Amended 2014 (Resolution 39)*

ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF A BREAST ULTRASOUND EXAMINATION

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[1]. 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 physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the practice parameters, 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 the practice parameters 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 the practice parameters. However, a practitioner who employs an approach substantially different from these practice parameters 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 these practice parameters 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 these practice parameters is to assist practitioners in achieving this objective.

[1] 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

This practice parameter has been developed to assist practitioners performing ultrasound examination of the breast. When ultrasound is used as guidance for interventional procedures or biopsy, relevant ACR practice parameters should be consulted.

II. INDICATIONS

Appropriate indications for breast sonography include, but are not limited to:

1. Evaluation and characterization of palpable masses and other breast related signs and/or symptoms [1-4].
2. Evaluation of suspected or apparent abnormalities detected on other imaging studies, such as mammography or magnetic resonance imaging (MRI) [5].
3. Initial imaging evaluation of palpable masses in women under 30 years of age who are not at high risk for development of breast cancer, and in lactating and pregnant women.
4. Evaluation of problems associated with breast implants [6].
5. Evaluation of breasts with microcalcifications and/or architectural distortion suspicious for malignancy or highly suggestive of malignancy in a setting of dense fibroglandular tissue, for detecting an underlying mass that may be obscured on the mammogram [6].
6. Guidance of breast biopsy and other interventional procedures [7].
7. Treatment planning for radiation therapy [6].
8. As a supplement to mammography, screening for occult cancers in certain populations of women (such as those with dense fibroglandular breasts who are also at elevated risk of breast cancer or with newly suspected breast cancer) who are not candidates for MRI [8-9] or have no easy access to MRI.
9. Identification and biopsy guidance of abnormal axillary lymph node(s), for example in patients with newly diagnosed or recurrent breast cancer [10-11] or with findings highly suggestive of malignancy or other significant etiology.

III. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

A. Physician

Physicians who supervise, perform, and/or interpret breast ultrasound examinations should be licensed medical practitioners who have a thorough understanding of the indications for ultrasound examinations as well as a familiarity with the basic physical principles and limitations of the technology of ultrasound imaging. They should be familiar with alternative and complementary imaging and diagnostic procedures and should be capable of correlating the results of these other procedures with the sonographic findings. They should have a thorough understanding of ultrasound technology and instrumentation, ultrasound power output, equipment calibration, and safety. Physicians responsible for breast ultrasound examinations should demonstrate familiarity with breast anatomy, physiology, and pathology. These physicians should provide evidence of the training and competence needed to perform breast ultrasound examinations successfully.

Physicians performing and/or interpreting breast ultrasound examinations should meet at least one of the following criteria:

Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec, and involvement with the supervision and/or performance, interpretation, and reporting of 300 breast ultrasound examinations within the last 36 months.[2]

or

[2]Completion of an accredited radiology residency in the past 24 months will be presumed to be satisfactory experience for the performance, reporting, and interpreting requirement.

Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved diagnostic radiology residency program and involvement with the supervision and/or performance, interpretation, and reporting of 300 breast ultrasound examinations in the past 36 months.[1]

or

Physicians not board certified in radiology or not trained in a diagnostic radiology residency program, and who assume these responsibilities for sonographic imaging of the breast, should meet the following criteria: completion of an ACGME approved residency program in specialty practice plus 200 hours of Category I continuing medical education (CME) in breast ultrasound; and supervision and/or performance, interpretation, and reporting of 500 breast ultrasound examinations during the past 36 months in a supervised situation.

Maintenance of Competence

All physicians performing ultrasound examinations should demonstrate evidence of continuing competence in the interpretation and reporting of those examinations. If competence is assured primarily based on continuing experience, a minimum of 100 examinations per year is recommended in order to maintain the physician's skills. Because a physician's practice or location may preclude this method, continued competency can also be assured through monitoring and evaluation that indicates acceptable technical success, accuracy of interpretation, and appropriateness of evaluation.

Continuing Medical Education

The physician's continuing education should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) and should include CME in ultrasonography as is appropriate to his or her practice.

B. Diagnostic Medical Sonographer

When a sonographer performs the examination, he or she should be qualified by appropriate training to do so. This qualification can be demonstrated by certification or eligibility for certification by a nationally recognized certifying body.

IV. WRITTEN REQUEST FOR THE EXAMINATION

The written or electronic request for a breast ultrasound examination 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)

V. SPECIFICATIONS FOR INDIVIDUAL EXAMINATIONS

A. Image labeling should include a permanent identification label that contains:

1. Facility name and location.
2. Examination date.
3. Patient's first and last name.
4. Identifying number and/or date of birth.
5. Designation of right or left breast.

