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ACR PRACTICE GUIDELINE FOR THE PERFORMANCE OF WHOLE BREAST DIGITAL MAMMOGRAPHY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. It should be recognized, therefore, that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

Digital mammography is a radiographic examination of the breast in which the image is acquired as an electronic signal in digital format. Technological advancement in the field can be expected. Routine clinical application of any digital approach to screening or diagnostic mammography requires that the images obtained be substantially equivalent to, or better than, high-quality screen-film mammograms in portraying clinically significant image detail.

X-ray detection and image display are separate functions in digital mammography. Issues related to both image detection and image display must be given careful consideration, and deficiencies in one cannot necessarily be overcome by special attention to the other. A variety of image archival strategies exist in digital mammography, but any storage method employed in clinical practice must preserve images of diagnostic quality for an appropriate interval.

The existence of mammographic images in digital form facilitates electronic image transmission, image processing, and computer-based image analysis. It is

important that application of any of these for primary diagnosis does not result in irretrievable loss of important image detail to the interpreting physician. This guideline defines goals, indications, and qualifications of personnel, equipment guidelines, communication, quality control, and quality improvement for digital mammography. While not all-inclusive, it should guide physicians and healthcare workers who utilize digital mammography.

II. GOALS

Screen-film mammography has been proven to be highly effective in screening and diagnosis but does have certain limitations, some of which may be overcome with digital mammography.

A major feature of digital mammography that may ultimately prove to be advantageous is its ability to provide improved image contrast over all regions of the breast. In contradistinction to the fixed characteristic curve of a given film type used in screen-film mammography, the exposure-density response curve of digital mammography may be determined by other means – for example, by image processing.

In addition, the ability to display, archive, and transmit digital mammography images may facilitate:

1. Telemammography – transmission of digital images to remote sites for purposes of off-site monitoring of diagnostic work-ups, interpretation, consultation, and conferencing.
2. Computer-aided detection and diagnostic assistance to radiologists.
3. Reduction in the number of repeats for technical reasons.
4. More efficient storage and retrieval of images.
5. Interventional techniques.
6. Digital tomosynthesis.

These and other potential advantages of digital mammography will have to be weighed against the potential disadvantages and technical challenges of current display monitors, design of efficient workstations, large data storage requirements, and system cost.

III. PATIENT SELECTION

For indications, frequency, and self-referral information see the ACR Practice Guideline for the Performance of Screening Mammography and the ACR Practice Guideline for the Performance of Diagnostic Mammography.

All imaging facilities should have policies and procedures that reasonably attempt to identify pregnant patients prior to the performance of any diagnostic examination involving ionizing radiation. If the patient is known to be pregnant, the potential radiation risks to the fetus and clinical benefits of the procedure should be considered before proceeding with the study (Res. 24, 1995).

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting physicians, medical physicists, and radiological technologists who work in mammography must meet the requirements of the Mammography Quality Standards Act (MQSA) final rule as published by the Food and Drug Administration (FDA) (see Appendix A). Those personnel must have at least 8 hours of training in digital mammography before beginning to use that modality. Interpreting physicians and radiologic technologists must earn at least six continuing education units in a 36-month period for digital mammography. Medical physicists must include training in digital mammography in a 36-month period.

V. SPECIFICATIONS OF THE EXAMINATION

See the ACR Practice Guideline for the Performance of Screening Mammography and the ACR Practice Guideline for the Performance of Diagnostic Mammography.

It is desirable that the acquisition process and resulting clinical digital mammography image be at least equivalent to screen-film mammography in terms of image sharpness, noise, and artifacts and that the average glandular dose to the breast be no more than that for the screen-film mammography.

A. Radiation Dose

The average glandular dose will be measured at least annually. For examination of a 4.2 cm-thick compressed breast consisting of 50% glandular and 50% adipose tissue, the dose will be no more than 0.3 rad (3 milligray) per craniocaudal view.

B. Comparison with Prior Mammograms

An attempt should be made to obtain prior mammograms when the interpreting physician deems it necessary. Under the MQSA final rule, facilities must provide original films.

Even when soft-copy reading is routinely used, facilities must have the ability to produce high-quality hard-copy images that can be provided for comparison or to referring physicians.

