CAR Practice Guidelines on

Breast Imaging and Interventions

Preamble

The practice guidelines 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 radiologist and medical physicist may modify an existing practice guideline as determined by the individual patient and available resources. Adherence to CAR practice guidelines will not assure a successful outcome in every situation. The practice guidelines 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 practice guidelines are not intended to establish a legal standard of care or conduct, and deviation from a practice guideline 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.

Introduction

The Canadian Association of Radiologists Breast Imaging Working Group developed these guidelines to present the best practices at the time of publication. This version updates the previous guidance contained in the CAR Breast Imaging and Intervention Guideline published in 2016, and complements the recently published Breast Disease Imaging Referral Guidelines, which provide guidance on the most appropriate breast imaging test for a given indication or patient population.[1]

These guidelines aim to provide radiologists, technologists, and other allied staff with a consensus-based approach to performing and interpreting breast imaging. These recommendations align with those published by the Canadian and American Cancer Societies, the National Comprehensive Cancer Network and the American College of Radiology. While the guidelines serve as an educational tool and outline best practices and minimum requirements, the Working Group acknowledges that alternative actions may be appropriate depending on available resources, patient factors, technological advances and evolving medical knowledge.

Ultimately, the supervising radiologist is responsible for determining the most appropriate examination or intervention for each patient.

Mammography

Digital mammography (DM) is used in both screening and diagnostic settings. Digital mammography is the gold standard for breast cancer screening.[2,3] Digital breast tomosynthesis is a well-established technology used in both screening and diagnostic settings and to guide procedures.[4]

The CAR Breast Disease Refjerral Guidelines detail the appropriate breast imaging modalities for various clinical situations, including screening mammography, diagnostic mammography, and tomosynthesis.[1]

Screening Mammography

The goal of mammography screening is to reduce breast cancer mortality by the diagnosis of breast cancer at an earlier stage, which also allows for more treatment options with less treatment-related morbidity. The screening examination can be performed without a radiologist in attendance. Screening mammography does not detect all breast cancers; therefore, any patient with clinical breast symptoms that could indicate underlying malignancy should be evaluated with diagnostic breast imaging. Providers are advised to consult the CAR Referral Guidelines for indications for diagnostic breast imaging.[1]

Diagnostic Mammography

Diagnostic mammographic evaluation is a comprehensive imaging evaluation of a symptomatic patient, a patient with an abnormal screening mammogram or other breast imaging or follow up of a mammographic finding. Patients with a personal history of breast cancer, those with augmented or reconstructed breasts, or asymptomatic post-cancer surveillance patients should receive diagnostic evaluation if they are not eligible for an organized screening program.[1] The mammogram should be correlated with the known physical findings and/or symptoms.

If a patient reports a clinical issue during a screening mammogram, it should be noted by the technologist and the information made available to the radiologist. When patients present with symptoms or for a screening mammography recall, the diagnostic mammogram should be customized by the supervising radiologist.

A radiologist must be available for consultation with the mammography technologist on a case-by-case basis. Ideally, the radiologist should be on site and available for supervision of the case and synchronous review of the images. The geographic realities in Canada may not permit the presence of an on-site supervising radiologist in all locations. If a radiologist cannot be available onsite, remote supervision via teleradiology may be utilized. A diagnostic evaluation is performed to assess the patient with an abnormal screening mammogram or clinical finding. During a diagnostic workup, the priority is a timely diagnosis. To support this, delays or protracted investigations should be avoided. Consideration should also be given to cost and radiation dose, following ALARA principles.[5,6]

Equipment

Equipment Specifications

The mammogram must be performed only on dedicated mammography equipment with an adequate compression device and a removable grid. Licensing from appropriate provincial and federal authorities/regulators is in place for each unit upon installation and before patient examinations take place. The facility is responsible for attaining licensing from the appropriate regulators (provincial or otherwise) as soon as installation takes place and before the unit is used for patient examinations. Further, the **Canadian Association of Radiologists' Mammography Accreditation Program (CAR MAP)** will only accredit facilities using equipment that holds an appropriate Canadian medical device license.*

The mammography unit must be evaluated at the time of installation before any patients are scheduled for mammography exams. A qualified mammographic medical physicist must verify the performance. All corrective actions required on non-compliant tests must be addressed before any mammograms are performed. The unit must then be checked at least annually or more frequently if required by provincial legislation.

* A searchable list of all actively licensed medical devices is also available at www.mdall.ca.

Compression devices should be designed to improve contrast, minimize radiographic scatter, ensure uniform density, and reduce dose and subject motion. Digital mammography systems may use various anode target materials, including filters of molybdenum, rhodium, aluminum or silver.

The focal spot size of the X-ray tube should be 0.3 mm for contact mammography and 0.1mm for magnification mammography. The focus-to-receptor distance for contact mammography should be 50 cm or more.

The physicist report must be approved and signed by a medical physicist certified in mammography by the Canadian College of Physicists in Medicine (CCPM) or its equivalent. Copies of maintenance and/or service reports should be kept for a minimum of three (3) years. A procedure manual and an adequately documented log of the tests performed as part of the quality control (QC) program must be maintained.

Workstation Specifications

- Facilities must use an IHE mammography image profile compliant review workstation with at minimum two 5-megapixel monitors or one 8 or larger megapixel widescreen display, with appropriate software.[7–9]
- All mammography workstations, including those used at home, require annual assessment by a medical physicist.
- Conduct regular assessments to ensure ongoing compliance with CAR Mammography Accreditation Program (CAR-MAP) requirements.

Radiation Dose

The average glandular dose for the standard breast must be determined at least annually. The average glandular dose cannot exceed 3 mGy for a CC projection. The standard breast is represented by a 4.0 cm thick PMMA phantom which attenuates similarly to a 4.5 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue.[10]

Radiation Protection

Aprons and collars are not routinely required.[5,11] Moreover, shielding in pregnancy is not recommended.[12–14]

Specifications of the Examination

Projections

The examination should include craniocaudal and mediolateral oblique projections of each breast. In diagnostic scenarios, additional views (spot magnification views, true lateral, spot compression view, or any other special view with the correlative 2-D DM or SM views) may be required to visualize breast tissue adequately. When a mammographic abnormality prompting further investigation exists, the patient is referred for additional imaging studies and/or biopsy.

Comparison with previous images

Where possible, correlation with previous studies is required. The report should include the availability of prior studies (or lack thereof).

Evaluation of Patients with Implants

Implants are not a contraindication for mammography and breast evaluation should follow the same protocol as those without implants.[15] In addition to standard views, implant displaced views are required for complete evaluation of the breast.[16] If displacement views cannot be performed due to immobility of the implant, 90-degree lateral images should be added to the standard views. Image labeling should conform to the specifications previously cited for screening mammography.

Image Labelling

Adequate documentation of the study is essential. The digital mammography image acquisition system must automatically transfer critical information to the stored DICOM image.

Systems must provide all the information fields listed below, ideally without additional manual entry by the operator. The DICOM header should contain the following tags:

- Facility Name
- Acquisition Date
- Acquisition Time
- Facility Address
- Station Name
- Operator Initials (or ID number)
- Patient's First and Last Names
- Patient ID and/or Date of Birth
- kV
- Exposure Time and X-ray Tube Current (mAs)

- Anode Target Material
- Filter Material
- View Position
- Patient Orientation
- Image Laterality
- Numerical mammography unit identification.

The MRT will use a monitor to ensure that the images are of diagnostic quality prior to image interpretation by a radiologist. One monitor must be available solely for technologists, with a recommended resolution of 3 megapixels.

Viewing conditions

Contrast is extremely important in the mammographic image and is degraded by extraneous light. Digital monitors should be maintained at adequate luminance, according to manufacturer specifications.

Mobile Screening

Screening mammography may be performed in nontraditional settings where a radiologist is not present. The examination must follow the standards and guidelines cited here as documented protocols.

The MRT should work under the same rules, whether in a fixed or mobile setting. Where practical, the facility supervising radiologist or an appropriately qualified delegate should be available for consultation and should visit the facility to observe the performance of mammograms and ensure that safe operating procedures are followed.

The supervising radiologist, or qualified delegate, should review the quality control documentation, and a log of these visits must be maintained.

Double Reading

Double reading of mammograms is performed when using two separate mammographers to interpret a single mammogram. It is shown to increase the sensitivity with a mild decrease in specificity, although this may be improved with arbitration.[17] It is used in some settings but is limited by cost and staffing limitations.

CAD and Artificial Intelligence

CAD

Computer-assisted detection or computer-aided diagnosis (CAD) was developed to overcome some of the practical limitations of double reading. The use of CAD in isolation is not recommended as it has been shown to reduce to specificity of screening mammography with no increase in sensitivity.

Artificial Intelligence

Artificial intelligence (AI) for applications in breast imaging have progressed from pilot and feasibility studies to clinical implementation, and the field is rapidly evolving.[18] AI has been shown to increase the accuracy of screening when employed as a second read, reducing false positives while increasing sensitivity.[19,20] Studies have also demonstrated that improved efficiency and accuracy can be achieved in clinical practice with the concurrent use of effective AI systems.[21] Newer systems embedding deep learning and machine learning algorithms into CAD systems are in development.[22–26]

Reporting

Basic Requirements

The report should follow standard BI-RADS® reporting guidelines.[27] Prior imaging for comparison should be noted. All areas of clinical or radiologic concern should be described in the report and imaging findings described using BI-RADS® descriptors and correlated with prior imaging if applicable. Reports should include, at minimum:

- Indication
- Comparison
- Breast density using ACR descriptors.
- Management of described findings
- BI-RADS® score.

Considerations for Screening Mammography

A small percentage of screening exams will be reported as abnormal. In these cases, the radiologist will recommend further diagnostic workup. Correlating the current study with any previous imaging is essential, where possible, and the availability (or lack) of prior studies should be mentioned. The report should describe any abnormalities detected and recommend the necessary diagnostic work-up. For abnormalities highly suggestive of malignancy, direct communication with the referring healthcare professional in a manner that ensures receipt and documentation of the reports, such as by telephone, fax or registered mail, is advised. In an organized screening program, communication

of abnormal results may be handled by a program nurse navigator.

After interpretation, there should be a BI-RADS® assessment and a recommendation for further investigation or continued screening.

Considerations for Diagnostic Mammography

The report should establish a level of suspicion based upon the imaging findings conveyed by the BI-RADS® final assessment category and provide specific recommendations for patient management. Screening recommendations may be included. For abnormalities highly suggestive of malignancy, direct communication with the referring healthcare professional in a manner that ensures receipt and documentation of the reports, such as by telephone, fax or registered mail, is advised.

