic results and less scarring detectable on future breast imaging
- B. Improved cost-effectiveness, with less time before resumption of normal activities
- C. Accuracy comparable to open surgical biopsy

Prior to the performance of any ultrasound-guided percutaneous procedure, the lesion should be evaluated completely with an ultrasound study in accordance with the [ACR Practice Parameter for the Performance of a Breast Ultrasound Examination](#) [4] and assessed by a physician qualified to interpret the examination (see section IV below). Findings on other imaging modalities (such as mammography or MRI) or on clinical examination should be correlated with those on ultrasound before the interventional procedure is undertaken.

Successful use of ultrasound to guide breast interventional procedures relies on high-quality imaging, expertise in lesion characterization patient selection, patient positioning, and experience in ultrasound-guided techniques for accurate lesion localization and targeting. Correlation of the imaging characteristics with histopathologic or cytopathologic results for concordance by the physician performing the biopsy is essential. Documentation of results and patient management recommendation records should be retained in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [5].

## III. INDICATIONS/CONTRAINDICATIONS

### A. Indications

Indications for percutaneous ultrasound-guided breast interventional procedures include, but are not limited to, the following:

1. Simple and complicated cysts when:
  - a. They are symptomatic.
  - b. It is unclear whether the lesion is a complicated cyst or a solid lesion.
  - c. Imaging guidance would help avoid complications such as penetration of the pectoral muscle and improve accuracy.
  - d. Correlation with other imaging findings (mammography, MRI) is likely to provide important diagnostic information that will guide patient management.

- e. Abscess or infection is suspected, and diagnostic aspiration and/or therapeutic drainage is clinically indicated.
2. Complex cystic and solid masses (see Appendix) when:
  - a. Masses are assessed as highly suggestive of malignancy according to the [ACR BI-RADS® Atlas](#) (Breast Imaging Reporting and Data System) 2013 [6], BI-RADS® Category 5, to confirm the diagnosis and guide definitive treatment.
  - b. Masses are assessed as suspicious (BI-RADS® Category 4).
  - c. There is >1 suspicious mass, particularly in a multicentric distribution, to facilitate treatment planning.
  - d. Masses are assessed as probably benign (BI-RADS® Category 3) but there are valid clinical indications for biopsy or when short-term-interval imaging follow-up would be difficult or unreasonable (eg, if the patient has a synchronous known breast cancer, is awaiting organ transplantation, plans to become pregnant in immediate future, etc) [7].
  - e. Masses seen on directed-ultrasound examination correlate with suspicious areas of enhancement present on contrast-enhanced breast MRI [8].

3. Microcalcifications when:

Microcalcifications seen on directed ultrasound examination correlate with suspicious calcifications visualized on mammography [9-11]. Specimen radiography should be performed in this setting to document adequate sampling of calcifications.

4. Repeat biopsy

Repeat ultrasound-guided percutaneous core or vacuum-assisted needle biopsy sampling is an alternative to surgical biopsy in cases when the initial core biopsy results are nondiagnostic or discordant with the imaging findings, additional tissue is necessary for tissue biomarker analysis, or if an initial FNA biopsy yields atypical, suspicious, or nondiagnostic cytology.

5. Presurgical localization

Ultrasound-guided localization may be performed when the lesion or an appropriately positioned tissue marker placed during a previous biopsy is identifiable with ultrasound [12].

6. Biopsy of lymph nodes in the axilla/axillary tail in cases of known or suspected malignancy

When the suspicion of malignancy is high and if abnormal lymph nodes are seen within the axilla or axillary tail, FNA or core biopsy sampling of the cortex of the abnormal lymph node(s) can be performed at the time of initial imaging-guided core biopsy of the suspicious breast mass or at a later time [13].

