



Standard for the Performance of Breast Ultrasound Examination

Approved in October 2003

The standards of the Canadian Association of Radiologists (CAR) are not rules, but are guidelines that attempt to define principles of practice that should generally produce radiological care. The physician and medical high-quality physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to CAR standards will not assure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.

I. INTRODUCTION

These standards have been developed to provide assistance to practitioners performing ultrasound examinations and are based on the standards published by the American College of Radiology and the American Institute of Ultrasound in Medicine. In some cases, additional and/or specialized examinations may be necessary. While it is not possible to detect every abnormality, adherence to the following standards will maximize the probability of detecting most of the abnormalities that occur.

Diagnostic Ultrasound is an established, effective, diagnostic imaging technique which employs the use of high frequency ultrasound waves for both Imaging and Doppler examinations.

Extensive experience has shown that ultrasound is a safe and effective diagnostic procedure. While no demonstrable harmful effects of ultrasound have been demonstrated at power levels used for diagnostic studies, quality assurance dictates it is necessary to utilize this imaging technique in the most appropriate and indicated fashion, and that studies be performed by qualified and knowledgeable physicians and/or sonographers using appropriate equipment and techniques. Diagnostic ultrasound examinations should be supervised and interpreted by trained and credentialed physician imaging specialists.

II. INDICATIONS

Appropriate indications for breast sonography include:

1. Identification and characterization of palpable and nonpalpable abnormalities and further evaluation of clinical and mammographic findings.
2. Guidance of interventional procedures.
3. Evaluation of problems associated with breast implants.
4. Treatment planning for radiation therapy.

Breast sonography is the initial imaging technique to evaluate palpable masses in women under 30 and in lactating and pregnant women.

Although the efficacy of ultrasound as a screening study for occult masses is an area for research at the current time, ultrasound is not indicated as a screening study for microcalcifications.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. SONOLOGIST'S CREDENTIALS CRITERIA

Physicians involved in the performance, supervision and interpretation of ultrasonography should be Diagnostic Radiologists and must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Also

acceptable are equivalent foreign Radiologist qualifications if the Radiologist is certified by a recognized certifying body and holds a valid provincial license.

As new imaging modalities and interventional techniques are developed additional clinical training, under supervision and with proper documentation, should be obtained before radiologists interpret or perform such examinations or procedures independently. Such additional training must meet with pertinent provincial/regional regulations. Continuing professional development must meet with the requirements of the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

B. SONOGRAPHER'S CREDENTIALS CRITERIA

Sonographers should be graduates of an accredited School of Sonography or have obtained certification by the American Registry of Diagnostic Medical Sonographers (ARDMS) or the Canadian Association of Registered Diagnostic Ultrasound Professionals (CARDUP). They should be members of their national or provincial professional organization. Continuing medical education should be mandatory consistent with the requirements of ARDMS or CARDUP.

CARDUP will have a national exam process for sonographers in place by 2004. At that time this will become the accepted standard for sonographers. As an interim measure, individual consideration of training and qualifications by a Task Force consisting of members of relevant societies can be recommended for all those whose training does not fall within appropriate guidelines.

C. SUPERVISION AND INTERPRETATION OF ULTRASOUND EXAMINATIONS

A sonologist must be available for consultation with the sonographer on a case by case basis. Ideally the sonologist should be on site and available to participate actively in the ultrasound examination when required.

It is recognized however that the geographic realities in Canada do not permit the presence of an on-site sonologist in all locations. Adequate documentation of each examination is critical. A videotape record may be useful as an adjunct to the hard copy images in difficult cases. Despite the geographic isolation of a community the reports must be timely. Furthermore, the sonologist must be available by telephone for consultation with the sonographer and the referring physician. The sonologist should visit the facility on a regular basis to provide on site review of ultrasound procedures and sonographer supervision.

IV. SPECIFICATIONS OF THE EXAMINATION

A. Lesion Characterization and Technical Factors

1. The breast sonogram should be correlated with mammographic and other appropriate breast imaging studies as well as with physical examination directed to the area in question. 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 two perpendicular projections; one view is insufficient.

2. At least one set of images of a lesion should be obtained without calipers. The maximal dimensions of a mass should be recorded in at least two dimensions.

3. The images should be labeled as to right or left breast, the lesion's location, and the orientation of the transducer with respect to the breast (e.g., transverse or longitudinal, radial or anti-radial). The location of the lesion should be recorded; the quadrant should be specified or the location can be indicated by using clock notation and distance from the nipple, or shown on a diagram of the breast.

