ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF DIGITAL BREAST TOMOSYNTHESIS (DBT)

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care[1]. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents 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 practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, 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 this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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. Therefore, it should be recognized that adherence to the guidance in this document 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 purpose of this document is to assist practitioners in achieving this objective.

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1 *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.*

I. INTRODUCTION

In 2011, the US Food and Drug Administration (FDA) approved digital breast tomosynthesis (DBT) as a new breast imaging modality, and it has been adopted into clinical practice. In 2015, the Center for Medicare and Medicaid Services approved reimbursement codes for DBT performed in addition to digital mammography (DM) for routine screening.

DBT reduces the masking effect of superimposed breast tissue, resulting in improved cancer detection, specificity, and lower recall rate compared to traditional 2-D DM [1-6]. Benefits of DBT are evident across all age and breast density groups [7], with the largest gains observed in patients with heterogeneously dense breast

tissue [8]. The improved outcomes are sustainable on subsequent screening rounds [9,10].

Implementation of DBT also increases detection of invasive breast cancers, without an increase in the proportion of detected ductal carcinoma in situ (DCIS) [3,11-13]. The additional invasive cancers detected at DBT have similar or more favorable tumor characteristics than cancers detected at 2-D DM, such as higher proportions of small, spiculated, low-grade tumors [2,12,14,15]. In a prospective population-based trial of over 14,000 women, the interval cancer rate was lower in women screened with DBT than in the 2-D DM screening control group [16].

DBT also plays an important role in diagnostic breast imaging. Multiple studies have found improved accuracy in evaluation of noncalcified lesions with DBT compared with 2-D DM spot compression views alone [17-19]. The number of additional views obtained is decreased or potentially eliminated [20] when evaluating noncalcified findings, making diagnostic work-ups more efficient. Diagnostic DBT has also shown an improved positive predictive value for biopsy while maintaining the cancer detection rate [21]. Additionally, there is a decrease in the number of patients for whom a short-interval follow-up is recommended when diagnostic evaluation is performed with DBT [22-25].

As DBT becomes increasingly widespread, indications, qualifications, and specifications of the examination must be standardized to ensure consistent performance. This document supplements the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [26] and specifically guides physicians performing and interpreting DBT.

II. INDICATIONS AND CONTRAINDICATIONS

A. Screening Mammography: Indications for screening DBT are the same as for 2-D See the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [26].

B. Diagnostic Mammography: Indications for diagnostic DBT are the same as for 2-D See the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [26].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting physicians, medical physicists, and radiologic technologists who work in mammography, including DBT, must meet the requirements set forth in the Mammography Quality Standards Act (MQSA) final rule published by the FDA [27].

Under MQSA, DBT is considered a new modality. Five DBT systems have been approved for marketing in the United States, and facilities that perform mammography using any of these DBT systems are subject to MQSA requirements [27].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

The FDA regulations specify "before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician must have at least eight hours of training in the new mammographic modality" [28]. The initial 8 hours of training does not have to be awarded the American Medical Association's Physician's Recognition Award (PRA) Category 1 Continuing Medical Education credit [29]. For interpreting physicians, initial training may be obtained during residency as long as attestation is provided by the residency program. The FDA provides a sample residency attestation letter on its website [30].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

B. Qualified Medical Physicist

In addition to the basic education, training, and experience requirements for the Qualified Medical Physicist, the FDA requires the Qualified Medical Physicist to receive 8 hours of DBT training. The training can be general or specific to a particular DBT system to fulfill the MQSA new modality training requirement [30].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

C. Radiologic Technologist

In addition to the basic education, training and experience requirements for the radiologic technologist, the FDA requires the radiologic technologist to receiver 8 hours of DBT training. The training can be general or specific to a particular DBT system to fulfill the MQSA new modality training requirement for DBT [31].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for a diagnostic mammography examination 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 stated scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

A. Synthetic Mammography (SM): SM is derived from the DBT source projection images, which are rendered to simulate 2-D DM [32]. The purpose of SM is to replace the 2-D DM component of the DBT examination, thereby eliminating the patient's radiation exposure from those views [33]. Several studies have demonstrated that improvement in cancer detection and reduction in recall rates with SM + DBT is comparable to that shown with DM + DBT [34-37]. Therefore, SM is an acceptable alternative to 2-D DM when used in conjunction with DBT. Please consult federal, state, or local regulatory requirements because the policies and procedures established by an organization, facility, or accrediting body may differ from the recommendations outlined in the Practice Parameters and Technical Standards. The recommendations in this document are not meant to be exhaustive of all applicable regulations and requirements.

B. Screening Mammography: A full examination should consist of at least two DBT acquisitions (craniocaudal [CC] and mediolateral oblique [MLO]) per breast with the correlative standard 2-D DM or SM CC and MLO views.

C. Diagnostic Mammography: At minimum, a diagnostic examination for signs or symptoms or evaluation of suspected masses, asymmetries or architectural distortion should include one DBT This may be a full-field view, spot compression view, or any other special view with the correlative 2-D DM or SM view. Diagnostic mammography performed to evaluate screen-detected calcifications may or may not include DBT images.

D. Special Scenarios:
- Implants: For patients with breast implants, implant displaced CC and MLO views are performed in addition to the routine implant in field CC and MLO views. If using DBT, a combination of 2-D DM CC and MLO implant in-field views and CC and MLO DBT implant-displaced views is recommended to minimize radiation in patients with implants while maintaining the improved cancer detection rate and reduced recall rate seen with DBT [33].
- Breasts larger than the detector: DBT may be used when patients with large breasts require multiple exposures in the same view to image the entire breast. If both 2-D DM and DBT images are being acquired, DBT should be applied only to the largest portion of the breast for each projection to minimize the number of views and associated radiation dose. In such situations, the remainder of the breast still must be imaged with tiled 2-D If synthesized 2-D images are being reconstructed in lieu of separately acquired 2-D DM views, DBT may be used for all portions of the examination .