## B. Contraindications

Inability to revisualize the target or breast lesion sonographically at the time of the biopsy is a contraindication to ultrasound-guided biopsy or drainage. Prior to the procedure, the patient should be asked about allergies; use of medications such as aspirin, anticoagulants, or other agents known to impact bleeding times; and whether there is a history of a bleeding diathesis are anticoagulated. However, a recent report suggested that it is safe to proceed with biopsy when patients are anticoagulated. [14]. Decisions regarding postponement or cancellation of a procedure or cessation of anticoagulants can be made on a case-by-case basis at a programmatic level.

## IV. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

### A. General Qualifications

Ultrasound-guided percutaneous breast interventional procedures should be performed by physicians who meet qualifications outlined in the [ACR Practice Parameter for the Performance of a Breast Ultrasound Examination](#) [4]. When the procedure is being performed for therapeutic reasons only (abscess drainage or aspiration), the physician should meet the initial qualifications above or meet those qualifications outlined in the [ACR–SIR–SPR Practice Parameter for Specifications and Performance of Image-Guided Percutaneous Drainage/Aspiration of Abscesses and Fluid Collections \(PDAFC\)](#) [15]. In cases where mammography has been performed, the physician should either meet the initial qualifications specified in the [ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography](#) [16] or should review the mammographic findings with a physician who has the qualifications specified in the Food and Drug Administration’s Mammography Quality Standards Act Final Regulations [17]. The physician should thoroughly understand the indications for and limitations of ultrasound examinations and ultrasound-guided percutaneous breast interventional procedures. The physician performing the breast interventional procedure should be familiar with breast ultrasound anatomy and must be capable of correlating the results of mammographic and other examinations, procedures and the biopsy pathology with the sonographic findings. The physician should thoroughly understand the basic physics of ultrasound, ultrasound instrumentation, imaging techniques, and ultrasound safety.

### B. Specific Qualifications

#### 1. Initial qualifications

Training in sonographic (and mammographic for correlation) image interpretation, medical physics and specific hands-on training in the performance of ultrasound-guided biopsy are imperative to successful performance of this procedure.

The initial qualification as outlined for the [Breast Ultrasound Accreditation Program Requirements](#) provide this foundation [18].

#### 2. Maintenance of competence

The physician should perform a sufficient number of procedures to maintain their skills. Continued competence should depend on participation in a quality control program as laid out under section VIII of this practice parameter.

#### 3. Continuing medical education

The physician’s continuing education should be in accordance with the [ACR Practice Parameter for Continuing Medical Education](#) [19].

### C. Responsibilities for Assessment of Concordance

Concordance is the agreement of imaging and histopathological findings such that the histopathology satisfactorily explains the imaging findings.

The physician who performs the procedure or, if unavailable, his/her qualified physician-designee, is responsible for obtaining pathologic results to determine if the lesion has been adequately biopsied and whether the pathology results are concordant or discordant with the imaging findings. The determination of concordance should be documented [20]. When discordant, biopsy should be repeated by imaging guidance or surgical excision [21]. These results should be communicated to the referring physician and/or to the patient, as appropriate.

## V. SPECIFICATIONS OF THE PROCEDURE

The written or electronic request for an ultrasound-guided breast procedure should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state's scope of practice requirements. (ACR Resolution 35, adopted in 2006)

The decision to perform an interventional procedure should conform to the general principles noted in Section II above. A complete ultrasound examination of the mass or area of the breast in which the procedure is planned should be performed (see the [ACR Practice Parameter for the Performance of a Breast Ultrasound Examination \[4\]](#)).

Benefits, limitations, and risks of the procedure as well as alternative procedures should be discussed with the patient. Informed consent should be obtained and documented.

Adherence to the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in nonoperating room settings, including bedside procedures.

The organization should have processes and systems in place for reconciling differences in staff responses during the "time-out."

The breast, ultrasound transducer, the field in which the procedure is to be performed, and physician performing the procedure should be prepared in conformity with the principles of infection control.

Using a high-frequency transducer with continuous visualization of the needle path is ideal. During performance of an ultrasound-guided intervention, the long axis of the needle, especially its tip, should be visible along the long axis of the transducer.