Tomosynthesis

Digital Breast Tomosynthesis (DBT), often referred to as "three-dimensional" (3D) mammography, is a technique that creates multiple contiguous slices of the breasts reconstructed from several digital mammographic images taken at different angles.[28] The slice thickness can be adjusted depending on the vendor and software used. Images are obtained in the same plane as the original compression plane and are read as planar images. Synthetic views are two-dimensional (2D) projection images reconstructed from the information acquired during DBT data acquisition.

DBT diminishes the effects of overlapping tissue by displaying one thin section of tissue at a time. It has proven valuable for detecting and evaluating focal asymmetries, architectural distortion and some apparent masses.[28] DBT is equal to, or better than, coned compression views for investigating 2D mammographically detected abnormalities.[29–31] Most studies have demonstrated no statistically significant difference in the detection of calcifications on DBT when compared with 2D DM.[32] Studies comparing DBT with 2D DM for patients recalled due to a questioned abnormality detected on routine mammography showed significantly improved specificity with DBT.[33] In screening, DBT has shown the potential to decrease false-positive recalls compared to 2D DM in screening settings.[34–36]

The radiation dose for a single DBT projection is similar to, or slightly higher than that of a single conventional mammographic image but well within acceptable dose limits.[37,38] In 2014, the FDA approved synthesized views from DBT to replace 2D DM. Using synthetic view rather than obtaining a direct digital mammogram decreases the dose associated with a DBT examination to a level similar to a standard digital mammogram. Several DBT systems are approved by Health Canada.

Indications

Screening

DBT is being introduced as a screening tool worldwide.[4,39–42] Large prospective and retrospective screening trial results have demonstrated improved cancer detection rates by up to 2.7 per 1000 and decreased callback rates of 15-17%.[35,43] The TMIST trial, a large Phase 3 randomized control trial, has enrolled over 100,000 patients across 30 sites, including 7 Canadian sites. The trial (TMIST) is comparing 2D-DM combined with DBT against 2D-DM alone.[44] The study is designed to investigate whether 2D-DM+DBT affects the screening population and whether it detects lethal cancers (advanced cancers or small cancers with aggressive markers). Many secondary aims, including recall rates, are being addressed.[45]

Diagnostic

When investigating findings from 2D screening, full view tomosynthesis is considered superior to spot tomosynthesis.[46,47] This suggests that a comprehensive DBT scan of the entire breast provides more useful diagnostic information than focused images of specific areas. When working up full view tomosynthesis findings, ultrasound may be the first choice, especially for mass-like findings. However, spot tomosynthesis may be useful, particularly in areas of subtle architectural distortion. These distortions can be challenging to visualize on ultrasound, making focused DBT images valuable in these cases.

MRI-directed "second look"

Second look ultrasound plus DBT found 75% of MRI-detected additional findings (52% and 50% for ultrasound alone and DBT alone, respectively).[48]

Equipment

Mammography equipment used for tomosynthesis should adhere *to* the same specifications as detailed above. All units must comply with local and provincial regulatory statutes.

Specifications of the DBT Examination

Synthetic mammography (SM) is intended to replace to 2D DM component of the DBT examination, eliminating the patient's radiation exposure from those views. SM is an acceptable alternative to 2D DM only when viewed in conjunction with the tomosynthesis image stack. Tomosynthesis should be obtained of both the CC and MLO view.

If tomosynthesis imaging is used in patients with implants, only the implant displaced views should be performed as tomosynthesis images. The standard views should be done as 2D digital mammography.

For individuals with large breast size: DBT should not be used for every image in the case of tiled views. Tomosynthesis should be obtained of both the CC view and MLO view that demonstrates most of the breast tissue in each breast, with the remaining tiled views obtained as 2D images.

Reporting

- DBT mammography reporting should follow the same standards as for 2D mammography.
- Include relevant DBT-specific descriptors in reports to accurately convey the nature of identified abnormalities.
- Where synthetic views are used without the addition of 2D imaging,[35,49] it is mandatory to review the tomosynthesis stack. Synthetic views must not be used independently.[50]

Clinical Practice Recommendations

- When DBT is used for either screening or diagnostic purposes, access to advanced breast imaging is essential. These may include tomosynthesis-guided biopsy, ultrasound and/or breast MRI. This ensures that subtle lesions not visible on standard 2D mammography can be properly biopsied.[51]
- Synthetic views may underestimate the suspicious morphology of some calcifications, thus use of 2D magnification spot compression views is strongly recommended for any new or indeterminate calcifications.[50]

Challenges to Implementation

Challenges to the implementation of DBT at the time of writing include, but are not limited to:[52]

- Interpretation time is at least 1.5 times to double that of routine 2D DM.[53,54]
- Protocols optimizing diagnostic accuracy, quality assurance, radiation dose and workflow have yet to be fully standardized. In particular, the CAR Mammography Accreditation Program (MAP) has not finalized an accreditation protocol specific to tomosynthesis at the time of writing.
- DBT has large digital storage requirements. The tomosynthesis stack and synthetic images must be stored. If 2D DM are performed in addition to tomosynthesis they must also be stored.
    - Future advances in data compression, storage costs, synthetic view image quality, and additional evidence of the safety of synthetic-view-only comparison may modify this recommendation.
- Although screening outcome benchmarks are improved with the use of DBT, longitudinal outcomes are unknown.

Additional Qualifications and Responsibilities of Personnel

In addition to standard mammography requirements, it is recommended that radiologists obtain an initial 8 hours of specific tomosynthesis training as per the ACR requirement, unless the radiologist was trained in tomosynthesis imaging during residency or fellowship.

Technologists and medical physicists should obtain appropriate training as available.

Personnel Requirements

Radiologist

Radiologists involved in the performance, supervision and interpretation of breast imaging 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. Equivalent foreign radiologist qualifications are also acceptable if the radiologist is certified by a recognized certifying body and holds a valid provincial license.

Before interpreting or performing new imaging modalities and interventional techniques independently, radiologists should obtain additional clinical training under supervision, with proper documentation, which must comply with

pertinent provincial/regional regulations. Continuing professional development must fulfill the Maintenance of Certification Program requirements of the Royal College of Physicians and Surgeons of Canada. Radiologists interpreting mammography should adhere to the CAR MAP requirements. For further information, please contact the CAR MAP directly.

In addition to standard mammography requirements, it is strongly recommended that radiologists willing to initiate reporting digital breast tomosynthesis (DBT) participate in an initial 8 hours of training specific to DBT. If radiologists had regular DBT training in residency or fellowship, or have been using it in regular practice, an extra 8 hours of dedicated DBT training is not required if appropriate ongoing practice maintenance is achieved.

Medical Radiation Technologist

Medical radiation technologists (MRTs) performing mammography must have Canadian Association of Medical Radiation Technologist (CAMRT) Certification or be certified by an equivalent recognized licensing body.

Under the overall supervision of the radiologist, the MRT will have the responsibility for patient comfort and safety, examination preparation and performance, image technical evaluation and quality, and applicable quality assurance. The MRT should receive regular feedback on image quality from the interpreting radiologists and lead technologists. Facilities should encourage technologist QA programs, including systematic reviews. The MRTs' training in specialty activities must meet the applicable provincial and national specialty qualifications. MRTs must receive mammography training either as part of their core curriculum or through special courses and must perform mammography regularly. The CAMRT encourages continued professional development in breast imaging, which should meet pertinent provincial and CAR MAP requirements.

Medical Physicist

A medical physicist must take responsibility for the initial acceptance testing, and for conducting and overseeing quality control testing of the mammographic unit and viewing chain for digital imaging.

The medical physicist shall have a graduate degree and be certified by the Canadian College of Physicists in Medicine (CCPM) in the specialty of Mammography, or its equivalent, or any relevant provincial or territorial license.

Training and experience shall include knowledge of the physics of mammography, systems components and performance, safety procedures, acceptance testing, quality control and CAR MAP requirements.

For more specific information about medical physicist responsibilities, please refer to the individual modality sections within this document.

Information Systems Specialist

An Information Systems Specialist (ISS) is required by facilities performing digital imaging. This individual must be either on site or available upon request. He/ she must be trained and experienced in installation, maintenance and quality control of information technology software and hardware. The required qualifications of this individual will depend highly on the type of facility and the type of equipment.

The ISS should possess any relevant qualifications required by federal/provincial/territorial regulations and statutes and should be certified according to a recognized standard such as that of the Society of Imaging Informatics in Medicine or the PACS Administrators Registry and Certification Association. Expertise should include computer and database basics, networking concepts (such as DICOM, HL7, RIS and HIS), security systems, medical imaging terminology, positioning and viewing characteristics, imaging characteristics of various modalities for image acquisition, transmission and storage, and facility workflow. The ISS should also be knowledgeable about federal, provincial, territorial and institutional privacy legislation and policies, such as the Personal Information Protection and Electronic Documents Act (PIPEDA).

Responsibilities include ensuring patient record confidentiality, understanding facility policies and procedures, and the importance and requirements of an information systems quality assurance program. They also include communicating any changes/upgrades to staff and the resulting operational impacts.

Quality Control

A documented quality control program with procedure manuals and logs should be maintained in accordance with

the CAR Mammography Accreditation Program's quality control specifications.[†]

Radiologist

If the radiologist identifies quality control-related issues or artifacts, they will provide feedback to the MRT/lead technologist.

Technologist

The medical radiation technologist will be responsible for routine tests, including quality control, digital reader cleanliness, monitors and viewing conditions, phantom images, artifact testing, visual checklist, repeat analysis, and compression.

Medical Physicist

The medical physicist will be responsible for the mammographic unit evaluation, collimation assessment, focal spot size and/or resolution measurements, beam quality assessment (half-value layer measurements), automatic exposure control system performance assessment, uniformity of screen speed entrance exposure, average glandular dose, and artifact evaluation.

Image Retention

The facility should retain original mammogram data and make it available to the patient in accordance with the provincial regulations in which testing is being performed. Mammograms must be retained for a statutory period consistent with clinical needs and relevant legal and local health care facility requirements.

Digital mammography images must have absolutely no lossy compression. Images sent to other facilities should be sent via media or electronically with non-proprietary lossless compression so that they can be displayed on the consulting physician's IHE-compliant workstation.

