Quality and safety considerations in breast cancer screening

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Abstract

Breast cancer is a leading cause of premature mortality among United States women. Early detection has been shown to reduce breast cancer morbidity, mortality and cost of treatment. The relative safety of breast cancer screening has been viewed in terms of benefits and harms. The quality and safety of breast cancer screening depends on both technical and human factors. Focusing on quality and safety considerations, we review two imaging modalities recommended for primary breast cancer screening: mammography and magnetic resonance imaging, and the use of ultrasound (US) for supplemental breast cancer screening.

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Introduction

Breast cancer is a leading cause of premature mortality among U.S. women. Early detection has been shown to reduce breast cancer morbidity, mortality and cost of treatment.[1-6] The relative safety of breast cancer screening has been viewed in terms of benefits and harms.[7] Varying judgments regarding the appropriate balance between the benefits and harms of screening have resulted in differences among recommendation guidelines for breast cancer screening (Table 1).[8-11] In 2014, The American Cancer Society (ACS) commissioned the Duke Evidence Group to conduct a systematic review of cancer screening literature for updating their breast cancer screening guidelines.[10, 12]

The quality and safety of breast cancer screening depends on both technical and human factors. The two primary imaging modalities used for primary breast cancer screening are mammography and magnetic resonance imaging (MRI). Nearly all mammograms in the U.S. are currently performed with digital technology, either as 2D mammography or DBT (digital breast tomosynthesis, a "pseudo-3D mammogram"), and frequently as combined 2D/DBT examinations. Though ultrasound is used as a

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supplemental breast cancer screening modality in some clinics, it is not universally employed or accepted at this point in time. We will briefly discuss its use as a supplemental screening modality to conventional mammography screening. However, in this paper, we focus primarily on the quality and safety considerations for the primary imaging modalities used for breast cancer screening: x-ray based digital mammography (2D or DBT) for average risk populations and MRI for high risk populations.

TABLE 1. Breast Cancer Screening Guidelines – Average Risk Women

American College of Obstetricians and Gynecologists [8,9]	**Women at average risk of breast cancer should be offered screening mammography starting at age 40 years. If they have not initiated screening in their 40s, they should begin screening mammography by no later than age 50 years.** **The decision about the age to begin mammography screening should be made through a shared decision- making process. This discussion should include information about the potential benefits and harms.** **Women at average risk of breast cancer should have screening mammography every one or two years based on an informed, shared decision-making process that includes a discussion of the benefits and harms of annual and biennial screening and incorporates patient values and preferences.** **Women at average risk of breast cancer should continue screening mammography until at least 75 years. Beyond age 75 years, the decision to discontinue screening mammography should be based on a shared decision making process informed by the woman's health status and longevity.**
American Cancer Society, 2015 [10]	**Women ages 40 to 44 should have the choice to start annual breast cancer screening with mammograms, if they wish to do so.** **Women age 45 to 54 should get mammograms every year. Women 55 and older can switch to mammograms every 2 years, or can continue yearly screening.** **Screening should continue as long as a woman is in good health and is expected to live 10 more years or longer.**
American College of Radiology / Society of Breast Imaging [11]	**Annual mammographic screening beginning at age 40.** **The age to stop should be based on each woman's health status rather than an age-based determination.** **Women should be helped to understand the risks of screening; weighing benefits and risks should be done by women, not for women.**

The Mammography Quality Standards Act (MQSA)

The standards for mammography quality and safety were largely established by the MQSA. In 1992, Congress enacted the law with the aim of ensuring quality and uniformity through federal regulation of mammography and other breast procedures involving ionizing radiation (i.e., X-rays). By 1994, FDA Interim Rules required all mammography facilities in the United States to be accredited, certified and inspected. The MQSA law established mandatory testing of equipment by physicists, specific training and experience criteria for radiologists and technologists (baseline training, continuing medical education hours, and number of mammograms a technologist should perform and a radiologist should read over 2-year time periods), and quantitative evaluation of image quality by ratings of phantom and clinical images. Throughout the 1990's, emphasis focused on inadequate equipment, radiation safety and improving the interpretation of mammographic images by radiologists. Under the MQSA law, FDA-approved accrediting bodies review clinical and phantom images from every facility once every 3 years to monitor compliance with quality standards and ensure patient safety.

