Standard for Breast Imaging

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

I. INTRODUCTION

Mammography is a sensitive proven technique for detecting malignant disease of the breasts, particularly at an early stage. In the presence of breast symptoms, mammography is used not only to further evaluate the breast but also, in some cases, to allow a definitive conclusion, as well as detection of other unsuspected neoplasms.

II. SCREENING MAMMOGRAPHY

A. Introduction

Various population-based trials have shown that periodic screening of large numbers of asymptomatic women can reduce mortality from breast cancer. As for other radiological examinations, optimum quality is required at all levels. Important considerations include credentialling and criteria for professionals, equipment specifications, monitoring and maintenance schedules, image quality standards, imaging evaluation standardization, meticulous record keeping, and periodic review and analysis of outcome data.

B. Definition

Screening involves the examination of asymptomatic women to detect abnormalities which may lead to a diagnosis of early stage breast cancer. When an abnormality exists which must be investigated further, such women are referred for additional study. Therefore the screening examination may be performed without a physician in attendance. Despite its sensitivity, mammography cannot detect all breast cancers and, therefore, mammography and clinical examination are complementary procedures, together with breast self examination.

C. Goal of screening

The goal is to create high quality images at the lowest radiation dose necessary to produce image information necessary for detection.

D. Indications

1. Being an asymptomatic woman at least 40 years of age.

2. Frequency: Currently, available data support a range of screening guidelines based upon age including recommendations for screening to begin at age 40 or 50. However, all women aged 50 to 70 should have screening at one to two-year intervals.

Women over the age of 70 should have screening mammography at one to two-year intervals if they are in good general health.

Screening mammography is not routinely recommended for women under the age of 40 but may have a role in selected individuals with extreme family histories. For example, where the family history is of pre-menopausal breast cancer referral for mammography at an age five to ten years younger than the first degree relative who developed breast cancer may be advised.

E. Self referral

It is becoming more common for organized screening programs to accept women for examination without direct physical referral. Commonly, a woman requesting screening is required to provide the name of her primary care physician to whom the report would be sent. If this is done, the woman should also be notified directly of her screening result. Where such confirmation is required and is not given, or if the woman is unable to provide the name of a physician, a pool of physicians willing to take such referrals can be maintained, and a name provided from such a list.

F. Credentials criteria and responsibilities of personnel

The personnel standards for education and conduct are determined by on the unique demands of mammography practice.

1. Radiologist

Physicians involved in the performance, supervision and interpretation of mammography should be Diagnostic Radiologists and must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Also acceptable are equivalent foreign Radiologist qualifications if the Radiologist is certified by a recognized certifying body and holds a valid provincial license.

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

Radiologists practising mammography should participate regularly in mammography continuing education programs. They should adhere to the requirement for CAR mammography accreditation.

2. Technologist

The medical radiation technologist must have Canadian Association of Medical Radiation Technologist (CAMRT) Certification or be certified by an equivalent licensing body recognized by the CAMRT.

Under the overall supervision of the radiologist, the technologist will have the responsibility for patient comfort and safety, for examination preparation and performance, and for image technical evaluation and quality and applicable quality assurance. The technologist should receive continuous supervision on image quality from the interpreting radiologists.

The training of technologists engaged in specialty activities shall meet with applicable and valid national and provincial specialty qualifications.

Continued education of technologists is encouraged by the CAMRT and should meet pertinent provincial regulations.

The technologist should have training in mammography either in his or her training curriculum or through special courses and must perform mammography on a regular basis.

3. Radiation physicist

A medical physicist shall have the responsibility for the initial acceptance testing and for conducting and overseeing quality control testing of the mammographic unit.

The medical physicist shall be certified by the Canadian Organization of Medical Physicists or possess equivalent qualifications from the Canadian College of Physicists in Medicine.

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

G. Equipment

1. Specifications

The equipment specifications must be precise.

The mammographic equipment should be designed especially for mammography and should have a compression device and removable grid.

Conventional radiographic equipment modified for xeromammography is no longer acceptable.

Equipment that has automatic exposure control (AEC) is preferable. Compression devices should be designed to improve contrast, minimize radiographic scatter, ensure uniform density and reduce dose and subject motion. Molybdenum target and filter tubes or other combinations which have been developed especially for mammography are appropriate for film screen mammography; tungsten target tubes with aluminium filtration are appropriate for xeromammography.

The focal spot size of the x-ray tube should be 0.6 mm nominal or less; 0.3 mm is a preferable size for film/screen mammography.

The focus reception distance should be 50 cm or more.

A dedicated film processor with developer time and temperature designed specifically for the single emulsion film being used for film/screen mammography is recommended or, as an alternative, mammography film designed for 90 seconds processing is acceptable.

2. Radiation dose

The average glandular dose will be measured at least annually. The average glandular dose determined by the dosimeter should not exceed 0.3 rads/3mGy for film/screen and 0.4 rads/4mGy per projection for xeromammography. These measurements apply to the standard of a 4.5 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue.