Quality Assurance

Comprehensive systems should be established to review outcome data from mammography. At a minimum, these systems should collect the following data:

- Date range of audit.
- Total number of exams performed.
- Number of BI-RADS®0, 4 and 5 cases and biopsy results of all BI-RADS® 4 and 5 cases. Data should include tumour size, nodal status, histologic type, and grade.
- Screening data should be distinguished from diagnostic data.
- Where possible, records of false-negative mammograms should be collected, and the cases analyzed.
- Cross references should be made with the provincial cancer registry.
- Performance should be correlated against established benchmarks.[55–60]

[†] Please contact a CAR MAP coordinator to receive a copy of the Quality Control Checklists.

Contrast-Enhanced Mammography

General Principles

The introduction of full-field digital mammography (FFDM) enabled the use of contrast-enhanced mammography (CEM), an iodine-based modified 2-dimensional (2D) digital mammography (DM) exam, which, like contrast-enhanced Magnetic Resonance Imaging (MRI), relies on tumor angiogenesis.[61] The current standard CEM utilizes upgraded standard mammography equipment, which enables the performing of dual-energy imaging.

These guidelines include the current applications of CEM, as well as fundamental requirements for CEM in clinical practice.

Indications

CEM is primarily used in the diagnostic setting and has shown high sensitivity, particularly with dense breasts.[62–64] Therefore, if it is estimated that enhancement information would be useful, it is legitimate to first implement CEM as an alternative to MRI or even in other diagnostic settings when MRI would not be considered due to access or patient limitations.[62–72]

Diagnostic setting

CEM may be performed along with additional studies, including but not limited to magnification views and breast sonography.

Examples:

- Evaluation of recalls from abnormal mammogram and problem-solving
- Breast symptoms
- Pre-operative staging: to assess the extent of disease in the affected breast and to screen for occult contralateral malignancy
- Occult breast cancer: to determine the site of a primary carcinoma in a patient presenting with metastatic breast carcinoma such as axillary lymphadenopathy or other site of bony or body metastases
- Monitoring response to treatment
- Intervention: to guide biopsy or localization procedures
- Short interval follow-up.

Screening setting

MRI is the modality of choice for supplementary screening for breast cancer in high-risk populations. The use of CEM in screening individuals with dense breasts or at intermediate risk for breast cancer has been investigated by several studies,[73–76] showing an overall high cancer detection rate when CEM was used in place of conventional DM in patients with a personal history or intermediate lifetime risk. When there is limited access to MRI or if MRI cannot be tolerated, CEM can be offered instead.

The use of CEM in screening high-risk populations was only investigated in a small number of patients.[77,78] Until further data becomes available, CEM cannot be offered as a replacement for MRI in the high-risk screening setting, especially in the scenario of BRCA mutation, where there is likely an increased risk of radiation-induced carcinogenesis.[79] However, if the patient cannot tolerate an MRI procedure, CEM can be offered as an alternative to supplementary screening ultrasound in non-BRCA high-risk patients. The best workflow for the patient needs to be discussed with the patient and the regional cancer care program representative.

Contraindications

The most significant challenge of CEM relates to the administration of Iodinated contrast and the risk of allergic reactions or, very seldom, contrast-associated acute kidney injury (AKI).[80]

For patients at risk for renal failure, evaluation of renal function is required prior to the performance of CEM following the same standard practice for Contrast Enhanced Computed Tomography (CE-CT).[81] In general, the risk for AKI is only important in patients with severe underlying chronic kidney disease (CKD) with an eGFR $\leq$ 30 mL/min/1.73m2, those with AKI, and/or those receiving a high volume of contrast especially through the arterial route. For more details, see recent CAR recommendations on contrast associated acute kidney injury.[82]

Adverse reactions to low-osmolality iodine agents can occur in 1-3% of patients and are often mild and self-limiting.[78] However, more severe reactions can occur in approximately 0.2-0.7% of the cases.[78] CEM procedure must be therefore supervised by a clinician who is trained to treat patients with allergic reaction.

It is generally recommended not to premedicate patients with a history of allergic reactions given the availability of alternatives such as MRI.

Qualifications and Responsibilities of Personnel

The personnel standards for education and conduct are determined by the unique demands of mammography practice, see the personnel requirements in the Mammography section above. Additional criteria are unique to CEM.

Radiologist

A CEM accreditation program is not currently available in Canada. However, the interpreting radiologist should practice and possess knowledge of imaging and diagnosis of breast disease. As new imaging modalities and interventional techniques are developed, additional clinical training should be obtained before radiologists independently interpret or perform such examinations or procedures. Continuing professional development must meet the Maintenance of Certification Program requirements of the Royal College of Physicians and Surgeons of Canada. The supervising radiologist should be familiar with the safety policies of appropriate iodine contrast use and treatment of adverse allergic reactions.

Technologist

The technologist is primarily responsible for performing the CEM and maintaining the overall safety of patients, staff and equipment. This includes careful screening for potential contrast iodine contraindications, ensuring patient comfort, adequate contrast delivery and adjustment of protocols (if required) to produce a high-quality exam.

As radiopaque devices to mark a palpable abnormality should be avoided with CEM, both the MRT and supervising radiologist should be aware of any sites of clinical concern to ensure adequate interpretation.

Medical Physicist

A medical physicist must take responsibility for the initial acceptance testing and for conducting and overseeing quality control testing of the dual-energy component. The medical physicist shall have a graduate degree and be certified by the Canadian College of Physicists in Medicine (CCPM) in the specialty of Mammography or its equivalent or any relevant provincial/territorial license. Please visit www.ccpm.ca for further information. Training and experience shall include knowledge of the physics of mammography, systems components and performance, safety procedures, acceptance testing, quality control and CAR MAP requirements.

Equipment

The same specifications for equipment and its use apply to screening and diagnostic mammography. However, for CEM, additional software capability and copper filter which will allow performing paired low-energy (23–32 kVp) and high-energy (45–49 kVp)[62–64] images for every view.

Radiation dose

Although CEM examination exposes the patient to a radiation approximately 30% higher than that of DM and Digital Breast Tomosynthesis (DBT), it should remain within the range of radiation doses patients receive for other common mammographic examinations[83–85] and the average glandular dose cannot exceed 3 mGy for a CC projection.

Radiation protection

Radiation protection is not mandatory to be used for patients who are pregnant and require urgent mammographic assessment.

Specifications of the Examination

In addition to the examination specifications for screening and diagnostic mammography, there are specifications unique to CEM.

- The study begins with an Intravenous (IV) injection of non-ionic low-osmolar iodinated contrast material with a concentration of 300-350 mg/ml, using a power injector, at a standard dose of 1.5 mL/kg, at a rate of 2.5-3 mL/s, through a 20-gauge cannula size, before any compression is applied.[62–64,81,86,87]
- Two minutes after the start of the injection, the breast is placed into compression. Low-energy (LE) and high-energy (HE) images are generated for each standard craniocaudal (CC) and mediolateral oblique (MLO) views.[62–64,81,86,87]
- Recombined views (RC) are formed by subtracting the LE images from the HE images, which allows the cancellation of the signal from background breast tissue and only highlights areas of iodine uptake.[81,86,87]
- The image acquisition should be completed within 7 minutes of IV contrast administration.[81,86,87]
- If known, it is recommended that the first or second image will include the side of concern and at least one view of the contralateral breast will be included within

the 1st-3rd images,[81,86,87] although there is no consensus on the order of image acquisition,[62–64,81]

- If required, additional views can be obtained subsequently after 7 minutes. If a suspected lesion is not expected on the routine views, a replacing view should be included in the first or second images.[81,87]

Timing during the menstrual cycle appears to have minimal effect on the degree of background parenchymal enhancement at CEM.[81,86]

CEM is subject to a multitude of artifacts that are unique to CEM, some of which are due to inadequate positioning, abnormal timing to contrast bolus, or trapped air within skin folds.[81,86,87]

When used with breast implants, the CEM images may be hampered since the recombination will not work, specifically with the presence of silicone.[81,86,87] Therefore, dual-energy exposure should only be obtained in adequate implant displacement views.[81]

If the patient cannot tolerate adequate compression or displacement views cannot be performed due to the immobility of the implant, then CEM should be avoided.

Documentation

The same documentation required for screening and diagnostic mammography is also mandatory for CEM.

The Diagnostic Report

The CEM images that are eventually available for interpretation are the LE and the recombined images (RC). In 2022, the CEM lexicon guidelines were published as complementary to the ACR BI-RADS® 2013 edition.[88] Because CEM is composed of LE images comparable to standard mammography[89,90] the mammographic descriptors of the BI-RADS® terminology[91] is adapted. Breast composition should be assessed on the LE images and characterized using categories similar to conventional mammography.

The descriptors for enhancement are similar to MRI descriptors of the BI-RADS® terminology[92] with some minor changes that are unique for CEM. The presence of BPE of the normal breast tissue should be described similar to MRI.

Three major categories can be distinguished:

1. Findings on LE images only,
2. enhancement on RC images only,
3. findings seen on LE images with associated enhancement on RC images.

For lesions detected on both LE and RC views, a lesion measurement should include the total extent of the disease.

One must avoid the pitfall of dismissing a non-enhancing suspicious finding on LE images as benign. If an abnormality has suspicious features on LE images but not on recombined ones, it should still be considered suspicious.

Quality Control

Radiologist

In addition, the responsibilities of the supervising and interpreting radiologist include:

- Review and validation of the clinical indication for the examination
- CEM protocol
- Use and dose of contrast
- Ensuring a physician is available when contrast is given
- Ensuring that medical radiation technologists have adequate training and maintenance of competence, including intravenous injection.

Until the present moment, there are no qualification standards for CEM radiologists by the CAR or American College of Radiologists. Recommended qualifications are similar to those for MRI:

- Supervise/interpret/report ≥150 CEM examinations in the last 36 months
  OR
- Interpret/report ≥100 CEM examinations in the last 36 months in a supervised situation
- 15 hours CME in mammography and MRI.

The criteria evaluated in the program must include the establishment and maintenance by the facility of an outcomes audit program to follow up positive interpretations and correlate histopathology with the imaging findings.

Additional staff training is required to administer contrast material and manage contrast agent–related complications. Adopting the same institutional regulations in place for the practice of Contrast Enhanced Computer Tomography (CE-CT) is suggested.

Technologist

In addition to the standard mammography practice, the medical radiation technologist will be responsible for:

Ensuring routine cleanliness of the mammography device and removal of any spilled iodine contrast

Performing weekly checks of image uniformity and bad-pixel tests on the high-energy images (Mo/Cu, Rh/Cu)

Performing monthly checks of the automatic exposure control parameter selection for CEM and signal-to-noise ratio (SNR).