Over the last 20 years, several amendments to the MQSA legislation have been made. For example, a modification was designed to ensure that women with abnormal mammograms were not lost to follow-up by requiring that mammography centers send women a copy of their mammogram report in lay language. In addition, although not required by the MQSA at this point in time, many states now require that mammography reports also inform women of their breast density. Now enacted in over 30 states, breast density notification laws vary widely but are intended to inform women who have undergone mammography about the risks posed by their breast density and to encourage discussions with their primary care providers about the need for supplemental screening. One very helpful website, created by the California Breast Density Information Group (CBDIG), includes educational materials for women[13] and for health care providers.[14] Most recently, on February 15, 2019, Congress passed a new federal law mandating that the FDA develop breast density reporting language that must be included in patient letters and healthcare provider reports. The exact language and effective date are still under development as proposed changes to the FDA/MQSA requirements.

Radiation Safety

An important safety concern regarding the equipment used to acquire mammograms during the initial 10 years of the MQSA was radiation dose.[15-17] Because women undergoing screening mammography are healthy (i.e., without breast symptoms), the initial MQSA regulations included requirements that specified a radiation dose limit for each of the four breast images acquired for a screening mammogram. Per exposure, the average x-ray dose is limited to no greater than 3 milligray (mGy) to a specialized mammography quality control phantom that simulates a compressed breast thickness of 4.2 cm and a breast composition of 50% adipose and 50% glandular tissue. A specialized phantom is used to measure radiation dose for 2D and DBT mammography as well as certain other aspects of image quality. Systems exceeding the allowed dose may not be used for patient imaging. Over time, the number of facilities failing to meet dose limits or other mammography system requirements dramatically declined, in part due to the transition from film-based to digital mammography.[18,19] In the current era of mammography technology, most systems operate well below the allowed dose. In fact, all contemporary systems are capable of obtaining both a 2D and DBT mammogram exposure within the dose limits for a single view.

Mammography Reporting and Interpretation Quality

An early screening mammography quality issue was the variability and ambiguity of mammography reports.[20-25] In the late 1980's, an expert panel for the American College of Radiology studied the lack of standardization and uniformity in mammography practice reporting and instituted the Breast Imaging Reporting and Data System, also known as BI-RADS.[26] A critical component of the system was a data-driven lexicon of descriptors for specific imaging findings predictive of benign and malignant disease. Now in its 5th edition, the BI-RADS mammography practice management system[27] includes (1) a lexicon of descriptors, (2) a recommended reporting structure including final assessment categories with accompanying management recommendations, and (3) a framework for data collection and auditing.[28] BI-RADS reporting enables radiologists to organize their reports to communicate clear and consistent results and specific management recommendations to referring healthcare providers. A summary of the BI-RADS categories, management recommendations, and likelihood of malignancy is provided in Table 2.

Another interpretation quality concern is the variability in radiologists' recommendations for recall for additional work-up and/or biopsy after a screening mammogram.[20,21,23-25,29] Recognized interventions shown to improve radiologists' mammographic interpretations include: fellowship training in breast imaging,[30] double reading and interpreting an adequate volume of screening mammograms,[22,31,32] ensuring that prior examinations are available to compare with the current exam[33] and technical tools such as computer-assisted detection (CAD) software programs that highlight imaging findings to assist recognition by the radiologist.[32,34,35] It should be noted that a recent publication found CAD not to be as useful for digital mammography.[36] The number of screening mammograms for which a radiologist recommends additional diagnostic imaging, commonly referred to as the "callback rate" or "recall rate", which do not result in a diagnosis of breast cancer (i.e., false positive mammography interpretations) is considered one of the "harms" of mammography. Similarly, recommendations for breast biopsy with negative, non-cancer pathology (i.e., false positive recommendation for biopsy) are also considered "harms".

For screening mammography, false positive rates tend to be considerably higher than false negative rates. Each is addressed by performing periodic practice audits that track recall rates for individual radiologists within breast imaging practices, allowing the radiologist to focus additional education on areas of concern.[28] The mammography practice audit is a quality assurance tool that allows facilities and practitioners to recognize areas of strength, as well as those areas that may need improvement. Acceptable interpretive performance criteria, derived by Carney et al.[37] in 2010, include: (1) recall rate 5% - 12%; (2) positive predictive value for abnormal interpretations on screening mammograms 3% - 8%; (3) positive predictive value for biopsy recommendation 20%-40%; and (4) cancer detection rate >2.5 per 1000 mammograms interpreted.