C. Image Labeling

Adequate documentation of the study is essential for high-quality patient care. All radiographic images shall be labeled in accordance with the MQSA final rule and the current ACR Mammography Quality Control Manual. Each mammography image shall have the following information permanently indicated on it so as not to obscure anatomic structure:

1. Facility name and location, including city, state, and zip code.
2. Patient's first and last names.
3. Unique identification number and/or date of birth.
4. Examination date.
5. Technologist's initials (or identification number).
6. Cassette number, where applicable.
7. Mammographic unit identification (if the facility has more than one).
8. View and laterality.

D. Viewing Issues

Film images obtained with digital mammographic systems should be viewed in accordance with recommendations for screen-film mammograms.

1. Electronic display

   Electronic displays (typically image monitors) should be operated at output light intensity to allow perception of subtle contrast by the interpreting physician.

2. Viewing images

   Viewboxes and electronic viewing stations 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.

   In the short term (at least the next 5 years) radiologists will be comparing digital images with previous conventional film mammograms. Variable-intensity viewboxes that can provide high intensity (greater than 3,000 cd/m^2) are recommended for viewing conventional mammograms. It is essential to mask the area around the mammograms to exclude extraneous light. Hot lights should also be available for viewing screen-film mammograms.

   Lower intensity (a minimum of 2,000 cd/m^2) conventional viewboxes are acceptable for reading hard-copy output of digital mammography.

   All viewboxes should be checked periodically to ensure that they are in optimal condition.

E. Image Retention

When digital mammograms are interpreted from film images, either these films shall be retained as the original in compliance with MQSA, or the original digital images shall be retained using a durable storage medium. When interpretation is from electronic display, the full data set of the digital mammographic images shall be retained using a durable storage medium. If both film and electronic images are used at the time of original image interpretation, the full data set of the digital mammographic images shall be retained using a durable storage medium. Images must be retained according to MQSA regulations.

F. Fixed and Mobile Mammography Units

Screening mammography may be performed in settings where there may not be an interpreting physician on-site. The mammography offered must follow all of the previously mentioned guidelines with strict adherence to documented protocols.

Satisfactory performance of mobile mammography unit(s) at each location must be verified after each move by means of a test method that establishes the adequacy of the image quality before any mammograms are performed.

VI. EQUIPMENT SPECIFICATIONS

See the ACR Practice Guideline for the Performance of Screening Mammography and the ACR Practice Guideline for the Performance of Diagnostic Mammography.

The following specifications are recommended for full-breast digital mammography systems:

A. The X-ray system shall be designed specifically for mammography. Where a digital detector is employed in addition to a screen-film image receptor, the system shall comply with all screen-film mammography regulations. The system should include a display system so that the technologist can view the digital image at the time of the examination to ensure that the positioning and image quality are acceptable along with a high-quality display system to allow image interpretation by the radiologist.

Any electronic display system should allow control of image display settings to enable the interpreting physician

to assess all of the relevant information in the digital image.

B. The X-ray field should not exceed the boundaries of the image receptor support or detector unit except at the chest wall, where it should extend to the edge of the image receptor (except for specialized "coned" views), but not extend beyond it by more than 1% of the source-to-image distance (SID).

C. The X-ray tube target and beam filtration should be capable of producing an X-ray spectrum matched to the breast thickness and composition and to the response characteristics of the X-ray detector so as to provide an acceptable level of signal-to-noise characteristics at an acceptable dose to the breast. Because of the greater flexibility in technique possible for digital mammography, it is not appropriate at this time to define specific requirements for the X-ray tube target material.

D. At 4.5 cm above the breast support plate, focal spot unsharpness should produce no additional perceptible loss of image resolution (beyond that of the image receptor itself).

E. It is expected that most digital detectors will also serve as the sensors for automatic exposure control. Multiple AEC modes such as “low noise” and “low dose” may still be valuable. A display of the actual mAs or radiation level used during the exposure should be provided and held or be retrievable until the next exposure. For systems where the filter can be varied, it is desirable that the filter in use be displayed. There should be a postexposure display of the final kilovoltage used if automatic kilovoltage mode is selected. A mode providing automatic spectral selection (e.g., target, kVp, filter) may be useful.

F. Ideally, the system should produce an image without artifacts, distortions, or non-uniformities that could potentially interfere with the detection or diagnosis of breast cancer.

VII. DOCUMENTATION AND COMMUNICATION

Reporting should be in accordance with the ACR Practice Guideline for Communication: Diagnostic Radiology and be consistent with the MQSA final rule.