Physicist

In addition to the quality control requirements for the standard mammographic unit, a medical physicist must take responsibility for the initial acceptance testing and for conducting and overseeing quality control testing of the dual-energy capability as specified by the vendor. These include mammography equipment evaluation and annual check of:

- Image uniformity and bad-pixels test on the high energy images (Mo/Cu, Rh/Cu)
- Automatic exposure control parameter selection for CEM and SNR
- Artifact Evaluation, Flat Field Uniformity
- Breast Entrance Exposure, Average Glandular Dose, and Reproducibility
- Beam Quality Assessment (Half–value Layer Measurement in High Energy and Low-Energy Configuration.) It should be noted that the HVL at 49 kV should be larger than 2.5 mm for both Mo and Rh targets. Low energy is computed as in Standard mode.

Quality Assurance

The CAR has established an accreditation program for quality assurance of breast mammography that can serve as a guideline for a CEM practice (see quality control above) and must follow the CAR MAP's quality control.

Original images from previous studies should be made available for consultation and second opinion where practical.

Management and Biopsy

CEM should be practiced in a facility that has the capacity for mammography, ultrasound (US) and breast intervention, including contrast imaging-guided biopsy. In the instance that negative or benign findings (BI-RADS® category 1 or 2) cannot be determined based on CEM alone, a second-look ultrasound (US) is usually needed. If CEM determines a probably benign lesion, short-term follow-up with CEM is necessary.

Suspicious findings (BI-RADS® category 4 or 5) should be sampled by percutaneous or surgical biopsy.

US-guided biopsy is an ideal technique for tissue sampling that provides real-time imaging. In case of no US abnormality to correlate to an area of abnormal enhancement on CEM, even subtle LE findings such as a mass, microcalcifications, asymmetry or distortion can be targeted for stereotactic-guided biopsy. A stereotactic-guided biopsy is also required if the abnormality is better or only seen on the LE images. If the suspicious abnormality is visible on DBT, it could be used to guide tissue sampling. Otherwise, CEM-guided biopsy is the option to consider. If CEM-guided biopsy is not available, MRI-guided biopsy would be an alternative.

In the absence of CEM or MRI-guided biopsy, an agreement with a center that offers the procedure is mandatory.

CEM-guided biopsy can be also used to sample enhancing lesions detected by MRI, especially if access to MRI-guided biopsy is limited.[87,93,94] As with MRI, vacuum-assisted biopsy needle is the preferred method.[93,94]

Regardless of the modality used for the biopsy, a tissue marker should be placed following the biopsy, and post-procedure mammography should be obtained in two orthogonal views to document the tissue marker position in relation to the initial CEM exam. Non-standard mammographic views may be required depending on the location of the lesion.

Imaging-pathology correlation is required after tissue sampling of areas of enhancement,[81,93] regardless of where the biopsy is performed. They should also be tracked by the radiologist who recommended the biopsy.

Excisional biopsy should be considered for any discordant results. CEM-guided preoperative localization is required for lesions detected by RC views only. Lesions detected only by recombined views and concordant benign biopsy results must be followed up with a repeat CEM exam starting at six months, similar to MRI.[81,87,93]

Ultrasound

Breast ultrasound is an established, effective, diagnostic imaging technique which employs the use of high-frequency ultrasound waves for imaging, Doppler assessment, and elastography. Appropriate indications for breast ultrasound can be reviewed in the Canadian Association of Radiologists Breast Disease Imaging Referral Guideline.[1]

Any facility performing breast ultrasound, including screening and diagnostic examinations, must be able to perform mammography at the same facility. This ensures proper follow-up and complete evaluation of any findings.

Technical Considerations

Equipment

- Breast ultrasound should be performed with a high-resolution and real-time linear array scanner operating at a center frequency of at least 12 MHz, preferably higher, with pulsed, colour and power Doppler.
- Equipment permitting electronic adjustment of focal zone(s) is required.
- 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 or a thick layer of gel may be helpful.

Documentation

Images of all important findings should be recorded on a retrievable and reviewable image storage format. In the case of interventional procedures, this includes the relationship of the needle to the lesion. Images should also include the skin and the chest wall. The radiologist's report of the sonographic findings should be placed in the patient's medical record.

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

Permanent identification labels should contain:

- The facility name and location
- Examination date
- Patient's first and last name
- Identification number and/or date of birth
- Sonographer and/or radiologist initials or another identifier

Image Labelling for Findings of Interest

- Anatomic location including side (left/right)
- Orientation of transducer (radial/antiradial or transverse/sagittal)
- Clock face, including distance from the nipple.
- Quadrant.

Reporting

Reporting for all ultrasound examinations should follow a structured format. Reporting should be in accordance with the American College of Radiology (ACR) document Breast Imaging Reporting Data Systems (BI-RADS®).[27]

Report inclusions:

- Indication for examination
- Note comparisons to previous exams or other imaging modalities.
- Describe technique (e.g. handheld versus automated whole breast ultrasound (AWBUS) and screening versus diagnostic) and breast composition if screening study.
- Detail findings using standardized BI-RADS® descriptors.
- Mention any technical limitations or artifacts affecting interpretation.
- Provide overall assessment using BI-RADS® classification.
- Include management recommendations.

Diagnostic Breast Ultrasound

Supervision and Interpretation of Ultrasound Examinations

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

The geographic realities in Canada do not permit the presence of an on-site radiologist in all locations. Adequate documentation for each examination is critical. A videotape or video-clip record may be useful as an adjunct to the static images in difficult cases. Despite the geographic isolation of

a community, the reports must be timely. Furthermore, the radiologist must be available by telephone for consultation with the sonographer and the referring healthcare professional. Where practical, the radiologist should visit the facility on a regular basis to provide on-site review of ultrasound procedures and sonographer supervision.

Specifications of the Examination

Lesion Characterization and Technical Factors

- Breast ultrasound should be performed with as high a resolution as is practical, allowing for the depth and echogenicity of the breast being imaged. Gain settings and focal zone selections should be optimized to obtain high quality images. It is acknowledged that mass characterization with sonography is highly dependent upon technical factors. Use of different modes and settings (tissue harmonic imaging, spatial and frequency compounding, colour and power Doppler) is encouraged.
- The patient should be positioned to minimize the thickness of the portion of the breast being evaluated. The arm should be elevated and the patient position in a semi lateral decubitus position.
- Image depth should be adjusted so that the breast tissue dominates the screen and where the chest wall is seen, it should appear at the posterior margin of the image.
- The ultrasound should be correlated with any prior breast imaging, including mammographic, sonographic and MRI studies.
- Any lesion or area of interest should be viewed and recorded in two orthogonal projections. One view is insufficient.
- 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.
- Breast mass characterization should be based on the following features: size, shape, orientation, margin, lesion boundary, echo pattern, posterior acoustic features, and surrounding tissue.
- Elastography can be performed as ancillary to other features of malignancy. The performer and interpreter should be knowledgeable in the type of elastography used: strain, shear wave or acoustic resonance frequency impulse. The colour scale representing velocity or elastography should be annotated to denote hardness or softness.

Axillary Node Characterization and Technical Factors

US features of axillary nodes are listed in BI-RADS® and include size, shape, cortical thickness, margin and assessment of the hilum. Number of abnormal axillary nodes is also important for locoregional staging. Knowledge of axillary node anatomy is also essential. Preoperative axillary ultrasound is important for breast cancer staging but emerging evidence from the Z0011 trial suggests it might not be beneficial to all early-stage breast cancer patients.[95]

It is important to work in a multidisciplinary capacity with local surgical and oncologic teams to determine how to incorporate guidelines in appropriate staging protocols and when to incorporate preoperative US axillary staging.

The axilla can be included as part of the breast ultrasound examination. Patients can be positioned in a supine oblique position with the ipsilateral arm raised and placed comfortably under their head to thin out the axillary tissue.

Cortical thickness and lymph node morphology are the most important factors in determining the likelihood of metastatic disease. Measurement of the maximum cortical thickness should be included. The number of pathologic nodes should be included in the report.

Whole Breast Screening Ultrasound

Handheld Ultrasound

Screening handheld whole breast ultrasound can be performed as an adjunct to mammography. It is not a stand-alone examination and is not a replacement for mammography. Screening ultrasound is not a replacement for MRI in high-risk screening populations (though can be used if MRI is contraindicated). Centers that perform whole breast ultrasound must be able to perform mammography at the same facility and be able to perform diagnostic workup (including US-guided biopsies) on their findings. Recent mammography and any other breast imaging should be available to the interpreting physician. If whole breast ultrasound has been performed previously, the current exam should be compared with prior examinations.

Handheld ultrasound screening relies heavily on the skill of the operator to identify and properly document any findings in real-time during the exam. The entire breast must be systematically scanned to ensure complete coverage. Proper training and experience of the operator is crucial. The

technologist or radiologist must have the skill to optimize ultrasound settings such as gain, focal zones, and field of view, and the ability to recognize abnormalities while scanning and capture appropriate images.

Clinical Practice Recommendations: Documentation

- Minimum of each quadrant + 1 nipple image
- Images obtained for documentation should be annotated and include side, clock face notation, distance from the nipple and transducer orientation. One view in each quadrant and retroareolar plane in a single orientation is sufficient for documentation.
- For any solid or complex masses found, orthogonal (perpendicular) views with and without measurement calipers should be captured. Images must be labelled with laterality, clock face location, distance from nipple, and transducer orientation.
- A solid or complex mass identified during whole breast screening US should be characterized in the report by BI-RADS® sonographic features for masses. Axilla may be included per facility practice.
- When a screening ultrasound is interpreted asynchronously, it may be given a BI-RADS® 0, 1, 2. For any BI-RADS® 0 examination, the patient will need to be recalled for a focused diagnostic ultrasound to evaluate any findings.
- When an abnormality is identified during handheld whole breast US screening and a diagnostic US of the lesion is done synchronously to further evaluate, then the exam should be given a BI-RADS® 2, 3, 4 or 5.

Automated Whole Breast Ultrasound

Automated whole breast ultrasound (AWBUS) allows for mechanized performance and recording of ultrasound scans of the whole breast for later review by the radiologist. Images can be reconstructed in 3 dimensions. Depending on the machine used, either static images or dynamic cineloops of the whole scan are obtained. Areas of interest detected on AWBUS should be recalled for focused handheld ultrasound assessment and should be done at the site with AWBUS technology.

AWBUS has potential advantages over hand-held breast US, including standardized reproducible examination, dynamic cineloop of ultrasound scanning, 3D and multiplanar reconstruction capability, reduced dependence on operator skill, decoupling of acquisition and review.