TABLE 2. BI-RADS Final Assessment Categories

Category		Management	Likelihood of cancer
0	Needs additional imaging and/or prior examinations	Recall for additional imaging and/or await prior examinations	N/A
1	Negative	Routine screening	0%
2	Benign	Routine screening	0%
3	Probably benign	Short interval follow-up (usually 6 months)	>0% but ≤ 2%
4	4a. Low suspicion for malignancy	Tissue diagnosis	>2% to ≤ 10%
	4b. Moderate suspicion for malignancy	Tissue diagnosis	>10% to ≤ 50%
	4c. High suspicion for malignancy	Tissue diagnosis	>50% to <95%
5	Highly suggestive of malignancy	Tissue diagnosis	≥95%
6	Known biopsy-proven	Surgical excision when clinically appropriate	N/A

Population-based screening mammography data collected by the National Cancer Institute (NCI) Breast Cancer Surveillance Consortium (BCSC)[38] has enabled performance benchmarking for screening mammography.[39,40] Regional registries within the BCSC link mammography data to a state tumor or Surveillance, Epidemiology and End Results (SEER) registry, and data are pooled at a central statistical coordinating center.[38] In 2006, Rosenberg et al.[39] analyzed data from 6 BSCS registries and found the following performance outcomes for U.S. mammography practices: (1) recall rate = 9.4%; (2) positive predictive value for abnormal interpretations on screening mammograms = 4.8%; (3) positive predictive value for biopsy recommendation = 25.0%; and (4) positive predictive value for biopsies performed = 32.6%. Cancer detection rate (mean cancer detection rate per 1000 mammograms) was 4.6 and the percentage of all cancers diagnosed as ductal carcinoma in situ (DCIS) was 21.6%. A follow-up analysis of BCSC data by Lehman et al 40 in 2017 found the following: (1) recall rate = 11.6%; (2) positive predictive value for abnormal interpretations on screening mammograms = 4.4%; (3) positive predictive value for biopsy recommendation = 25.1%; (4) positive predictive value for biopsies performed = 31.8%; (5) cancer detection rate = 5.1 per 1000 mammograms; and, (6) percentage of all cancers diagnosed as ductal carcinoma in situ (DCIS) = 31.0%. These authors found the sensitivity of screening mammography increased from 78.7% to 86.9% between 1996 and 2008, and that more than 92% of radiologists achieve the recommended cancer detection rate of 2.5 per 1000 women screened. However, they found that 40% of radiologists had higher recall rates than the recommended upper range of 12% by Carney et al.[37] Overall, the majority of radiologists surpassed performance recommendations by the ACR, with the exception of recall rate. Excessively high recall rates are associated with unnecessary additional imaging and/or biopsy,[29,31,37,40,42] increased costs[43] and patient anxiety.[44-46] Lehman et al. recommended that practices establish quality improvement programs based on their audit data. For example, mammograms recalled by radiologists with high recall rates were second reviewed by radiologists with documented high performance for both recall and cancer detection rates.[40] Overall, the tradeoff between recall rate and high cancer detection rate must be balanced to achieve success in breast cancer screening.[47]

The Most Widespread Quality and Patient Safety Concern of Present-Day Breast Screening Programs

Currently, the most common quality concern and the most frequent cause of mammography facility accreditation failures is inadequate positioning of the breast by the technologist when acquiring the images.[48] In 2015, the American College of Radiology, the largest FDA-approved accreditation body, found that of all clinical images that were deficient on the first attempt at accreditation, 92% were deficient in positioning and that 79% of all unit failures that year were due to inadequate positioning. Poor positioning poses a significant risk to an individual woman because cancers present in any portion of the breast not imaged on the mammogram cannot be detected. Maintaining proper positioning requires that the interpreting radiologist communicate regularly with the technologist to provide feedback on the adequacy of positioning and initiate corrective actions when problems are identified. In 2017, the EQUIP initiative (Enhancing Quality Using the Inspection Program) was instituted under the MQSA.[49] The aims of EQUIP are to ensure each facility has procedures for corrective action when clinical images are of poor quality, including mechanisms to provide ongoing feedback to mammography technologists and to document the corrective actions taken. To ensure compliance with clinical image quality standards for accreditation, a sample of mammograms performed by each technologist is reviewed regularly by the supervising radiologist. During each annual inspection, facilities must present documentation of their clinical image reviews since their last inspection.