3. Radiation protection

Aprons and collars are not required as radiation protection for mammography in view of the negligible amount of scattered radiation.

H. Specification of the examination

The examination should ordinarily be limited to a craniocaudal and mediolateral oblique view of each breast. Occasionally additional views may be required to visualize breast tissue adequately. When an abnormality exists which must be investigated further, such women are referred for additional imaging studies.

1. Comparison with previous films

All original images of previous studies should be obtained when practical.

2. Film labelling

Adequate documentation of the study is essential for high quality patient care. All radiographic images should be labelled in accordance with the current recommendations of the CAR Mammography Accreditation Program. Film labelling should include an identification label containing:

a. Facility name and location
b. Patient's first and last names
c. Unique identification number and/or date of birth
d. Examination date
e. Technologist's initials (or identification number)
f. Cassette (screen) number
g. The film should also include a radiopaque marker placed on the film near the axilla for identification of laterality and view. This marker should not obscure image information.

3. Viewing conditions

a. View boxes

View boxes should provide a relatively high luminance level. This is generally higher than that required for viewing conventional radiographs. It is essential to mask the area around the mammograms to exclude extraneous light which reduces image contrast and limits

maximum densities that can be seen without "bright-lighting" each film. Magnification lenses and bright light capabilities should be available.

All view boxes should be checked periodically to assure that they are in optimal condition.

b. Viewing conditions
Contrast is extremely important in the mammographic image and is degraded by extraneous light. View boxes should be positioned to avoid light from windows, other viewboxes, and other sources of bright light, either direct or reflected. General lighting should be at a low level and diffuse.

4. Film retention
Mammograms should be retained for a statutory period which should be consistent with clinical needs and relevant legal and local health care facility requirements.

5. Free standing and mobile settings
Screening mammography may be performed in non-traditional settings where a physician may not be in attendance.
Essentially, the examination offered must follow all of the described standards and guidelines cited here as documented protocols.

The radiologic technologist should work under the same rules whether in a fixed or mobile setting.

The radiologist supervising the facility should be available for consultation and must visit the facility at least monthly to observe the performance of mammograms and assure that safe operating procedures are adhered to.

He or she should review all quality control documentation and ensure that a log of these visits is maintained.

I. The screening mammography report
For screening the intent is not to render a definitive diagnosis. Commonly, recommendations are made in the report for further diagnostic study for those in the high probability group. Reporting should be according to the CAR Standards for Communication. As well, the American College of Radiology (ACR) document "Breast Imaging Reporting Data Systems" (BIRADS) has been adopted as a reference document and is available on request from the ACR office. A description of abnormalities detected at screening and recommendations for work up should be included in the report. For abnormalities which are in the highly suspicious category suggestive of malignancy, the report should be communicated to the referring physician directly in a manner that ensures receipt and documentation of the reports, such as by telephone, fax or registered mail.

J. 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.

1. Radiologist
The radiologist will be responsible for ensuring that technologists have adequate training and maintenance of competence; he/she or a designate must ensure that the technologists and physicists perform the appropriate tests on schedule, and that all records are properly maintained and that the quality of clinical images is acceptable.

2. Technologist
The radiology technologist will be responsible for various routine tests including darkroom cleanliness, processing quality control, screen cleanliness, viewboxes and viewing conditions, phantom images, visual checklist, repeat analysis, analysis of fixer retention in film, darkroom fog, screen film contact and compression.

3. Physicist
The medical physicist will be responsible for the mammographic unit evaluation, collimation assessment, focal spot size measurements, kVp accuracy and reproducibility.

Beam quality assessment [half value layer measurements], automatic exposure control system performance assessment, uniformity of screen speed entrance exposure, average glandular dose and artefact evaluation.

Phantom evaluation of image quality and artefact assessment and appropriate tests should be

performed on an annual basis.

The ACR Committee on Mammography Quality Assurance has published a document entitled "Mammography Quality Control" addressing, specifically, radiology technologists and physicists responsibilities. This document has been reviewed and acknowledged by the Task Force on Mammography and is recommended as a reference document.

K. Professional quality assurance

1. Outcome data

Systems for reviewing outcome data from mammography should be established. The minimum data which should be collected include disposition of positive mammograms and correlation of surgical biopsy results with mammogram reports, enabling an assessment of the true and false positive rates. Where possible, records of false negative mammograms should be collected and the cases analyzed. The number of cancers detected - both occult and clinically palpable - should be recorded.

2. Comparison with previous mammograms

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

III. DIAGNOSTIC MAMMOGRAPHY AND PROBLEM SOLVING BREAST EVALUATION

A. Introduction

As contrasted with screening mammography, diagnostic mammography is intended to evaluate patients with clinically detected or screening detected abnormalities.