A description of abnormalities and recommendations for subsequent follow-up studies should be included in the report. The overall final assessment of findings shall be classified using the categories defined in the ACR Breast Imaging Reporting and Data System (BI-RADS®), 3rd ed., 1998, and in compliance with the MQSA final rule.

Follow-up diagnostic imaging studies should be done under the direct supervision of a qualified mammography physician.

For specific information regarding classifications of findings and communication of results, see the ACR Practice Guideline for the Performance of Screening Mammography.

VIII. QUALITY CONTROL PROGRAM

A documented quality control program with procedure manuals and logs must be maintained and be in compliance with the MQSA final rule and must be substantially the same as the QC program recommended by the manufacturer. However, the current ACR Mammography Quality Control Manual should be followed for guidance where applicable.

IX. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

Each facility shall establish and maintain a mammography medical outcomes audit program to follow up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure reliability, clarity, and accuracy in the interpretation of mammograms. These outcome data shall be analyzed individually and collectively for all interpreting physicians at a facility at least annually. It is understood that in some practice situations it will not be possible to obtain follow-up information on all positive mammograms.

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APPENDIX A

QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Interpreting Physician

Initial Qualifications:

Be licensed to practice medicine.

and

Certification in Radiology or Diagnostic Radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada;

or

Have at least 3 months (2 months if initially qualified before April 28, 1999) of documented training in mammography interpretation, radiation physics, radiation effects, and radiation protection.

and

Have 60 hours of documented Category I continuing medical education (CME) in mammography (40 hours if

initially qualified before April 28, 1999), at least 15 of which must have been acquired in the 3 years immediately prior to the physician meeting his/her initial requirements.

and

Have interpreted mammograms from examinations of 240 patients within the 6 months immediately prior to the physician's qualifying date or in any 6 months within the last 2 years of residency, if the physician becomes board certified at his/her first possible opportunity.

and

The interpreting physician must receive at least 8 hours of training in any mammographic modality (e.g., digital) for which he or she was not previously trained before beginning to use that modality.

Continuing Experience:

Continue to interpret or multi-read at least 960 mammographic examinations over a 24-month period.

Continuing Education:

Earn at least 15 Category I CME hours in a 36-month period, at least 6 of which must be related to each mammographic modality used.

B. Medical Physicist

Initial Qualifications:

Either be licensed or approved by a state

or

Be certified in Diagnostic Radiological Physics or Radiological Physics by the ABR, or in Diagnostic Imaging Physics by the American Board of Medical Physics.

and

Either have a master's degree or higher in a physical science, 20 semester hours of physics, 20 contact hours of training in conducting surveys of mammography facilities, and experience in conducting mammography surveys of at least 10 units and at least 1 facility.

or

By April 28, 1999, have qualified as a medical physicist under the interim regulations, and have a bachelor's degree or higher in a physical science, 10 semester hours of physics, 40 contact hours of training in conducting surveys of mammography facilities, and experience in conducting mammography surveys of at least 20 units and at least 1 facility.

and

Before surveying units of any mammographic modality (e.g., digital), the medical physicist must have at least 8 hours of training with that modality.

Continuing Experience:
Survey at least 2 mammography facilities and a total of at least 6 mammography units within a 24-month period.

Continuing Education:
Earn at least 15 CME hours/continuing education units (CEU) in a 36-month period, which includes appropriate hours of training for each mammographic modality for which physics services are provided.

C. Radiologic Technologist

Initial Qualifications:

Have general certification from the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiologic Technologists.

or

Be licensed to perform general radiographic procedures in a state. (Technologists are <u>not</u> required to have passed the ARRT special competency examination in mammography.)

and

Technologists initially qualifying on or after April 28, 1999, must meet the mammography-specific training requirements by having at least 40 hours of documented training in mammography, including:

1. Training in breast anatomy and physiology, positioning and compression, quality-assurance/ quality-control techniques, and imaging of patients with breast implants.
2. Performance of a minimum of 25 mammography examinations under direct supervision of an appropriate MQSA-qualified individual.
3. At least 8 hours of training in using any mammographic modality (e.g., digital) before beginning to use that modality independently.

Continuing Experience:
Perform at least 200 mammography examinations in a 24-month period.

Continuing Education:
Earn at least 15 CEUs in a 36-month period that must include at least six CEUs in each mammographic modality used.