INTRODUCTION

he ACR BI-RADS[®] is a quality assurance tool designed to standardize reporting, reduce confusion in breast imaging interpretations and management recommendations, and facilitate outcomes monitoring. Through a medical audit and outcomes monitoring, BI-RADS[®] provides important structure for collecting peer-review and quality assurance data that may improve the quality of patient care.

All interpreting physicians and referring health care providers should be aware of the benefits and limitations of breast imaging technologies. There are two major categories of women who may benefit from breast imaging studies.

Screening

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The major role for mammography is the earlier detection of breast cancer in asymptomatic women. The efficacy of mammographic screening has been established by randomized controlled trials in which significant breast cancer mortality reduction has been achieved by the ability of mammography to depict ductal carcinoma in situ and infiltrating cancers at a smaller size and earlier stage than in control groups not offered screening. Data are also accumulating that indicate the adjunctive use of US and MRI is useful in the screening setting for certain groups of high-risk women, which is covered in detail in the US and MRI sections of the BI-RADS® Atlas. Although mammography can detect the majority of breast cancers, there are some that elude detection by imaging yet may be palpable. Thus, despite the paucity of studies demonstrating the efficacy for the clinical breast examination (CBE), the committee feels this remains an important component of screening. In addition, although breast cancer mortality reduction has not been demonstrated for breast self-examination, it seems prudent to encourage its use, if only as a means to promote awareness of good breast health practices that include screening with mammography. By definition, mammographic screening involves the performance of the mediolateral-oblique and craniocaudal projections. Its goal is to identify the small subset of women who require further diagnostic imaging evaluation among the much larger group of well women for whom periodic screening is recommended. In some clinical practice settings, additional mammographic images and/or adjunctive breast imaging studies will be undertaken immediately to solve a question raised on a screening examination. In the more common setting, involving the batch reading of screening examinations, the patient will be recalled for further evaluation to answer a question raised on the screening study.

Diagnostic Breast Evaluation

Mammography and other breast imaging modalities, such as US and MRI, also are useful in the evaluation of women who have signs or symptoms that may suggest breast cancer. However, **there is no test or group of tests that ensure that a woman does not have breast cancer.** Physical examination evaluates different tissue characteristics than mammography and provides a unique set of information concerning the tissues being studied. Just as decisions must be made based on mammographic suspicion in the face of a normal clinical examination, management decisions also must be made based on clinical findings in the face of a negative mammogram. Because it is a well-established fact that mammography does not reveal all breast cancers, some of which may be palpable, a statement indicating diminished accuracy of mammography in the dense breast is often warranted.

In addition, a finding of clinical concern that has no mammographic correlate must be evaluated independently of the mammographic findings. US is often helpful in this setting; given the combination of a negative mammogram and negative sonogram, the likelihood of malignancy has been shown to range from 2013

0.1% to 4%.¹⁻⁶ A statement in the report should be included indicating the need for final management based on findings at clinical breast examination, in which the laterality, clock-face position, and distance from the nipple of the symptomatic lesion are described (to the extent known) in order to aid the referring clinician in identifying the site at which CBE should be targeted. However, universal (nontailored) disclaimers are unnecessary since it is well established that a negative mammogram does not exclude cancer and a clinically suspicious area should be biopsied even if the mammogram is negative.

Despite the fact that biopsy may be performed for a suspicious palpable abnormality, mammography is still important to evaluate the area in question as well as to screen the remaining ipsilateral and the contralateral breast for clinically occult cancer. It also is important for women and their physicians to understand that mammography screening is not perfect and that any noncyclic breast change should be brought to the physician's attention regardless of how soon this occurs following negative mammography and clinical breast examinations.

The ACR BI-RADS® — Mammography is divided into three sections with two additional appendices.

SECTION I: Breast Imaging Lexicon — Mammography

SECTION II: Reporting System

SECTION III: Guidance

APPENDIX A: Mammographic Views

APPENDIX B: ACR BI-RADS® — Mammography Lexicon Classification Form

The following is a brief summary of each section.

I. Breast Imaging Lexicon — Mammography

The terminology used to describe mammographic findings has evolved over many years, and the diversity of this terminology may cause confusion. The descriptive terms and definitions that follow have been approved by the ACR Committee on BI-RADS[®], and it is hoped that all those involved in breast imaging will adopt these terms and use them exclusively so that reports will be clear, concise, and standardized. It is believed that these terms provide a reasonably complete evidence-based categorization of mammographic lesions. Any proposed substantive changes should be submitted to the ACR for review by the Committee on BI-RADS[®], as indicated in the Preface.

II. Reporting System

The reporting system is designed to provide an organized approach to image interpretation and reporting. It does not absolutely require use of computer-based reporting software, but such use is strongly recommended. Not only does this facilitate clear, concise, and standardized reporting, but it also permits simultaneous data collection for the maintenance of a database used for future outcomes review (audit). This will allow individual interpreting physicians and mammography facilities to monitor their own results and appraise the accuracy of image interpretation so that they can adjust interpretive thresholds appropriately. The ideal computer-based reporting software has not yet been developed, but it is strongly recommended that use of software should involve a minimum of data entry. The interpreting physician's attention should be focused on the evaluation of images, not on interaction with a software program. The simplest input utilizes a single screen for normal examinations and only limited interaction for abnormal examinations. The goals are to maximize the image viewing time and minimize the distractions inherent in reporting. If practical, we recommend use of a scribe to enter the data. Note that use of ACR-approved computer-based reporting software is required for participation in the ACR National Mammography Database (NMD) (https://nrdr.acr.org/Portal/NMD/Main/page.aspx), a quality assurance