AWBUS is indicated solely for supplemental screening; it is adjunctive to mammography screening. It is not a stand-alone examination and is not a replacement for mammography. AWBUS is not a replacement for MRI in high-risk screening populations. It is not a replacement for diagnostic breast ultrasound assessment of mammographic and/or MRI-detected abnormalities.[96]

Centres that perform automated whole breast ultrasound must be able to perform diagnostic handheld ultrasound and mammography at the same or an associated facility. Mammography and any other breast imaging should be available to the interpreting physician. If patient has had previous AWBUS, the current exam should be compared with the previous exam.

Limitations

- Unlike handheld ultrasound, AWBUS cannot perform a synchronous diagnostic assessment of any lesions identified, thus requiring the patient to be recalled for a hand-held diagnostic US.
- Cannot assess the axilla (armpit area), vascularization, or tissue elasticity.
- May require additional views for larger breasts.
- Potential for artifacts due to poor positioning or lack of contact
- Cannot do immediate diagnostic assessment of any lesions identified; patients will need to be recalled for diagnostic handheld ultrasound.

Additional reporting inclusions for AWBUS

When AWBUS is performed in conjunction with mammography, a single integrated report that combines findings from both modalities should be provided rather than separate reports for each modality. This helps communicate a final assessment based on the highest likelihood of malignancy and provides appropriate management recommendations.

Quality Improvement

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

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

Personnel Requirements

Radiologist

Radiologists involved in the performance, supervision and interpretation of breast ultrasound 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. Equivalent foreign radiologist qualifications are also acceptable if the radiologist is certified by a recognized certifying body and holds a valid provincial license.

Radiologists interpreting breast ultrasound should be knowledgeable in the appropriate indication, benefits and limitations of breast ultrasound. They should understand the anatomy, physiology and pathology of the breast and axilla. They should be competent in mammography interpretation and must be able to correlate multimodality imaging of the breast. The radiologist should be CAR MAP approved, reading a minimum of 1000 mammograms per year and meeting the CAR MAP CPD requirements.

In order to maintain competency, the radiologist should also meet the requirements set out by the ACR, of having overseen, performed, and interpreted at least 200 breast ultrasound examinations in the prior 36 months.[97]

Medical Radiation Technologist

Technologists performing breast sonography should be graduates of an accredited School of Sonography or have obtained certification from the American Registry of Diagnostic Medical Sonographers (ARDMS), the Canadian Association of Registered Diagnostic Ultrasound Professionals (CARDUP), the Medical Technology Management Institute (MTMI), or the equivalent. Mammography technologists performing breast sonography must have specific qualifications in breast ultrasound. They should also be members of their national or provincial professional organization.

Consistent with the requirements of ARDMS or CARDUP, continuing medical education and minimum volumes should be mandatory. Sonographers should perform breast ultrasounds regularly to maintain a high level of quality.

Information Systems Specialist

An Information Systems Specialist (ISS) is required by facilities performing digital imaging. This individual must be either on site or available upon request. He/ she must be trained and experienced in installation, maintenance and quality control of information technology software and hardware. The required qualifications of this individual will depend highly on the type of facility and the type of equipment.

The ISS should possess any relevant qualifications required by federal/provincial/territorial regulations and statutes and should be certified according to a recognized standard such as that of the Society of Imaging Informatics in Medicine or the PACS Administrators Registry and Certification Association. Expertise should include computer and database basics, networking concepts (such as DICOM, HL7, RIS and HIS), security systems, medical imaging terminology, positioning and viewing characteristics, imaging characteristics of various modalities for image acquisition, transmission and storage, and facility workflow. The ISS should also be knowledgeable about federal, provincial, territorial and institutional privacy legislation and policies, such as the Personal Information Protection and Electronic Documents Act (PIPEDA).

Responsibilities include ensuring patient record confidentiality, understanding facility policies and procedures, and the importance and requirements of an information systems quality assurance program. They also include communicating any changes/upgrades to staff and the resulting operational impacts.

MRI

Breast MRI is the most sensitive clinical imaging tool available for detecting breast cancer, whether used for problem-solving, screening, or staging patients.[98] These guidelines outline the current applications of breast MRI as well as the fundamental requirements for its use in clinical practice.

Appropriate indications for breast MRI can be reviewed in the Canadian Association of Radiologists Breast Disease Imaging Referral Guideline.[1]

Technique

With few exceptions, patients should undergo standard mammography prior to breast MRI, and the mammography study and report should be available for review at the time of interpretation of the MRI. The prior mammograms should have been performed six months or less before the MRI examination.

In the diagnostic setting, MRI should be performed in a timely fashion according to the indication.[1] Radiologists should work with their technologists and equipment vendors to ensure that their protocols are as efficient as possible.

Basic Requirements

- **Minimum field strength:** 1.5T
- **Dedicated Breast Coil:** Various options are available on the market. If the system does not have the ability to biopsy, a compatible biopsy unit should be onsite.
- **Temporal Resolution:** 2 minute maximum, but ideally 90 seconds with center of k-space filling at 80-110 seconds for wash-in. Aim for 1–3 minutes; ideally 60–90 seconds per acquisition.
- **Dynamic Imaging:** First post contrast should have center of k-space filled at optimal wash-in time 80-110 sec and washout scanned ending no later than 10 minutes post contrast injection. Take an additional image for kinetics plotting taken right after wash-in. It is essential to obtain an image approximately 60–90 seconds after contrast material administration, as most breast cancers will show peak enhancement at that time.[98]
- **Spatial Resolution:** Use the largest imaging matrix possible; the image matrix should be 448x448 or higher. In-plane pixel size should be 0.5 x 0.5 to 1.0 x 1.0 mm, and through-plane pixel size should be 1–3 mm. For optimal imaging, ensure isovolumetric imaging and voxel size of 1 mm or less.
- **Specific Imaging Parameters:** Including repetition time and echo time etc., and types of T2 and T1-weighted pulse sequences (e.g. short tau invasion recovery, conventional spin echo, gradient echo, etc.) should be determined at the facility or programmatic level.
- **Bilateral Imaging Protocols:** Required for all individuals undergoing screening (especially those at increased risk) and for staging known breast cancer. This enables contralateral assessment and comparison to reduce diagnostic errors; unilateral imaging is rarely indicated.
- **Fat Suppression**: If fat suppression is used, measures should be taken to achieve homogeneous fat saturation across the entire field of view.
- **Subtraction imaging**: Good subtraction is essential to improve the contrast between enhancing and non-enhancing regions.
- **Kinetic Data Acquisition**: Software may be used to automate assessment of kinetic curves. Careful attention should be paid that patient motion has not corrupted the curve.
- **GRE T2 Imaging:** Use with or without fat saturation to evaluate fluid, cysts, and edema in the breasts. STIR can be used as an alternative sequence.
- **Gadolinium Contrast:** Must be administered as a bolus with a standard dose of 0.1 mmol/kg followed by a saline flush of at least 10 mL.

Additional Sequences

- GRE T1 without fat saturation- for evaluation of fat, lymph nodes, and architecture of the breast and to see clip placed after previous image guided biopsy.
- Silicone Saturation and STIR with water saturation sequences can be used to determine the integrity of breast implants.

Documentation

Image labelling should include a permanent identification label that contains:

- The facility name and location
- Examination date
- Patient's first and last name

- Identification number and/or date of birth

The radiologist's report of the MRI findings should be placed in the patient's medical record. Retention of the breast MRI 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. Images of all important findings should be recorded on a retrievable and reviewable image storage format. Images should also include the skin and the chest wall.

Reporting should be in accordance with the CAR Standard for Communication of Diagnostic Imaging Findings[99] and should include:

- All pertinent observations, including assessment of parenchyma and background enhancement.
- Documentation/correlation with prior imaging studies and/or procedures
- Areas of clinical or radiologic concern
- Level of suspicion based on imaging findings.
- Specific recommendations for patient management
- BI-RADS® classification.

Facilities and Quality Assurance

Given the rising prevalence of MRI in the screening and diagnosis of breast cancer, it is imperative that facilities contemplating the establishment of breast MRI programs take comprehensive steps to ensure optimal patient care. Specifically, these facilities must possess not only the capability to perform breast MRI but also the proficiency to conduct MRI-guided biopsies. Therefore, any facility considering the acquisition of new MRI coils must ensure that these coils are compatible with and fully supportive of biopsy procedures, and that there is sufficient administrative capacity to launch a robust breast MRI program. Facilities that overlook this aspect risk compromising the quality of care provided to patients, potentially leading to delays in diagnosis and treatment.

Clinical Practice Recommendations

- Breast MRI should be practiced in a facility with the capacity for mammography, ultrasound and breast intervention, including MRI-guided biopsy.
- Facilities are strongly discouraged from performing breast MRI without the capacity to perform breast MRI-guided biopsies. If MRI-guided biopsy is not offered by the facility, a defined relationship with a referral centre offering MRI-guided biopsy is required.
- The results of biopsies initiated based on MRI findings require radiologic-pathologic correlation regardless of where the biopsy is performed. They should also be tracked by the radiologist recommending the biopsy.
- Emergency equipment, along with necessary medications, should be readily accessible to address any adverse reactions related to administered medications, including gadolinium-based contrast agents.
- Staff at the facility must be trained in the proper use of this emergency equipment and medications, following the guidelines outlined in the ACR Manual on Contrast Media.[100]

A breast MRI accreditation program is not currently available in Canada. The ACR has established an accreditation program for quality assurance of a breast MRI program that can serve as a guideline for a breast MRI practice. The criteria evaluated in the program include:

- Establishment and maintenance by the facility of an outcomes audit program to follow-up positive interpretations and correlate histopathology with the imaging findings
- Reporting that uses the BI-RADS® terminology and final assessment codes
- Calculation of statistics for each radiologist and facility.

Personnel Requirements

Radiologist

Radiologists involved in the performance, supervision and interpretation of magnetic resonance imaging 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.

Equivalent foreign radiologist qualifications are also acceptable if the radiologist is certified by a recognized certifying body and holds a valid provincial license.

Before interpreting or performing new imaging modalities and interventional techniques independently, radiologists should obtain additional clinical training under supervision, with proper documentation, which must comply with pertinent provincial/regional regulations. Continuing professional development must fulfill the Maintenance of

Certification Program requirements of the Royal College of Physicians and Surgeons of Canada.

To ensure a safe MRI practice, the supervising radiologist should be familiar with the MRI safety literature including the ACR Manual on MRI Safety,[101] and policies of appropriate contrast and sedation use.

Breast MRI should only be conducted and reported in facilities where there is multi-modality breast imaging, and support for patients across the care pathway.

In addition, the interpreting radiologist should practice and possess knowledge of imaging and diagnosis of breast disease.

