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CAR Practice Guidelines on Breast Imaging and Interventions: Mammography and Digital Breast Tomosynthesis

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Abstract

This guideline presents Part I of the Canadian Association of Radiologists (CAR) Practice Guidelines on Breast Imaging and Intervention and focuses on mammography and digital breast tomosynthesis (DBT). Developed by the CAR Breast Imaging Working Group, this guideline provides updated, evidence-based recommendations for screening and diagnostic mammography, reflecting advances in digital imaging, tomosynthesis, artificial intelligence, and quality assurance since the previous consolidated guidelines published in 2016. Key areas addressed include clinical indications, equipment and technical standards, radiation dose considerations, reporting using BI-RADS®, personnel qualifications, and performance benchmarks. This guideline emphasizes the central role of mammography and DBT in breast cancer detection while supporting the integration of emerging technologies to improve diagnostic accuracy and efficiency. It is intended to be used in conjunction with the other 4 components of the CAR Breast Practice Guidelines on Breast Imaging and Intervention and alongside the CAR Breast Disease Imaging Referral Guidelines. While outlining best practices and minimum expectations, this guideline acknowledges that practice variation may be appropriate based on patient factors and available resources, with ultimate responsibility for clinical decision-making resting with the supervising radiologist.

Résumé

La présente ligne directrice expose la partie I des Lignes directrices de pratique en matière d'imagerie et des interventions mammaires de la CAR, et porte sur la mammographie et la tomosynthèse numérique mammaire. Élaborée par le Groupe de travail de la CAR sur l'imagerie mammaire, cette ligne directrice fournit des recommandations mises à jour et fondées sur des données probantes pour la mammographie de dépistage et de diagnostic, reflétant les progrès réalisés en matière d'imagerie numérique, de tomosynthèse, d'intelligence artificielle et d'assurance de la qualité depuis la publication des lignes directrices consolidées précédentes en 2016. Les principaux domaines abordés comprennent les indications cliniques, les normes relatives à l'équipement et aux caractéristiques techniques, les considérations relatives à la dose de rayonnement, la production de rapports selon le système BI-RADS®, les qualifications du personnel et les indicateurs de rendement. Cette ligne directrice souligne le rôle central de la mammographie et de la tomosynthèse numérique mammaire dans la détection du cancer du sein, tout en favorisant l'intégration des technologies émergentes afin d'améliorer la précision diagnostique et l'efficacité. Elle est destinée à être utilisée conjointement avec les quatre autres composantes de la série des Lignes directrices d'imagerie mammaire de la CAR, ainsi qu'avec les Lignes directrices relatives aux demandes d'examen pour les maladies du sein de la CAR. Tout en définissant les meilleures pratiques et les attentes minimales, cette ligne directrice reconnaît que des variations dans la pratique peuvent être appropriées selon les facteurs propres à chaque patient et des ressources disponibles, la responsabilité ultime de la prise de décisions cliniques incombant au radiologiste superviseur.

Keywords

practice guideline, mammography, digital breast tomosynthesis, breast neoplasms, mass screening, early detection of cancer

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 may not ensure 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 **CAR Practice Guidelines on Breast Imaging and Intervention** have been published as a comprehensive five-part series in the *Canadian Association of Radiologists Journal (CARJ)* to provide targeted, modality-specific guidance. While this section focuses on **Mammography and Digital Breast Tomosynthesis**, it is intended to be used in conjunction with the other 4 components of the update:

- **Part I: Mammography and Digital Breast Tomosynthesis**
- **Part II: Contrast-Enhanced Mammography (CEM)**[1]
- **Part III: Breast Ultrasound**[2]
- **Part IV: Breast Magnetic Resonance Imaging (MRI)**[3]
- **Part V: Breast Intervention and Biopsy Procedures**[4]

Together, these documents replace the previous 2016 consolidated guidelines to reflect the current evidence base and clinical landscape in Canadian breast imaging, and complement 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.[5]

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.[6,7] Digital breast tomosynthesis is a well-established technology used in both screening and diagnostic settings and to guide procedures.[8]

The CAR Breast Disease Referral Guidelines detail the appropriate breast imaging modalities for various clinical situations, including screening mammography, diagnostic mammography, and tomosynthesis.[5]

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

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referral guidelines for indications for diagnostic breast imaging.[5]

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.[5] 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.[9,10]

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

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.

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 0.1 mm 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 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.[11,12]
- All mammography workstations, including those used at home, require annual assessment by a medical physicist.
- Conduct regular assessments to ensure ongoing compliance with 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.[13]

Radiation Protection

Aprons and collars are not routinely required.[9,14] Moreover, shielding in pregnancy is not recommended.[15-17]

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.[18] In addition to standard views, implant displaced views are required for complete evaluation of the breast.[19] 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 Labeling

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 Name
- 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 2 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.[20] 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 the 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.[21] AI has been shown to increase the accuracy of screening when employed as a second read, reducing false positives while increasing sensitivity.[22,23] Studies have also demonstrated that improved efficiency and accuracy can be achieved in clinical practice with the concurrent use of effective AI systems.[24] Newer systems embedding deep learning and machine learning algorithms into CAD systems are in development.[25-29]

Reporting

Basic Requirements

The report should follow standard BI-RADS® reporting guidelines.[30] 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. 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.[31] It has proven valuable for detecting and evaluating focal asymmetries, architectural distortion, and some apparent masses.[32,33] DBT is equal to, or better than, coned compression views for investigating 2D mammographically detected abnormalities.[34-36] Most studies have demonstrated no statistically significant difference in the detection of calcifications on DBT when compared with 2D DM.[37] Studies comparing DBT with 2D DM for patients recalled due to a questioned abnormality detected on routine mammography showed significantly improved specificity with DBT.[38] In screening, DBT has shown the potential to decrease false-positive recalls compared to 2D DM in screening settings.[39-41]

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.[42,43] 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.[8,44-47] 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% to 17%.[40,48] The TMIST trial, a large Phase 3 randomized control trial, has enrolled over 100 000 patients across 30 sites, including 7 Canadian sites. TMIST is comparing 2D-DM combined with DBT against 2D-DM alone.[49] 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.[50]

Diagnostic. When investigating findings from 2D screening, full view tomosynthesis is considered superior to spot tomosynthesis.[51,52] 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).[53]

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 the 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,[40,54] it is mandatory to review the tomosynthesis stack. Synthetic views must not be used independently.[55]

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.[56]
- Synthetic views may underestimate the suspicious morphology of some calcifications, thus the use of 2D magnification spot compression views is strongly recommended for any new or indeterminate calcifications.[55]

Challenges to Implementation

Challenges to the implementation of DBT at the time of writing include, but are not limited to[57]:

- Interpretation time is at least 1.5 times to double that of routine 2D DM.[58,59]
- Protocols optimizing diagnostic accuracy, quality assurance, radiation dose, and workflow have yet to be fully standardized. In particular, the CAR MAP has not finalized an accreditation protocol specific to tomosynthesis.
- DBT has large digital storage requirements. The tomosynthesis stack and synthetic images must be stored. If 2D DM is 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.

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 MAP's quality control specifications (Please contact a CAR MAP coordinator to receive a copy of the Quality Control Checklists.).

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 tumor size, nodal status, histological 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[60-65]

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