B. Definition

This is a comprehensive imaging evaluation of a patient with a breast mass, nipple discharge, pain, dimpling, an abnormal or questionable screening mammogram or other physical finding. Women with augmented or reconstructed breasts will be included for diagnostic evaluation if they are not eligible for a screening program. The mammogram should be correlated with the known physical findings and/or symptoms.

The diagnostic mammogram is planned and tailored for the needs of the individual patient. It should be done under the direct supervision of a radiologist qualified in mammography.

The diagnostic mammogram may indicate the need for additional study such as breast sonography, imaging guided needle biopsy, galactography or MRI.

C. Goal

The goal of such an evaluation is to provide definitive information for referred patients with signs or symptoms of an abnormal screening mammogram. After interpretation, there should be a specific conclusion and/or additional recommendation for management.

D. Indications

1. Signs and symptoms suggestive of breast cancer including a lump or thickening localized nodularity, dimpling or contour deformity, a persistent focal area of pain, and spontaneous serous or sanguineous nipple discharge from a single duct. Other types of discharges may not reflect pathology and women with such symptoms would be candidates for screening mammography.

2. Women with abnormal screening mammograms.

3. Follow-up of women with previous breast cancer.

4. Short interval follow-up (less than one year for clinical or radiologic concern).

5. Suspected complications of breast implants.

6. Any circumstance in which direct involvement of the radiologist is required for monitoring sonography, physical examination and consultation.

E. Qualifications of personnel

The same criteria apply as for screening mammography.

F. Equipment

The same specifications for equipment and its use apply as for screening mammography. However, for diagnostic mammography, equipment must have magnification and spot compression capability.

G. Specifications of the examination

The nature and site of clinical or mammography concern should be documented prior to the examination and acknowledged in the report. The location should be described according to various conventions including the clock face position, distance from the nipple, breast quadrant and location within the coronal plane.

Areas of interest can be marked using opaque devices to confirm that the area of interest was included on the film and to provide positioning guidance. Additional views such as spot compression, spot compression with magnification, tangential views, views with markers and other specialized views may be selected by the radiologist. It is preferable to place the area of concern closest to the image.

Both the technologist and supervising radiologist should be aware of any sites of clinical concern to ensure adequate monitoring during the study.

Implant evaluation should include craniocaudal and mediolateral oblique as well as implant displacement views.

Prior films should be obtained for comparison when possible.

Film labelling should conform to the specifications previously cited for screening mammography.

H. The diagnostic report

All areas of clinical or radiologic concern should be acknowledged in the report. The report should describe the pertinent observations, establish a level of suspicion based upon the imaging findings and provide specific recommendations for patient management. The report should also document any other breast imaging studies or procedures which have been performed and should correlate these results with the mammographic findings. Screening recommendations may be included.

The same criteria for reporting and communication as for screening mammography apply.

IV. SONOGRAPHY

A. Indications

1. Identification and characterization of palpable abnormalities.
2. Evaluation of ambiguous mammographic findings in the determination of cystic versus solid characteristics.
3. Evaluation of patients with suspected silicone implant rupture.
4. Guidance for interventional procedures.

In younger patients, sonography may be performed as the initial investigation. Sonography is not acceptable for screening or as a technique to search for microcalcifications.

B. Specifications

The breast sonogram should be correlated with the physical examination and mammogram, and any other breast imaging studies which have been conducted.

Lesions should be viewed in two perpendicular projections.

Breast sonography should be performed with real-time using high frequency transducers of 7.5 MHZ or higher.

It is acknowledged that mass characterization with sonography is highly dependent upon technical factors. However, by using strict criteria, cysts can be separated from solid lesions and when indicated the latter can be further evaluated by the fine needle aspiration or core biopsy.

Histological results should be correlated with all other imaging studies and this correlation used to make recommendations for additional intervention or follow up. Hard copy images of abnormalities only are required and should be recorded on a retrievable and reviewable image storage format. The images should be identified with a permanent label and designate the patient's name, identification number and date of birth, the name and location of the facility, and the date of the examination.

In addition, the images should be accurately labelled using either a clock-face or diagrammatic designation. Where possible, distance from the nipple or other landmark can be documented.

V. THERMOGRAPHY

At present thermography should be regarded as an experimental procedure with no established clinical indications. Its use should be restricted to properly controlled prospective studies and to evaluate possible clinical efficiency.

VI. PRE-OPERATIVE LOCALIZATION OF NON-PALPABLE BREAST LESIONS

Imaging guided localization should be performed pre-operatively on all non-palpable lesions.

VII. SPECIMEN RADIOGRAPHY

Specimen radiography should be performed on all resections on non-palpable breast lesions to confirm that the abnormality in question has been removed. This can be done with dedicated mammography units or with specialized radiographic units designed for specimen work.

Since dose is no concern, magnification is desirable. A kV setting lower than that used for clinical mammography - 22 to 26 kVp to ensure adequate contrast is typically used depending on the unit. Radiography should be performed with compression to allow for improved visualization of the lesion and confirmation of excision. There should be direct communication between the surgeon and radiologist to ensure adequacy of excision.