- The radiologist should be CAR MAP approved, reading a minimum of 1000 mammograms per year and meeting the CAR MAP CPD requirements.
- The radiologist should also meet the ultrasound requirements set out by the American College of Radiology, of having overseen, performed, and interpreted 200 breast ultrasound examinations in the prior 36 months.
- The radiologist should be reading at least 100 breast MRI annually to maintain competence.

The responsibilities of the supervising and interpreting radiologist include:

- Review and validation of the clinical indication for the examination.
- MRI protocol
- Use and dose of contrast.
- Ensuring a physician is available when contrast is given.
- Interpretation of imaging, including review of pertinent prior breast imaging studies and clinicopathologic review.
- Provision of a report
- Quality assurance of the imaging examination and interpretation.

Medical Radiation Technologist

The technologist is primarily responsible for performing the MRI scans and maintaining the overall safety of patients, staff and equipment within the MR environment. This includes careful screening and preparation of patients, ensuring patient comfort, adjustment of protocols (if required) to produce high quality, diagnostic scans, technical and quality evaluation of images and relevant quality assurance. MR technologists are also responsible for the MRI room safety and ensuring that no maintenance staff enters the room without direct supervision. All personnel must be screened and educated about MRI by the MR technologist. MR technologists, if adequately trained, could also perform intravenous gadolinium injections requested by the responsible radiologist. Continued education of MR technologists is encouraged by the CAMRT and should meet pertinent provincial regulations.

Medical Physicist

An MRI medical physicist should perform initial acceptance testing of the MRI system immediately following installation, and prior to any clinical scanning. The medical physicist is preferably someone on site, but they can also be contracted to perform the testing. The credentials of the medical physicist should include a college certification in MRI physics (or other related MRI technology). Furthermore, they should also be accredited by either the Canadian College of Physicists in Medicine (CCPM), or one of the affiliated professional engineering societies in Canada (i.e. P.Eng) and shall have specific training and experience in MRI. Training and experience shall include detailed knowledge of the physics of MRI, system components and performance, safety procedures, acceptance testing, and quality control testing. Acceptance testing may be done by a team of medical physicists as long as at least one of the group members has the credentials and takes responsibility for signing the report.

Information Systems Specialist

An Information Systems Specialist (ISS) is required by facilities performing digital imaging. This individual must be either on site or available upon request. He/ she must be trained and experienced in installation, maintenance and quality control of information technology software and hardware. The required qualifications of this individual will depend highly on the type of facility and the type of equipment.

The ISS should possess any relevant qualifications required by federal/provincial/territorial regulations and statutes and should be certified according to a recognized standard such as that of the Society of Imaging Informatics in Medicine or the PACS Administrators Registry and Certification Association. Expertise should include computer and database basics, networking concepts (such as DICOM, HL7, RIS and HIS), security systems, medical imaging

terminology, positioning and viewing characteristics, imaging characteristics of various modalities for image acquisition, transmission and storage, and facility workflow. The ISS should also be knowledgeable about federal, provincial, territorial and institutional privacy legislation and policies, such as the Personal Information Protection and Electronic Documents Act (PIPEDA).

Responsibilities include ensuring patient record confidentiality, understanding facility policies and procedures, and the importance and requirements of an information systems quality assurance program. They also include communicating any changes/upgrades to staff and the resulting operational impacts.

Breast Intervention

Breast interventional procedures may be diagnostic, therapeutic, or both. Diagnostic procedures include but are not limited to pre-surgical localization, fine needle aspiration (FNAB) biopsy, spring-loaded core needle biopsy (CNB) and vacuum-assisted breast biopsy (VAB). Diagnostic/therapeutic procedures include cyst aspiration and abscess drainage. Minimally invasive image-guided biopsy is the most common method for diagnosing both palpable and non-palpable breast lesions. This type of biopsy offers similar accuracy to surgical biopsy, along with several advantages: it is more convenient for patients, less costly, associated with lower morbidity, better cosmetic results, and a lower complication rate.[102]

Image guidance should be used for biopsy of both palpable and non-palpable masses provided that the masses are visualized. Palpation guidance is only necessary if the lesion is not seen by any imaging method. The shortest distance from the skin to the lesion should be used when possible. Image guided percutaneous biopsy is superior to open surgical biopsy for several reasons, including increased accuracy, decreased cost and wait times, and decreased surgical morbidity and cosmetic deformity.

The first section of this guideline details general pre-procedure information applicable to interventions regardless of imaging modality, including indications and contraindications, equipment selection, and documentation. Subsequent sections cover technical and procedural details specific to procedures separated by imaging modality or technique. The final section covers post-procedure considerations applicable to all modalities.

It is recommended that all personnel involved in interventional procedures adhere to the requirements listed for the relevant modality in earlier sections of these guidelines (e.g. for stereotactic-guided interventions, that radiologists and technologists meet the requirements detailed in the mammography section of the guideline).

General Guidance for Interventional Procedures

Indications and Contraindications

The decision to perform an interventional procedure should conform to the general principles noted in the introduction. For a summary of indications and contraindications by imaging modality, please see **Table 1**.

Pre-Procedure Preparation

- Discuss the benefits, limitations, and risks of the procedure with the patient.
- Obtain informed consent.
- Prepare the breast, procedure field, and physician conducting the procedure according to infection control principles.
- Obtain scout imaging (stereotactic- and tomosynthesis-guided).
- Position the unaffected breast out of field for unilateral biopsies (MRI-guided).
- For bilateral biopsies, compress both breasts using open coils with bilateral lateral access (MRI-guided)
- Place a fiducial marker within grid for localization (MRI-guided).

Equipment

Modality-Specific Equipment

For recommendations associated with mammographic, ultrasound, and MRI equipment, please refer to the CAR Breast Guidelines on the relevant modality.

Biopsy Devices and Sampling

- Spring-loaded needle systems typically provide adequate samples for diagnosis.
- 14-gauge and larger needles are recommended for spring-loaded devices.
- Vacuum-assisted core-needle biopsy systems are also suitable for ultrasound-guided procedures.
- Other biopsy systems may be used under ultrasound guidance.
- Accurate targeting and sampling are crucial for diagnostic success.

Biopsy-Needle Selection

Several needle biopsy devices are available for stereotactic-guided procedures, including automated core needles, vacuum-assisted devices, and other tissue biopsy systems. The choice of biopsy device depends on the type of lesion as well as the operator's experience. MRI-guided biopsy is almost exclusively vacuum-assisted (VAB), whereas all types of needles are used for ultrasound guided procedures. Stereotactic or DBT-guided biopsies can be performed with spring-loaded and vacuum-assisted needles; VAB is

preferred as it can yield larger, more accurate samples while minimizing patient discomfort and procedure time.

Table 1: Indications and Contraindications for Image-Guided Procedures, by Modality

	Stereotactic and DBT-Guided Interventions	Ultrasound-Guided Interventions	MRI-Guided Interventions
Indications	**Biopsy for primary diagnosis of** • Lesions assessed as BI-RADS® Category 4 or 5[27] • Multiple suspicious lesions, particularly in a multifocal or multicentric distribution, to facilitate treatment planning. • Lesions identified on mammography that correlate with suspicious areas of enhancement present on contrast-enhanced breast MRI. **Repeat biopsy** **Placement of Markers**: To mark lesion locations post-biopsy, for correlation with imaging, or to assist in surgical removal. Markers are typically left permanently. In rare occasions, they can be removed if causing issues. **Presurgical Localization**: to guide surgical excision when the lesion or a marker is visible on ultrasound, using wire or non-wire devices.	**Biopsy for primary diagnosis of:** • Lesions assessed as BI-RADS® Category 4 or 5[27] • Multiple suspicious lesions, particularly in a multifocal or multicentric distribution, to facilitate treatment planning. • Lesions identified on ultrasound that correlate with suspicious areas of enhancement present on contrast-enhanced breast MRI. **Repeat Biopsy**: to obtain additional samples if initial core biopsy results are non-diagnostic or discordant with imaging. **Aspiration of Cysts:** • Symptomatic cysts: When the patient seeks relief. • Diagnostic uncertainty: When it is unclear if the lesion is a complicated cyst or a solid mass. • Correlation with other imaging: When aspiration might provide important diagnostic information that requires follow-up imaging. **Suspected abscess or infection**: When diagnostic aspiration or therapeutic drainage is needed. **Additional suspicious lesions in known malignancy**: where histology affects treatment. **Suspicious axillary lymph nodes**: Especially with a suspicious breast mass or proven cancer; fine needle aspiration (FNA) can be used as an alternative. **Placement of Markers**: To mark lesion locations post-biopsy, for correlation with imaging, or to assist in surgical removal. Markers can be left permanently or removed if causing discomfort. **Presurgical Localization**: to guide surgical excision when the lesion or a marker is visible on ultrasound, using wire or non-wire devices. **Percutaneous Drainage**: placement of a drainage catheter under ultrasound guidance in appropriate clinical scenarios, following established guidelines.	**Biopsy for primary diagnosis of suspicious lesions assessed as** BI-RADS® Category 4 or 5[27] **visible only on MRI**. Percutaneous biopsy is recommended to confirm diagnosis and obtain tissue for molecular profiling.' **Repeat biopsy** as an alternative to surgical excision for nondiagnostic or imaging-discordant initial biopsy results. **MRI-guided presurgical localization** • Lesions not amenable to MRI-guided core biopsy due to location or breast size • Bracketed excision of MRI-demonstrated malignancy larger than visible on other imaging modalities • Excision of suspicious MRI-only lesions with discordant or nondiagnostic biopsy results **Biopsy marker placement** for subsequent localization using ultrasound or mammographic guidance. If the biopsy target cannot be visualized following contrast injection: • Verify that the patient received a successful bolus of contrast, and that arterial inflow is not impeded by excessive breast compression. • Consider delayed postcontrast imaging if compression affects arterial inflow. • Recommend short-interval follow-up MRI if target remains nonvisualized (occurs in up to 13% of cases)
	Biopsy of probably benign lesions (BI-RADS® Category 3) where there are clinical indications for biopsy, patient preference for biopsy over follow-up, or when short-term imaging follow-up would be difficult or unreasonable. (e.g., synchronous known breast cancer, pending organ transplantation, immediate pregnancy plans		

Patient Considerations	Prior to the procedure, assess for allergies, use of medications affecting bleeding, and any history of bleeding disorders. If the target lesion cannot be confidently identified at the time of the biopsy, the procedure should not proceed. Patients on anticoagulants or medications affecting bleeding times. ○ Literature suggests that it is safe to proceed with biopsy despite anticoagulation. Decisions regarding postponement or cancellation of the procedure, or cessation of anticoagulants should be made on a case-by-case basis, balancing the risk of bleeding and hematoma formation with that of interrupting anticoagulation. Radiologists should follow their local institutional practices regarding anticoagulation management.

