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The American College of Radiology will periodically define new practice guidelines and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

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ACR PRACTICE GUIDELINE FOR THE PERFORMANCE OF DIAGNOSTIC 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,

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. Therefore, it should be recognized 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

The goal of all mammography is the detection of breast cancer, but unlike screening mammography, diagnostic mammography is intended to provide specific analytic evaluation of patients with clinically detected or screen detected abnormalities. The request for diagnostic mammography should be regarded as a request for diagnostic breast imaging consultation, which may also include additional separate studies (e.g., ultrasound, magnetic resonance imaging [MRI]) as indicated).

II. DEFINITION

Diagnostic mammography is a radiographic examination performed to provide additional information about patients who have signs and/or symptoms of breast disease, radiographic findings of concern, or in situations

where direct supervision¹ of the imaging is deemed appropriate by the interpreting physician. A diagnostic mammogram is performed under the direct supervision of a qualified physician in mammography and may include mediolateral oblique (MLO), craniocaudal (CC), and/or additional views.

The patient's history, symptoms and signs, reported findings on physical examination, and results of any prior mammography will focus the diagnostic breast evaluation.

III. GOAL

The goal of diagnostic mammography is to obtain information that leads to specific interpretive conclusions and/or further diagnostic and management recommendations or courses of action.

IV. PATIENT SELECTION

Indications for diagnostic mammography may include:

1. Specific focus of clinical concern including, but not limited to, mass, induration, axillary lymphadenopathy, some types of nipple discharge, skin changes, or persistent focal areas of pain or tenderness.
2. Possible radiographic abnormalities detected on screening mammography.
3. Short-interval follow-up (e.g., less than 1 year) for probably benign radiographic concerns as defined by the ACR Breast Imaging Reporting and Data System (BI-RADS[®]).
4. Any patient whose examination requires direct involvement of the radiologist for special views, breast physical examination, or consultation.
5. Women who have implants.
6. Women who have been treated for breast cancer.

All imaging facilities should have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of any 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. (1995, 2005 - ACR Resolution 1a)

However, the potential risk of mammography to the fetus is negligible, and diagnostic mammography is not contraindicated for the pregnant patient [15].

¹Direct supervision is defined as the physician being present and immediately available to furnish assistance and direction throughout the performance of the procedure.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

The same qualifications stated for personnel performing screening mammography apply to diagnostic mammography (see the [ACR Practice Guideline for the Performance of Screening Mammography](#) and the FDA final rule for MQSA that went into effect April 28, 1999).

VI. SPECIFICATIONS OF THE EXAMINATION

See also the [ACR Practice Guideline for the Performance of Screening Mammography](#) and the FDA final rule for MQSA that went into effect April 28, 1999.

A. The written or electronic request for a diagnostic mammography should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. (2006 - ACR Resolution 35)

B. Appropriate markers may be used to identify areas of clinical concern, areas of prior intervention, skin abnormalities, etc. and to help correlate them with ultrasound findings. Radiographic demonstration of surface markers may provide positioning guidance for routine views, spot compression, tangential, and other views.

C. A diagnostic mammogram may include additional views to evaluate an area of clinical or radiographic concern. Additional mammographic views might include spot compression, spot compression with magnification, tangential views, or other special views. When selecting a view, the proximity of the area of concern to the image receptor should be considered.

D. Evaluation of the augmented breast should include, when possible, standard CC and MLO or lateral views as well as implant displacement views.

E. Adequate documentation of pertinent patient and technical information is essential for high-quality patient care. All radiographic images should be labeled in accordance with the current ACR Mammography Quality Control Manual and the FDA final rule for MQSA that went into effect April 28, 1999. Image labeling should include the following information in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

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 (screen) number for nondigital images.
7. Mammographic unit identification, if there is more than one unit in the facility.
8. View and laterality (placed on the image in a position near the axilla).