The needle should be kept as parallel to the chest wall and transducer face as possible throughout the performance of an ultrasound-guided intervention to ensure that the chest wall is not penetrated. Occasionally, during an FNA biopsy, cyst aspiration, or needle localization, depending on the location of the lesion, a steeper (nonparallel) approach may be appropriate. The selection of a nonthrow biopsy device could be considered if the lesion is in a precarious position. If desired or if there is concern for partial volume averaging within a small lesion, the transducer can be rotated 90° to visualize the echogenic dot of the needle within the lesion. Documentation of appropriate needle positioning for sampling should be part of the medical record. Coaxial techniques may also be used with ultrasound-guided FNA and CNB [22]. The number of samples required for adequate analysis depends upon lesion type and biopsy device; a minimum of 3-6 samples is usually obtained from each lesion [23].

Following performance of a core biopsy and as appropriate following aspiration or FNA biopsy, placement of a localizing tissue marker at the biopsy or aspiration site should be strongly considered to facilitate surgical excision, if necessary, especially for lesions that may be difficult to visualize on subsequent ultrasound examinations, for mammographically occult lesions, for those that may undergo neoadjuvant chemotherapy, and for correlation with findings on other imaging modalities [24]. When multiple lesions are present and biopsy of >1 suspicious lesion is performed to establish multicentricity, placement of markers of different shapes should be considered.

When a tissue marker has been placed, a postbiopsy mammogram consisting of craniocaudal and 90° lateral views is recommended following the procedure to document tissue marker location. Additional views, such as exaggerated craniocaudal (CC) or mediolateral oblique views, may be necessary to visualize the tissue marker and help correlate the biopsied lesion to the mammographic image.

To minimize hematoma formation following biopsy or aspiration, especially in patients who are at risk for bleeding, the biopsy and skin entry sites and the path of the needle should be adequately compressed until hemostasis is achieved.

## **VI. DOCUMENTATION**

Permanent records of ultrasound-guided breast interventional procedures should be documented in a retrievable image storage format. When appropriate, correlative mammography should be performed in conjunction with the procedure.

A. Image labeling should include the following:

1. Patient's first and last names
2. Identifying number and/or date of birth
3. Examination date
4. Facility name and location
5. Designation of the left or right breast
6. Anatomic location using clock face notation and/or labeled diagram of the breast
7. Distance from the nipple to the lesion in centimeters
8. Transducer orientation
9. Sonographer's and/or physician's identification number, initials, or other symbol

Other information that can be entered on the permanent record includes the technologist's and physician's initials.

B. The physician's report of ultrasound-guided interventional procedures of the breast should include the following:

1. Procedure performed
2. Designation of left or right breast
3. Description and location of the lesion in the breast using clock face or other consistent accepted notation
4. Safety time-out having been performed
5. Skin incision, if made
6. Type and amount of local anesthesia
7. Gauge of needle and type of device (spring-loaded, vacuum-assisted, etc)
8. Number of specimen cores or samples, if applicable
9. Complications and treatment, if any
10. Results of sonographic or radiographic specimen images, if performed
11. Localizing tissue marker information including shape, if placed. If multiple tissue markers are placed, they should be clearly identified according to shape and site.
12. Documented presence or absence of a sonographically evident residual mass for future localization and follow-up purposes
13. Postprocedure mammogram and/or sonogram, if obtained, documenting tissue marker placement and location of the tissue marker with respect to the biopsied lesion

C. Postprocedure patient follow-up should include the following:

1. Documentation of any delayed complications and treatment administered
2. A determination of concordance of pathology results with imaging findings by the physician who performed the procedure or his/her physician-designee, with documentation in the record. When results are benign and concordant, the patient may return to annual screening. When discordant, biopsy should be repeated by imaging guidance or surgical excision [21].
3. Recommendations based on tissue sampling results, imaging information, and concordance analysis. Surgical consultation is usually recommended for high-risk lesions known to be subject to upgrade, including atypical ductal hyperplasia, flat epithelial atypia, lobular neoplasia (atypical lobular hyperplasia and lobular carcinoma in situ), radial scar, complex sclerosing lesion, phyllodes tumor, and, to a lesser degree, papilloma, may be recommended [25-36]. However, controversies exist regarding high-risk lesions, and care should be individualized when appropriate. For malignant results, patients are usually referred for consultation to a surgeon or oncologist.
4. Record of communications with the patient and/or referring physician

D. Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [5].