Vacuum-assisted devices of 11-gauge and larger have been shown to be most effective in the biopsy of microcalcifications, under stereotactic, tomosynthesis or ultrasound guidance.[103] VAB is also indicated for architectural distortion without a mass. If a finding is visible and accessible on ultrasound, US-guided biopsy is preferable for patient comfort and to limit radiation dose. Due to the location of the biopsy target or body habitus of the patient, some patients may require a smaller-gauge vacuum-assisted device.

14- gauge needles are often recommended for US-guided core biopsy due to the quality of the sample. However, selection of a different needle size or semi-automatic needle may be dependent on lesion location and size. Co-axial technique may be helpful for sampling difficult to access lesions or lesions in dense tissue.

In the case of lesions located very close to vital structures, including axillary structures, initial biopsy may be performed with a small gauge or non-advancing core needle. A fine needle may also be a last resort in order to avoid trauma to surrounding structures. FNAB is accepted for axillary node biopsy; however, core biopsy is preferred when safe to do so, as core biopsy is more likely to yield a diagnostic sample.

Biopsy Markers

Biopsy markers are used to ensure accurate identification of lesions during follow-up or subsequent localization.[104] Breast biopsy markers help to confirm the agreement between radiologic and pathologic findings, especially when the pathology result is benign. They also serve to establish this concordance for suspicious lesions seen on one imaging technique but biopsied using another. Marker placement can help identify the correct lesion location when visibility is challenging, such as with small lesions or in patients receiving neoadjuvant chemotherapy where the target lesion may disappear during treatment.

Markers can migrate, and in those cases, either the remaining lesion or other landmarks can be used for localization if necessary. The type of marker selected should be based on its required visibility on a particular imaging modality (e.g., ultrasound or MRI) or a nickel-free option if the patient has an allergy.

Indications

Placement of a radiologically- or ultrasound-visible clip/marker or carbon-marking at the time of biopsy is essential recommended in the following situations:

- Lesions difficult to identify at follow-up or subsequent localization.
- Complete or near-complete removal at sampling.
- Modifications to the lesion post-biopsy (e.g., small, solid intracystic lesions).
- Lesions with ambiguous distribution or morphology (e.g., multiple lesions).
- Lesions that will potentially be treated with neoadjuvant chemotherapy.
- Lesions biopsied under MRI guidance.
- Lesions that may be confused with adjacent lesions.
- Ultrasound-, stereotactic- and tomosynthesis-guided biopsies for MRI-detected lesions require a marker, to ensure correlation.

Clinical Practice Recommendations

- Avoid leaving suspicious microcalcifications intentionally as markers, as this may lead to under-sampling.
- Use different-shaped clips for multiple placements in the same breast.
- Post-biopsy mammograms are recommended when a marker is left in place (CC and lateral views).
- Include comments on the marker's positioning relative to the lesion in the report.
- Limited post-biopsy unenhanced MRI views can be used in addition to mammography after ultrasound guided biopsy of MRI-detected lesion if there is doubt the lesions correlation.
- Be aware of potential marker migration or misplacement following biopsy.
- A patient declining a clip or tissue marker is not an absolute contraindication for continuing with the biopsy.

Documentation

A permanent record of interventional procedures should be documented on a retrievable image storage format. Specific details of documentation vary with the type of procedure performed. Retention of procedure imaging should be compliant with federal and provincial policies, with local health care facility procedures, and with clinical need.

Reporting should be in accordance with the CAR Standard for the Communication of Diagnostic Imaging Findings.[99] Permanent records of image-guided breast interventions should be documented in retrievable image storage format. For image labelling requirements and recommended report inclusions, please see **Table 2**.

Stereotactic and Tomosynthesis-Guided Biopsies

Stereotactic-guided breast biopsies are appropriate for most lesions visible on mammograms, including microcalcifications, masses, asymmetries, and architectural distortions. When available, stereotactic guidance is preferred over grid-type mammographic guidance because it is more accurate for the calculation of the Z position of a lesion, is faster, and requires less radiation.

Digital breast tomosynthesis (DBT) guidance can be utilized for findings suitable for the stereotactic technique, as described above. If lesions are visible only or more clearly on DBT compared to 2D mammography, a DBT-guided percutaneous biopsy is preferred, if available.

Specifications of the Procedure

Lesion Targeting and Documentation

- The physician performing/supervising the procedure targets the lesion.
- Document needle positioning with paired pre-fire stereotactic images or DBT image.
- Obtain post-fire imaging at the proceduralist's discretion.
- For non-fire mode, capture paired stereotactic or DBT images with the needle in final pre-biopsy position.

Biopsy and Verification

- VAB is preferred over spring-loaded devices.
- A needle gauge of 12 or larger is recommended except in specific scenarios that may necessitate a smaller gauge.
- For microcalcifications, obtain magnified specimen radiograph to verify adequate sampling.
- Place tissue marker post-biopsy, especially for potentially obscured lesions or multiple biopsies, with imaging to document placement.
- Use markers with different characteristics for multiple lesions.

Ultrasound-Guided Procedures

Ultrasound guidance can be used when a lesion (usually a mass or lymph node) is visualized on ultrasound. Prior to the performance of any ultrasound-guided percutaneous procedure, the finding should be re-assessed. The primary advantage of ultrasound-guided procedures is real-time confirmation of target sampling. Other advantages include accessibility, cost-effectiveness, and lack of patient exposure to radiation or contrast.

Specifications of the Procedure

Needle Positioning and Approach

- Perform the procedure under real-time imaging guidance, using a high-frequency linear transducer
- The long axis of the needle should be visible along the long axis of the transducer.
- Keep the needle relatively parallel to the chest wall and transducer face.
- Choose an insertion point balancing a parallel approach and minimal tissue traversal.
- Maintain greater parallelism for devices with a throw. Taking a parallel approach improves the visibility of the needle during the procedure.

Image Documentation

- Prior to sampling, obtain images of the target lesion or area of interest. These images should not include the needle.
- When markers are placed, obtain imaging that documents the marker.
- For core needle biopsies (CNB), fine needle aspirations (FNA), and wire localizations:
    - Capture an image showing the needle traversing the lesion
    - May capture 2 orthogonal images of the needle through the lesion instead of a single image
- For vacuum-assisted biopsies and cyst aspirations:
    - Take lengthwise images of the needle and lesion before sampling/aspiration
    - Image the area after sampling/aspiration to document any residual lesion.

MRI-Guided Biopsies

Image-guided CNB under MRI guidance has decreased both the number of benign surgical biopsies and the number of surgical procedures needed to treat breast cancer.[105,106]

Facilities performing breast MRI should have the ability to perform correlation with mammography, MRI-directed breast ultrasound, and MRI-guided interventions. If MRI-guided biopsy is not offered at the facility performing the breast MRI, a referral arrangement should be established with a cooperating facility to provide these services without the need to repeat the MRI examination.

Specifications of the Procedure

Initial Imaging and Targeting

- Perform a 3-plane localizer sequence.
- Obtain pre-contrast T1-weighted images to confirm adequate positioning.
- Administer contrast and perform post-contrast T1-weighted imaging.
- Create subtraction images if needed for subtle findings
- Use manual targeting (paper method) or computer-aided evaluation (CAE) systems.
- Calculate and note skin entry coordinates and target depth.

Lesion Targeting and Documentation

- Move the patient table out of MR scanner bore.
- Place biopsy guidance sheath with obturator to calculated depth.
- Confirm accurate placement with sagittal and axial imaging.
- Adjust targeting if necessary.

Biopsy and Verification

- Vacuum-assisted biopsy (VAB) is preferred for MRI-detected lesions. A needle gauge of 12 or larger is recommended.
- Avoid 14-gauge spring-loaded core biopsy due to insufficient sampling.
- Obtain sufficient samples depending on lesion size, device gauge, and clinical scenario, to get accurate diagnosis.
- Place tissue marker post-biopsy, obtain a mammogram to document marker position.

Additional Considerations

- Approximately 10% of lesions may not persist; recommend 6-month follow-up if not seen on MRI
- MRI-detected lesions are often small with high incidence of atypia.
- MRI-guided biopsies have a higher underestimation rate compared to stereotactic biopsies.
- Precision in targeting is crucial, especially considering the lesion position relative to grid.

Technical Guidelines

Examinations should be performed with a dedicated open interventional MRI coil equipped with a localization device.

Imaging Protocol

- Spatial resolution should be high enough to identify the target(s) of interest.
- Images need to be obtained quickly to ensure visualization of the finding prior to contrast washout.
- The resolution may not match that of a diagnostic protocol, due to the goal being target identification rather than detection and characterization.
- Faster sequence acquisition should be used to minimize overall procedure time, reducing patient discomfort and motion.
- Perform simultaneous bilateral imaging when findings in each breast are being biopsied concurrentl.y

Image Enhancement Techniques

- Slice thickness and in-plane spatial resolution should be similar to adequately visualize the finding
- Consider using fat suppression and subtraction imaging to identify the target finding. Note that subtraction may cause misregistration due to patient motion.
- Motion-correction software can help reduce subtraction artifacts

Contrast Administration

- Gadolinium contrast is generally necessary to identify the target lesion
- Use standard dose of 0.1 mmol/kg as a bolus
- Follow with at least 10 mL saline flush.

Scan timing

- For optimal lesion visibility, capture images before contrast washout

- For single postcontrast scans, complete within 4 minutes of bolus injection.

