ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF WHOLE-BREAST ULTRASOUND FOR SCREENING AND STAGING

The American College of Radiology, with more than 40,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

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 practitioner considering 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 variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 purpose of this document is to assist practitioners in achieving this objective.

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1 *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (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 an entire breast. When ultrasound is used in a focused manner to evaluate specific areas of clinical or imaging concern, or as guidance for interventional procedures or biopsy, relevant American College of Radiology (ACR) practice parameters (see the ACR Practice Parameter for the Performance of a Diagnostic Breast Ultrasound Examination and the ACR Practice Parameter for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures [1,2]) should be consulted.

Although mammography is the only imaging modality proven through randomized controlled trials to reduce breast cancer–related mortality, mammography has a reduced sensitivity for identifying cancers in dense fibroglandular tissue. In addition to the masking phenomenon of dense breast tissue on mammograms, concern for dense fibroglandular tissue as an independent risk factor for breast cancer has led many practices to offer supplemental screening for patients with dense breasts, often with ultrasound (US).

The potential additive benefit of supplemental screening ultrasound is supported by an ACR Imaging Network multicenter screening trial of physician-performed handheld whole-breast ultrasound combined with mammography compared with mammography alone in women with elevated risk and dense breasts, ACRIN 6666. First-year results of that study dentified 4.2 cancers per 1,000 women screened in addition to those detected with mammography [3] but with less than 10% positive predictive value for biopsies (PPV3). Additional screening studies, both multiple and single site, initially had similar results. A report of combined results for years 2 and 3 of ACRIN 6666 showed doubling of PPV3 for the combination of mammography plus ultrasound ompared to mammography alone [4]. Thus, high false-positive rates were expected to diminish after continuing experience with adjunctive screening using US and did so in one 4-year follow-up report of several Connecticut practices, where the aggregate positive predictive values for biopsy nearly tripled [5].

In a single-institution retrospective analysis, mammographic plus ultrasound screening significantly reduced advanced-stage cancers by 5.7% for all stages and 10.8% for invasive cancers compared to mammographic screening alone [6]. Supplemental screening ultrasound uncommonly detects in situ breast cancers.When comparing screening mammography with or without same-day breast ultrasonography in two breast cancer surveillance consortium registries, cancer detection and interval cancer rates were similar. However, false-positive biopsy and short-interval follow-up rates were significantly higher and PPV3 was significantly lower with supplemental ultrasound screening [7]. Increased recall rates of women who undergo supplemental ultrasound screening may be tempered, at least initially during early-phase adoption, by the use of double reading [8]. Additionally, the use of computer-aided detection has the potential to decrease interpretation times without compromising screening performance [9,10].

Routine axillary scanning during screening breast ultrasound had no effect on additional cancer detection but increased the number of false-positive results in a retrospective analysis of 12,844 screening ultrasound examinations in 8,664 women over three years [11].

Whole-breast ultrasound can also be used for locoregional staging or restaging, particularly when that patient is unable to undergo breast magnetic resonance imaging (MRI) . When interpreted in conjunction with diagnostic mammography and performed alongside ultrasound evaluation of the regional nodal basins, whole-breast ultrasound has the potential to reduce underestimation of disease burden for newly diagnosed patients with breast cancer [12]. In a single-institution retrospective study of 160 lesions (108 malignant and 52 benign), diagnostic accuracy of digital breast tomosynthesis (DBT) plus automated whole-breast ultrasound (ABUS) versus MRI was comparable for known cancers, but DBT plus ABUS showed lower sensitivity and positive predictive values for additional disease [13]. ABUS may also be a suitable method to conduct neoadjuvant response assessment and facilitate preoperative planning [14] in those patients who cannot undergo breast MRI.

II. INDICATIONS

Indications for whole-breast ultrasound may include, but are not limited to:

1. Screening, as an optional adjunct to screening mammography, for:
    a. Patients with a high lifetime breast cancer risk (20% or greater) who are not candidates for breast MRI, who are unable to tolerate or elect not to undergo MRI, or who cannot easily access breast MRI;
    b. Patients with heterogeneously or extremely dense breasts for whom supplemental screening options have been suggested [15,16].