6. Anatomic location using clock face notation or a labeled diagram of the breast. Transducer orientation and distance from the nipple to the abnormality, if present, are required.
7. Sonographer's and/or physician's identification number, initials, or other symbol.

B. Lesion Characterization and Technical Factors [3]

1. The breast sonogram should be correlated with clinical signs and/or symptoms and with mammographic and other appropriate breast imaging studies. If sonography has been performed previously, the current examination should be compared with prior sonograms, as appropriate. A lesion or any area of the breast being studied should be viewed in 2 perpendicular projections, and real-time scanning by the interpreter is encouraged.

2. The size of a lesion should be determined by recording its maximal dimensions in at least 2 planes; orthogonal planes are recommended. At least 1 set of images of a lesion should be obtained without calipers.

3. The images should be labeled as to right or left breast, location of lesions, and the orientation of the transducer with respect to the breast (e.g., transverse or longitudinal, radial or antiradial). The location of the lesion should be recorded using clock face notation and distance from the nipple, and/or shown on a diagram of the breast. The length of the transducer face (footprint), usually between 3.5 cm and 5 cm, can be used to estimate the distance from the nipple. Measurements should not be made from the edge of the areola, as areolar width is widely variable.

4. Sonographic features are helpful in characterizing breast masses. These feature categories and their descriptors are listed and exemplified in the ACR Breast Imaging Reporting and Data System® (BI-RADS®). The BI-RADS sonographic categories include size, shape, orientation, margin, echogenicity, lesion boundary, attenuation (e.g., shadowing or enhancement), special cases, vascularity, and surrounding tissue [3].

5. Elastography, or tissue stiffness assessment, is among the new feature categories applicable to sonographic analysis of masses, to be included in the Associated Findings section in BI-RADS – Ultrasound, edition 2. To minimize errors in communication or interpretation, if elastography is performed, the color scales should be annotated to denote hardness or softness.

6. Mass characterization with ultrasonography is highly dependent on technical factors.

   Breast ultrasound should be performed with a high-resolution scanner (see section VII). Gain settings, focal zone selections**,** and fields of view should be optimized to obtain high-quality images. The patient should be positioned to minimize the thickness of the portion of the breast being evaluated. For evaluation of lesions in, on, or just beneath the skin, a stand-off device or thick layer of gel may be helpful.

C. Guidance of Interventional Procedures

(See the ACR Practice Parameter for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures.)

When ultrasound guidance is used to assist in needle placement for interventional procedures, care should be taken to ensure that scanning geometry and transducer placement permit adequate visualization of the needle and the needle tip.

VI. DOCUMENTATION

Images of all important findings, including, in the case of interventional procedures, the relationship of the needle to the lesion, should be recorded in a retrievable and reviewable image storage format. It is recommended that documentation of a negative targeted or whole breast ultrasound examination be performed.

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. Variations from normal size should generally be accompanied by measurement. The initials of the operator should be accessible on the images or electronically on PACS. Images should be labeled with the patient identification, facility identification, examination date, and image orientation. An official interpretation (final report) of the ultrasound examination should be included in the patient's medical record. It is recommended that the report include a description of the area scanned. Retention of the ultrasound examination images should be based on clinical need and with relevant legal and local health care facility requirements.

If ultrasound is performed for evaluating clinical signs and/or symptoms or a finding on mammography, MRI, or other breast imaging modality, the finding(s) should be referred to in the report. Reporting of lesions should generally include measurements. Use of an accepted reporting system, such as BI-RADS® US, is recommended.

Reporting should be in accordance with ACR Practice Parameter for Communication of Diagnostic Imaging Findings.

VII. EQUIPMENT SPECIFICATIONS

Breast ultrasound should be performed with a high-resolution real-time linear array scanner operating at a center frequency of at least 10 MHz and preferably higher. Other transducers may be utilized in special circumstances. Focal zones should be electronically adjustable. In general, the highest frequency capable of adequate penetration to the depth of interest should be used. For evaluating superficial lesions, scanning through a thin stand-off device or thick layer of gel may be helpful in offsetting the transducer face from the uppermost layer of skin, to bring it into the focal zone of the transducer.

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 Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment.

ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading *The Process for Developing ACR Practice Parameters and Technical Standards* on the ACR website (http://www.acr.org/guidelines) by the Joint Committee on Breast Imaging for Appropriateness Criteria and Guidelines of the ACR Commission on Breast Imaging and by the Guidelines and Standards Committee of the ACR Commission on Ultrasound.

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*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.

Development Chronology for this Practice Parameter
1994 (Resolution 22)
Revised 1998 (Resolution 33)
Revised 2002 (Resolution 31)
Amended 2006 (Resolution 35)
Revised 2007 (Resolution 34)
Revised 2011 (Resolution 11)
Amended 2014 (Resolution 39)