Table 2: Documentation of Image-Guided Interventions

<table>
<tr><th></th><th>Stereotactic and DBT-Guided Interventions</th><th>Ultrasound-Guided Interventions</th><th>MRI-Guided Interventions</th></tr>
<tr><td rowspan="2">Image Labelling</td><td colspan="3">• Patient's first and last names
• Identifying number and/or date of birth
• Examination date
• Facility name and location
Designation of left or right breast</td></tr>
<tr><td>Annotation of mammographic view (e.g., craniocaudal, mediolateral oblique (MLO), 90° mediolateral [ML]</td><td>• Anatomic location using clockface notation
• Distance from the nipple to the lesion in centimeters
• Transducer orientation
• Performing physician or sonographer</td><td>• Annotation of MRI sequences used
• Technologist's identification number or initials</td></tr>
<tr><td rowspan="2">Report Inclusions</td><td colspan="3">• Procedure performed
• Designation of left or right breast
• Description and location of the lesion
• Informed consent is obtained
• Safety time-out having been performed
• Approach used
• Type and amount of local anesthesia
• Skin incision, if made
• Needle gauge and device type (spring-loaded, vacuum-assisted, etc.)
• Specimen images, if performed, and findings
• Localizing tissue marker information including shape, if placed. If multiple tissue markers are placed, they should be clearly identified according to shape and site
• Complications and treatment, if any
• Post-procedure mammography, if obtained, describing location of tissue marker with respect to the biopsied lesion</td></tr>
<tr><td>Other information may include presence or absence of residual target calcifications or mammographic abnormality for future localization and follow-up purposes.</td><td>Other information may include documented presence or absence of a sonographically-evident residual mass for future localization and follow-up purposes</td><td></td></tr>
</table>

Investigation of Nipple Discharge Using Galactography

Galactography or ductography may be used as an alternative to MRI for the investigation of pathologic nipple discharge, when MRI is not available or contraindicated. Ductography is minimally invasive, may be uncomfortable, and can be time-consuming. The procedure is technically challenging. The rate of incomplete or failed ductograms may be as high as 15–23%.[107]

Ductography is performed with a 30-gauge blunt-tipped straight or angled cannula gently inserted into the orifice of the discharging duct. 1–3 mL of nonionic iodinated contrast medium is slowly administered through the cannula, and two orthogonal views are obtained, with additional views obtained as necessary.

The discharge must be present on the day of ductography so that a cannula can be placed in the correct duct. Failure to cannulate the discharging duct may lead to a false negative result.

Ductography is not recommended in lactating women or patients with active mastitis. Known hypersensitivity to iodinated contrast agents is a relative contraindication. A negative ductogram does not reliably exclude an underlying cancer or high-risk lesion, with the false-negative rate reported to be as high as 20% to 30%.[108]

Post-Procedure Follow-Up

Post-Procedure Care

- Compress the biopsy site, skin entry site, and needle path until hemostasis is achieved. Compression time varies based on patient factors and extent of bleeding. Note: Absence of external bleeding doesn't guarantee internal hemostasis
- Post-biopsy mammogram, to assess for residual calcifications and to check clip placement (if used).
- Additional views may be necessary to visualize the tissue marker
- Include DBT images for DBT-only visible findings.
- Report should state marker position relative to the biopsy site.
- Monitor and document any delayed complications; record any treatments administered

Submission of Pathology Specimen(s)

Submitting a specimen for histopathology is a request for a consultant opinion. For this opinion to be effective, accurate identification and good preservation of the specimen are essential. Providing good clinical details is vital as the histopathological findings are interpreted in the clinical context.

The requisition should be properly filled out with the following information:

- Patient complete name, age, date of birth, and collection date
- Clinical history
- Side and source of tissue
- Number of needle core biopsies submitted.

Specimen containers should be labelled completely with patient information, collection site, date and physician's name. When multiple specimens are to be examined and diagnosed individually, each specimen must be submitted in a separate container completely labelled as indicated above

Specimens should be placed in buffered formalin within approximately ten minutes of their removal from the patient. Increased cold ischemic time will interfere with the assessment and staining of the tissues. The volume of formalin is ideally twenty times that of the specimen, but for very large specimens this may be reduced to ten times the volume of the specimen. Very small specimens should be placed in formalin almost immediately (within one or two minutes depending on the size); otherwise marked drying artifacts will occur. Larger specimens with a high fat content, which float, may be covered within a few layers of paper towels to allow formalin to reach the upper surface of the specimen. The container obviously must be able to accommodate the specimen plus many times its volume in formalin. The specimens should fit through the opening of the container with ease.

Radiologic-Pathologic Correlation[109,110]

Ideally, the physician who performed the procedure should determine the concordance between pathology results and imaging findings. If that physician is not available a designated physician may determine concordance to facilitate timely management of the patient. Radiologic-pathologic correlation is crucial due to potentially higher upgrade rates and false-negatives.[111–113] Technical constraints inherent to MRI can make determination of

radiologic-pathologic concordance challenging because there is not confirmatory method to verify adequate sampling.

Following receipt of the pathology report, an addendum to the biopsy report should be produced by the radiologist in charge of the biopsy or by his/her assigned proxy when required to expedite results. This addendum should include the radiologist's opinion on radiologic-pathologic concordance or discordance as well as a suggestion for the appropriate management follow-up, such as the need for further imaging, imaging follow-up, repeat biopsy or surgical consultation.

- Discussion with the pathologist is strongly encouraged when determining appropriate management for patients with questionable radiology-pathology concordance.
- Regular Radiology-Pathology Breast Biopsy Correlation rounds are recommended as a method to facilitate case review and determination of concordance between imaging findings and biopsy results

Management Recommendations

Benign concordant results: for lesions with a definitive benign diagnosis (e.g. lymph node, fibroadenoma), follow-up should be considered at 6-12 months, based on the radiologist's discretion. For lesions with concordant benign diagnosis that is nonspecific (e.g. benign/fibrous breast tissue), a six-month assessment as well as longer term follow-up may be prudent in order to decrease the chance of missed diagnosis.[114] At the radiologist's discretion, patients may return to routine screening after the lesion-based follow-up.

Benign discordant results: recommend repeat biopsy via image-guided percutaneous method or surgical excision.

High-Risk Lesions: Surgical consultation is typically recommended for high-risk lesions prone to malignancy upgrade at excision. Management of high-risk lesions may be individualized when appropriate, as controversies exist.

Malignant results: recommend referral to a surgeon or oncologist for consultation.

In cases of insufficient sampling, repeat biopsy should be recommended, preferably using a method that achieves a larger sample size than that of the original biopsy.

Additional considerations for MRI:

- There is a higher upgrade rate for MRI-detected high-risk lesions compared to mammography or ultrasound.[115–119]
- For concordant benign findings, further intervention or excision is not usually required.
    - Consider short-term follow-up with diagnostic breast MRI at 6 months due to challenges in determining concordance.

Preoperative Localization

Preoperative image-guided localization has become an essential component in the management of nonpalpable breast abnormalities prior to surgical excision. This approach has evolved into the standard of care, providing surgeons with guidance to ensure successful removal of target tissue. The technique of preoperative localization through image-guided wire placement, which was pioneered in the 1970s, continues to be a reliable and safe method for breast lesion localization.

In recent years, there have been significant advancements in non-wire localization (NWL) techniques. These innovations aim to address some of the limitations associated with traditional wire localization methods, potentially enhancing patient care and streamlining clinical workflows. NWL devices lack a component external to the breast after placement (as is present with the proximal wire segment when a wire is placed). The absence of an external component in NWL offers increased patient comfort and decreased risk of displacement or transection of the localizing device compared with wires.[120] All forms of NWL typically have two components: a single-use sterilized device preloaded into a needle introducer and a console with a handheld probe for the detection of deployment by the radiologist and for surgical guidance by the surgeon. The localizing device may be placed at the breast lesion, adjacent to the biopsy marker (if it lies at the site of the lesion), or at the post-biopsy hematoma if the lesion itself cannot be visualized and if a biopsy marker is not present. In addition to some type-specific limitations (outlined below), NWL may be subject to imprecise positioning during placement or deployment. An important limitation of NWL is that once deployed, they currently cannot be repositioned.

Specifications of the Procedure

The radiologist should meet the recommended qualifications and personnel requirements for each modality listed above.

See **Table 3** for more information.

Table 3: Localization Procedure Specifications

Prior to Localization

- The radiologist should review all pertinent imaging examinations to determine the extent of the target
- Determine whether biopsy markers were placed in the appropriate position, or if they have migrated
- For patients who have undergone neoadjuvant therapy, assess both the original extent of disease and the visible residual disease.

	Hook Wire Localization	**Non-Wire Localization**	**Surgical Specimen Imaging**
Purpose	Used to guide the excision of an impalpable breast lesion.	Non-wire localization is used to guide the excision of an impalpable breast lesion, addressing some limitations of conventional wire localization.	Surgical specimen imaging is used to confirm the excision of lesions localized with imaging guidance.
Equipment	Use a flexible wire specifically designed for breast localization.	Radioactive seed localization uses a titanium seed containing a small amount of iodine-125 material. Other techniques include magnetic seed localization, and the placement of RFID tags	
Imaging Guidance	• Mammographic • Ultrasound • MRI	• Mammographic • Ultrasound	• Mammographic • Ultrasound
Timing	Wire placement should occur on the same day as the surgical excision and as close to the time of surgery as possible to minimize wire migration.	Placement of the device can occur prior to surgery. Time interval prior to surgery varies depending on the device.	Coordinate with the surgical team to ensure prompt specimen review, especially if the patient is under general anesthesia.
Technique	• The wire should traverse the lesion and extend a short distance beyond it. • The shortest distance from the skin to the lesion should be utilized when possible. • For large lesions or clusters of calcifications, bracketing wire localization may be performed using two or more wires. • Obtain orthogonal (CC and 90-degree mediolateral) mammographic images immediately after wire placement.	• The device should be placed within the lesion, with its position confirmed via mammography. • For large lesions or clusters of calcifications, bracketing wire localization may be performed using two or more NWL devices in compliance with the device-specific parameters for spacing. • The surgeon will use a probe to locate the device in the breast during surgery.	• Surgical specimen radiography should be performed for localized lesions. • If visible on ultrasound, specimen sonography may also be performed. The surgical team should appropriately identify and mark the specimen for orientation.
Multidisciplinary Coordination	Ongoing communication is essential between the surgical and radiological teams regarding documentation preferences and needle types.	Ongoing communication between surgical and radiological teams is essential for documentation and equipment preferences.	• If the lesion is not fully excised, communicate this to the surgeon promptly. • Ensure the pathologist has access to specimen images for identifying areas of interest.

Documentation ***Consultation with local teams is recommended to determine the specific information that each surgeon prefers to receive post-localization.***	Forward the following to the surgeon: • Pre- and post-localization images. • Diagrammatic representation of localization. • Patient data. • Laterality • Relationship between wire, lesion, and breast anatomic landmarks. • Size of lesion. • Total length of wire. • Length of wire below the skin. • Distance from lesion to skin. • Length of wire beyond the lesion. • Contact information for the radiologist.	Forward the following to the surgeon: • Post localization images • Patient data • Size of the lesion • Pertinent measurements • Laterality • Relationship of localization device to lesion • Contact information for the radiologist.	• Report the closest margins between the lesion and specimen edges, noting the limitations of 2D imaging. • Compare specimen images with preoperative images to verify complete excision. • Note any localizing device/clip placement details.

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