F. Retention of mammographic images should be consistent with clinical need (see the [ACR Practice Guideline for the Performance of Screening Mammography](#)) and be in compliance with federal and state regulations and local healthcare facility requirements and regulations.

VII. DOCUMENTATION AND COMMUNICATION OF RESULTS

See also the FDA final rule for MQSA that went into effect April 28, 1999.

A. The Mammographic Report

The clinical or radiographic concern(s) that prompted the diagnostic mammogram should be acknowledged. The location of mammographic abnormalities can be indicated by using clock position; quadrant of the breast; and/or location within the anterior, middle, or posterior third of the breast. The diagnostic mammogram report should describe pertinent observations, establish levels of suspicion of malignancy based on the imaging findings, and provide recommendations for patient diagnosis and management. If additional, separate breast imaging studies or procedures are performed or are available, they may be correlated in the diagnostic mammography report. The ACR BI-RADS[®] is available to provide a framework for reporting, lesion assessment, imaging-pathologic correlation, and quality improvement. Reporting should be in accordance with the [ACR Practice Guideline for Communication of Diagnostic Imaging Findings](#) and

consistent with the FDA final rule for MQSA, that went into effect April 28, 1999.

A description of detected abnormalities and recommendations for subsequent follow-up studies should be included in the report. Overall final assessment of findings shall be classified using the categories defined in the ACR BI-RADS[®] 3rd ed. 1998, and may be based on all imaging studies performed that day.

B. Communication of Mammography Results to Healthcare Providers

When the patient has a referring healthcare provider or has named a healthcare provider, the facility shall:

1. Provide a written report of the mammography examination, including the name of the patient and an additional patient identifier, to that healthcare provider as soon as possible, but no later than 30 days from the date of the mammography examination; and
2. Make reasonable attempts to communicate directly with the healthcare provider as soon as possible, if the assessment is "suspicious" or "highly suggestive of malignancy." If the healthcare provider is unavailable, a report should be given to the responsible designee of the healthcare provider. The actual or attempted direct communication should be documented.

C. Written Communication to Patients

1. The facility shall send or give directly to all patients a written summary, in lay terms, of the results of the study no later than 30 days from the date of the mammographic examination. If assessments are "suspicious" or "highly suggestive of malignancy" the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.
2. For self-referred patients (patients who do not name a healthcare provider), the facility must send or directly give the patient the actual mammographic report and a summary in lay terms no later than 30 days from the date of the mammographic examination. Facilities must also have a system to refer such patients to a healthcare provider when clinically indicated. Reports in the categories of "needs additional imaging evaluation," "probably benign, short-interval follow-up," "suspicious abnormality," or "highly suggestive of malignancy" should be communicated as soon as possible to the self-referred patient.

VIII. EQUIPMENT SPECIFICATIONS

In addition to the specifications stated for screening mammographic units (see the [ACR Practice Guideline for the Performance of Screening Mammography](#) and the FDA final rule for MQSA, that went into effect April 28, 1999), equipment used for diagnostic mammography must have magnification and spot-compression capability.

IX. COMPARISON WITH PRIOR BREAST IMAGING STUDIES

Comparison with prior breast imaging studies may be an important part of diagnostic mammography. If previous breast imaging studies are needed for assessment of mammographic findings, an attempt should be made to obtain them.

X. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This is the concept “As Low As Reasonably Achievable (ALARA)”.

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active or manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Patient radiation doses should be periodically measured by a medical physicist in accordance with the appropriate ACR Technical Standard. (2006 - ACR Resolution 17)

XI. 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, Safety, Infection Control, and Patient Education appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

Quality improvement and quality control programs that are required for screening mammography are also required for diagnostic mammography practices (see current ACR Mammography Quality Control Manual and

the FDA final rule for MQSA, that went into effect April 28, 1999).

Accurate record keeping, patient tracking, and outcome analysis are important for effective, diagnostic mammographic imaging evaluations.

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