E. Request for Tomosynthesis: A separate physician order is not required for DBT. The performance of DBT

should be at the discretion of the interpreting radiologist, the patient, and in accordance with individual breast center imaging protocols.

F. Image Labeling: The 2-D DM component of the examination should follow the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [26]. For DBT images, there must be a way to determine the relative position of a slice within the Slice numbers alone are insufficient; the orientation of the first slice relative to the detector must be specified because slice numbering varies by DBT manufacturer and picture archiving and communication system. Breast imaging facilities should be aware of their equipment parameters, and the interpreting physician should be knowledgeable about how the DBT slices are labeled. Slice number, thickness, and location relative to the side of the breast should be indicated on the workstation display as well as on printed images. It is recommended that if a facility uses DBT systems from more than one manufacturer, slice numbering should be standardized across the systems to avoid confusion.

   2-D synthetic mammography views : If SM is used, it must be labeled as such to distinguish it from a separately acquired 2-D DM

G. Image Transfer: The DICOM standard for DBT is the Breast Tomosynthesis Object (BTO). Some manufacturers generate DBT images in
proprietary format. Before transfer of imaging to other facilities, it is recommended that the host institution convert any DBT images in proprietary format to the standard format [38].

   If DBT images are being sent to a site that does not have the capability of viewing DBT, or if the practitioner at the receiving facility is not qualified to interpret DBT, it is acceptable, although not optimal, to review only the 2-D DM portion of the examination. In this circumstance, it is advised that the report state clearly that the interpretation was without the benefit of all the information acquired at the host institution. 2-D SM images are occasionally submitted for review or consult without the DBT images; every effort should be made to obtain the DBT images, and if impossible, this should be stated as a limitation in the report.

H. Guidance for Interventional Procedures
   a. DBT-guided biopsy allows for percutaneous sampling of calcified and noncalcified lesions visible on 2-D DM and/or DBT. One study has demonstrated that approximately 7% of breast lesions recommended for biopsy are visible only on DBT [39]. Technical success is achieved more often with DBT guidance than with 2-D stereotactic-guided biopsy [40,41]. Therefore, access to biopsy equipment capable of localizing lesions with DBT is recommended but not mandatory.
   b. Performance of breast biopsy under DBT guidance should follow the ACR Practice Parameter for the Performance of Stereotactic/Tomosynthesis-Guided Breast Interventional Procedures [42]. However, there are occasions when both stereotactic and DBT guidance may be used to obtain tissue. The current procedural terminology (CPT) codes for DBT biopsy differ depending on whether or not stereotactic guidance was incorporated during the procedure. Therefore, documentation in the report that stereotactic images were obtained in addition to DBT is recommended, and CPT code assignment must reflect what was performed.
   c. If DBT guidance is not available for a tomosynthesis-only finding, it is acceptable to perform a stereotactic biopsy using adjacent tissue landmarks for guidance if possible. However, a biopsy marker should be placed with postprocedure DBT images in two projections to demonstrate that the original finding was properly targeted and sampled.

Please consult federal, state, or local regulatory requirements because the policies and procedures established by an organization, facility, or accrediting body may differ from the recommendations outlined in the Practice Parameters and Technical Standards. The recommendations in this document are not meant to be exhaustive of all applicable regulations and requirements.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [43].
The report should follow the guidelines for terminology, including descriptions of lesion features and location, as published in the ACR Breast Imaging Reporting and Data System (BI-RADS®) Lexicon. To aid identification of lesions seen only on DBT, it is suggested that the view and slice number(s) on which tomosynthesis findings are identified be included in the report. The BI-RADS® assessment category should be included in the conclusion of the report.

VI. EQUIPMENT SPECIFICATIONS

Mammography equipment must meet the MQSA regulations published by the FDA [27]. ACR–AAPM–SIIM Practice Parameter for Determinants of Image Quality in Digital Mammography provides additional guidance for digital mammography and DBT acquisition and display equipment [44].

Because different clinical DBT protocols have been the basis for FDA approval of different vendor products, radiologists should consider how to best incorporate such protocols into their clinical practice to optimize both the current examination and provide a basis for future comparison studies. When necessary, judicious use of off-label approaches that cannot be formally recommended by a vendor can be considered so long as they are consistent with FDA guidelines.

VII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

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 appearing under the heading *ACR Position Statement on Quality Control and Improvement, Safety, Infection Control*, *and Patient Education* on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement). Examinations should be systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Monitoring should include evaluation of the accuracy of interpretation as well as the appropriateness of the examinations. Complications and adverse events or activities that may have the potential for sentinel events must be monitored, analyzed, reported, and periodically reviewed to identify opportunities to improve patient care. These data should be collected in a manner that complies with statutory and regulatory peer- review procedures to ensure the confidentiality of the peer-review process.

In accordance with standards of 2-D DM imaging, each facility should establish and maintain a medical outcome audit program to follow up positive assessments and to correlate pathology results with the interpreting physician's findings. If a facility does not perform DBT-guided intervention and refers tomosynthesis-only findings for biopsy to another accredited facility, it should have access to correlative pathology results from the procedure facility. The audit should assess the accuracy of interpretation as well as the clinical appropriateness of the examination. Facilities should use the BI-RADS® final assessment codes and terminology for reporting and tracking outcomes. The BI-RADS® Atlas contains guidance on monitoring outcomes and conducting the audit. Summary statistics and comparisons generated for each physician and each facility should be reviewed annually by the lead interpreting physician.

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