2. Cancer staging, in patients newly diagnosed with breast cancer who are not candidates for breast MRI, who are unable to tolerate or elect not to undergo MRI, or who cannot easily access breast MRI [17,18].

III. QUALIFICATIONS AND RESPONSIBILTIES OF THE PERSONNEL

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 should be capable of correlating the results of these 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 knowledge of breast anatomy, physiology, and pathology. These physicians should provide evidence of the training and competence needed to perform breast ultrasound examinations successfully. The initial qualifications as outlined in the ACR Breast Ultrasound Accreditation Program Requirements provide this foundation [19].

Maintenance of Competence

Physicians must perform a sufficient number of overall procedures to maintain their skills. Continued competence should depend on participation in a quality improvement program. Consideration should be given to the physician's lifetime practice experience.

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 the physician's practice [20].

III. QUALIFICATIONS AND RESPONSIBILTIES OF THE PERSONNEL

B. Sonographer or Technologist

The sonographer or technologist performing the examination should be certified or eligible for breast ultrasound certification by a nationally recognized certifying body.

IV. SPECIFICATIONS FOR INDIVIDUAL EXAMINATIONS

A.

Examinations should include permanent identification containing:

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 and/or left breast
6. Sonographer's and/or physician's identification number, initials, or other identifier

IV. SPECIFICATIONS FOR INDIVIDUAL EXAMINATIONS

B. Methods and Technical Factors [16]

1. Whole-breast ultrasound can be performed with a general-purpose ultrasound machine or any of several systems designed specifically for whole-breast ultrasound. If a general-purpose machine is employed, a linear high-frequency transducer with a center frequency of at least 12 MHz if possible should be used for breast scanning. Handheld whole-breast screening ultrasound relies on the operator to identify and capture images of any findings. Because lesion characterization by ultrasonography is highly dependent on technical factors, operators should optimize gain settings, focal zone selections, and fields of view when capturing images of specific findings. Please see the ACR Practice Parameter for the Performance of a Diagnostic Breast Ultrasound Examination [1].

2. Semiautomated whole-breast ultrasound involves adding a robotic arm to a general-purpose ultrasound machine on which the high-frequency linear transducer is mounted. The arm guides the transducer over the breast, producing uniplanar images in sequential scan rows that are stitched together into a single continuous video for each breast. Because a trained operator is needed to position the transducer for each scan and maintain appropriate pressure throughout the examination, this technique is considered semiautomated. Proprietary viewing software enables the localization of findings by using the nipple, scan row, and frame number as reference points.

3. Several manufacturers have developeddedicated automated breast ultrasound systems with special transducers and proprietary viewing software. These scanners vary in patient positioning (supine or prone), transducer configuration, and multiplanar image reconstruction algorithms, but all have methods for imaging the entire breast and depicting it in the coronal plane. Supine automated systems cover the whole breast by obtaining multiple acquisitions in the transverse plane using wide linear or reverse curvilinear high-resolution transducers. Prone automated systems ordinarily obtain a single acquisition for each breast in the coronal plane using helical or torus-type transducers, some with the breast suspended in a water bath. Examinations are interpreted on workstations using proprietary software tools that localize and correlate findings on each view. A detailed description of the unique features and operational parameters of each of these devices is beyond the scope of this document.

IV. SPECIFICATIONS FOR INDIVIDUAL EXAMINATIONS

C. Practice Considerations

1. Prior to beginning a whole-breast ultrasound screening examination, careful note should be taken of any clinical signs, symptoms, or previously identified abnormalities for which further imaging evaluation has been recommended. The interpreting physician should be advised of any such circumstances. If any of these exist, a diagnostic examination is appropriate and should be recommended. If a patient who needs diagnostic breast imaging undergoes screening whole-breast ultrasound, the report should note this and include recommendation for appropriate diagnostic imaging.