Several sonographic features may be helpful in characterizing breast masses. These features should be noted: size, shape, echogenicity, margin features, orientation, and attenuation (e.g., shadowing or enhancement).

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

Breast ultrasound should be performed with a high-resolution scanner (Section VI). Proper gain settings and focal zone selections 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 superficial lesions, a stand off device may be helpful.

B. Guidance of Interventional Procedures (see CAR Standard for 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.

V. DOCUMENTATION

Images of all important findings, including, in the case of interventional procedures, the relationship of the needle to the lesion, should be recorded on a retrievable and reviewable image storage format.

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

1. The facility name and location.
2. Examination date.
3. Patient's first and last name.
4. Identification number and/or date of birth.
5. Anatomic location using quadrant, clock notation, or labeled diagram of the breast. Indication of the distance of the abnormality from the nipple also may be helpful.
6. Sonographer's or sonologist's identification number, initials, or other symbol.

B. The physician's report of the ultrasonographic findings should be placed in the patient's medical record.

C. Retention of the breast ultrasonographic images should be consistent with the policies for retention of mammograms, in compliance with federal and provincial regulations, local health care facility procedures, and clinical need.

D. Reporting should be in accordance with CAR Standard for Communication: Diagnostic Radiology.

VI. EQUIPMENT SPECIFICATIONS

Breast ultrasound should be performed with a high-resolution and real-time linear array scanner operating at a center frequency of at least 7 MHz. Equipment permitting electronic adjustment of focal zone(s) is recommended. In general, the highest frequency capable of adequate penetration to the depth of interest should be used. For evaluation of superficial lesions, a stand off device may be helpful.

VII. QUALITY IMPROVEMENT PROGRAMS

Procedures should be systematically monitored and evaluated as part of the overall quality improvement program of the facility. Monitoring should include the evaluation of the accuracy of interpretation as well as the appropriateness of the examination.

Incidence of complications and adverse reactions should be recorded and periodically reviewed in order to identify opportunities to improve patient care.

Data should be collected in a manner which complies with the statutory and regulatory peer review procedures in order to protect confidentiality of the peer review data.

REFERENCES

1. Bassett LW, Kimme-Smith C. Breast sonography. *AJR* 1991; 156:449-455.
2. Feig SA. The role of ultrasound in a breast imaging center. *Semin Ultrasound CT MR* 1989; 10:90-105.
3. Fornage BD. Ultrasonography of the breast. *Ultrasound Quarterly* 1993; 11:1-39.
4. Fornage BD, Sneige N, Faroux MJ, et al. Sonographic appearance and ultrasound-guided fine-needle

- aspiration biopsy of breast carcinomas smaller than 1 cm 3 . J Ultrasound Med 1990; 9:559-568.
5. Hilton SV, Leopold GR, Olson LK, et al. Real-time breast sonography: application in 300 consecutive patients. AJR 1986; 147:479-486.
 6. Jackson VP. Breast sonography. In: Bassett LW, Jackson VP, Jahan R, et al, eds. Diagnosis of the diseases of the breast. Philadelphia, Pa: WB Saunders, 1997:185-196.
 7. Jackson VP. The role of ultrasound in breast imaging. Radiology 1990; 177:305-311.
 8. Mendelson EB. Breast ultrasound. In: Rumack CM, Wilson RI, Charboneau JW, eds. Diagnostic ultrasound. 2nd ed., vol. 1. St. Louis, Mo: Mosby-Yearbook, 1998:751-789.
 9. Parker SH, Dennis MA. Ultrasound-guided large-core breast biopsy. In: Parker SH, Jobe WE, eds. Percutaneous breast biopsy. New York, NY: Raven Press, 1993:147-163.
 10. Parker SH, Jobe WE, Dennis MA, et al. US-guided automated large-core breast biopsy. Radiology 1993; 187:507-511.
 11. Parker SH, Stavros AT. Interventional breast ultrasound. In: Parker SH, Jobe WE, eds. Percutaneous breast biopsy. New York, NY: Raven Press, 1993:129-146.
 12. Rubin E, Miller VE, Berland LL, et al. Hand-held real-time breast sonography. AJR 1985; 144:623-627.
 13. Sickles EA. Periodic mammographic follow-up of probably benign lesions: results in 3,184 consecutive cases. Radiology 1991; 179:463-468.
 14. Stavros AT, Thickman D, Rapp CL, et al. Solid breast nodules: use of sonography to distinguish between benign and malignant lesions. Radiology 1995; 196:123-134.