E. Retention of the procedure images, including specimen images if obtained, should be consistent with the facility's policies for retention of images and in compliance with federal and state regulations.

## VII. EQUIPMENT SPECIFICATIONS

### A. Ultrasound

High-resolution, linear-array, broad-bandwidth transducers are preferred for breast ultrasound examinations and percutaneous procedures. The transducers should be operated at the highest clinically appropriate frequency. Ordinarily, transducer frequencies of 12 MHz or higher are used for breast imaging and interventional procedures. All equipment should be in accordance with the [ACR Practice Parameter for the Performance of a Breast Ultrasound Examination](#) [4].

### B. Tissue Acquisition Needle Systems

For cyst aspiration and FNA biopsy, the appropriate gauge needle for the procedure should be used with any aspirating device, tubing, or syringes.

Assuming accurate targeting and sampling, spring-loaded needle systems provide samples adequate for diagnosis of most lesions amenable to ultrasound-guided biopsy. For spring-loaded devices, most data support the use of 14-gauge and larger needles. Vacuum-assisted core-needle biopsy and other biopsy systems are also available for use in ultrasound-guided procedures [37-42].

## VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<http://www.acr.org/guidelines>)

Equipment performance monitoring should be in accordance with the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment](#) [43].

Results of ultrasound-guided as well as other imaging-guided percutaneous breast interventional procedures should be monitored. The following records should be maintained for the facility, practice, and individual physicians:

- Total number of procedures
- Total number of cancers found
- Total number of benign lesions
- Total number of ultrasound-guided biopsies needing repeat biopsy, categorized by reason and type of biopsy (eg, CNB, FNA):

<i>Reason for Repeat Biopsy</i>	<i>Data</i>
Insufficient sample	<ul style="list-style-type: none"> <li>• Total number of cases</li> <li>• Number with repeat biopsy</li> <li>• Final pathology results</li> </ul>
Discordance with imaging	<ul style="list-style-type: none"> <li>• Total number of cases</li> <li>• Number with repeat biopsy</li> <li>• Final pathology results</li> </ul>
High-risk lesions	<ul style="list-style-type: none"> <li>• Total number of cases</li> <li>• Number with repeat biopsy</li> <li>• Final pathology results</li> </ul>

Imaging findings and pathologic interpretation should be correlated by the physician who performs the biopsy or his/her qualified physician-designee. Postbiopsy patient follow-up should be performed to detect and record any false-negative and false-positive results.

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**APPENDIX**

**ACR BI-RADS® ATLAS (BREAST IMAGING REPORTING AND DATA SYSTEM) 2013 [6] (BI-RADS® Category 5)**

Assessment	Management	Likelihood of Cancer
Category 0: Incomplete – Need additional imaging evaluation	Recall for additional imaging	N/A
Category 1: Negative	Routine screening	Essentially 0% likelihood of malignancy
Category 2: Benign	Routine screening	Essentially 0% likelihood of malignancy
Category 3: Probably benign	Short-interval (6-month) follow-up or continued surveillance	>0% but ≤2% likelihood of malignancy
Category 4: Suspicious Category 4A: <i>Low suspicion</i> for malignancy Category 4B: <i>Moderate suspicion</i> for malignancy Category 4C: <i>High suspicion</i> for malignancy	Tissue diagnosis	>2% but <95% likelihood of malignancy >2% to ≤10% likelihood of malignancy >10% to ≤50% likelihood of malignancy >50% to <95% likelihood of malignancy
Category 5: Highly suggestive of malignancy	Tissue diagnosis	≥95% likelihood of malignancy
Category 6: Known biopsy-proven malignancy	Surgical excision when clinically appropriate	N/A

\*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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