2. Whole-breast ultrasound should be interpreted in the context of mammography if performed. Contemporaneous mammograms are not necessary for all patients, but any recent mammographic images should be available to the physician interpreting the whole-breast ultrasound. Older mammograms can also be useful to confirmstability of mammographic correlates for benign-appearing sonographic findings. If whole-breast ultrasound has been performed previously, the current examination should be compared with prior studies, if available.

3. Interpretation of whole-breast ultrasound performed as a screening examination should focus on identifying any findings that merit diagnostic evaluation. Such findings may or may not be sufficiently

characterized by semiautomated or automated whole-breast ultrasound, or technologist-performed handheld whole-breast ultrasound. Patients with indeterminate findings should receive an ACR Breast Imaging Reporting and Data System® (BI-RADS®) assessment of Incomplete: Need Additional Imaging Evaluation (BI-RADS Category 0) and be recalled for diagnostic imaging.

4. Handheld whole-breast ultrasound negative images obtained for documentation—those not showing a lesion—should be annotated with breast side (right or left), location (quadrant or clock-face notation), and transducer orientation. Single images of each quadrant as well as one image of the retroareolar region are sufficient for documentation.
5. Images of specific findings captured during handheld whole-breast ultrasound should be obtained in two projections, preferably orthogonal, and labeled with laterality, clock-face location, distance from the nipple, and transducer orientation. It is preferable to use clock-face rather than quadrant notation for specific findings. Distance from the nipple should be measured from the nipple itself rather than the edge of the areola, because areolar width varies.

6. Variability in tissue composition encountered on ultrasound mirrors the variability of density seen mammographically, and conspicuity of lesions may be affected by a heterogeneous background echotexture. For this reason, tissue composition should be reported for supplemental screening ultrasound examinations.

7. Patients may undergo screening whole-breast ultrasound and subsequent diagnostic breast imaging on the same date. Each examination should receive its own assessment, although a single report may be generated with an overall assessment and management recommendations for the combined examinations. Therefore, physicians performing handheld whole-breast ultrasound screening may wish to consider ending the screening examination before performing diagnostic (ie, focused) evaluation of any findings.

8. For the minority of whole-breast ultrasound studies performed in the diagnostic setting, the practice parameters for focused breast ultrasound apply. Lesions should be characterized by feature categories and descriptors as listed and exemplified in BI-RADS[16].

9. In accordance with BI-RADS [16,17], at least three measurements should be given for each lesion when possible. To facilitate reproducibility, lesions should be evaluated and measured in two orthogonal planes (radial and antiradial; transverse and longitudinal). The longest dimension in each plane should be given, as well as a third measurement perpendicular to either of the first two. If the maximum dimension is on a plane oblique to the standard orientation used, it also should be recorded.

10. As for all radiographic imaging, interpreting physicians are responsible for assessing image quality. Facilities should have policies and protocols for remediating technically inadequate studies.

11. When whole-breast ultrasound is used for cancer staging, the regional lymph node basins can be assessed sonographically. This could include the axilla, infraclavicular and supraclavicular regions, lower cervical region, and the internal mammary chain. The decision to evaluate the axilla preoperatively with ultrasound varies by practice, and consensus between the radiologists, medical oncologists, and breast surgeons is beneficial for optimal patient management.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [21].

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Images should be recorded in a retrievable and reviewable image storage format. Retention of the ultrasound examination images should be based on clinical need and in accordance with relevant legal and local health care facility requirements.

A whole-breast handheld ultrasound screening examination should document with archived images at minimum each of the four quadrants and the subareolar region [22]. The axilla may be included per facility practice and as per examination indication.

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: the indication, specifically whether the examination was performed for screening or diagnostic purposes, and the areas scanned. Any findings should be described by location, applicable descriptors, and measurements, if appropriate. The use of an accepted reporting system such as BI-RADS US is recommended.

VI. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [23].

Breast ultrasound should be performed with a high-resolution, real-time, linear-array, broad-bandwidth transducer operating at a center frequency of at least 12 MHz,and preferably higher. Automated whole-breast ultrasound may be performed with a dedicated system that has been cleared by the Food and Drug Administration (FDA). Focal zones should be electronically adjustable. In general, the highest frequency capable of adequate penetration to the depth of interest should be used.

VII. 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 (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

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