Supplemental Screening with Breast MRI for High-Risk Women

While screening mammography has been shown to reduce breast cancer mortality by more than 40% in women aged 40 years and older, some women of higher-than-average risk should begin screening at an earlier age and possibly using a multimodality approach. In this section, the quality and safety concerns of breast MRI will be discussed.

Women undergoing screening who are identified with potentially increased risk of breast cancer should have further risk assessment. Validated assessment tools include Gail, BRCAPRO, Tyrer-Cuzick, or the Claus models. Based on the risk assessment, women may benefit from genetic counseling, enhanced screening such as MRI, more frequent clinical breast exams, or risk-reduction strategies.[50-53] Recommendations for high risk screening from the American College of Obstetricians and Gynecologists,[50,51] the American Cancer Society,[52] and the American College of Radiology/Society of Breast Imaging[53] are summarized in Table 3.

Compared with the general population, women with higher risk are more likely to be diagnosed with larger, node-positive malignancies on screening examinations, and also experience higher interval cancer rates.[53] One of the ancillary studies that may be performed on these higher-risk women is breast MRI. Contrast-enhanced breast MRI increases cancer detection in higher-risk women and is more sensitive than either mammography or ultrasound. Breast MRI can significantly improve detection of cancer that is otherwise clinically, mammographically, and sonographically occult. While routine screening breast MRI currently is not recommended for asymptomatic, average-risk women, breast MRI is recommended as a high-risk screening exam for women with a calculated risk of 20% or more of developing breast cancer in her lifetime, in addition to mammography.[50-53] Examples include women with genetic predisposition, as determined by gene testing or family pedigree, and women who received chest radiation therapy before age 30. For these high-risk women, screening breast MRI should be performed annually beginning at age 25 to 30. After age 30, both MRI and mammography are recommended; many women prefer to alternate the screening tests so that either MRI or mammography is performed every 6 months.

Assuring Patient Safety for Breast MRI

Women should be interviewed and screened for possible contraindications for MRI. Possible contraindications include presence of most cardiac pacemakers, ferromagnetic intracranial aneurysm clips, certain neurostimulators, and cochlear implants. In addition, patients suffering from anxiety or claustrophobia may require sedation or additional assistance.

TABLE 3. Breast Cancer Screening Guidelines – High Risk Women

American College of Obstetricians and Gynecologists[49,50]	**CBE every 6-12 months and annual breast MRI, ages 25-29; for ages> 29, CBE every 6-12 months, annual mammography and breast MRI (may alternate tests every six months) for women who:** • **are estimated to have a lifetime risk of breast cancer of 20% or greater, based on risk models that rely largely on family history, but who are either untested or test negative for BRCA gene mutations** • **test positive for BRCA1 or BRCA2 mutations** • **have first-degree relatives with these mutations but who are untested are generally managed as if they carry these mutations until their BRCA status is known** • **have a personal history of high-risk breast biopsy results, including atypical hyperplasia and lobular carcinoma in situ** **Women and girls who received thoracic irradiation between age 10 years and 30 years have an increased risk of cancer and should be advised to receive the following screening regimen:** • **beginning 8–10 years after they received treatment or at age 25 years, whichever occurs later: annual mammography, annual breast magnetic resonance imaging (MRI), and screening clinical breast examination every 6–12 months.**
American Cancer Society[51]	**Women who are at high risk for breast cancer should have an MRI and a mammogram every year, typically starting at age 30. This includes women who have a lifetime risk of breast cancer of ≥20% or greater, according to risk assessment tools that are based mainly on family history, including women who:** • **Have a known *BRCA1* or *BRCA2* gene mutation** • **Have a first-degree relative (parent, brother, sister, or child) with a *BRCA1* or *BRCA2* gene mutation, and have not had genetic testing themselves** • **Had radiation therapy to the chest when they were between the ages of 10 and 30 years** • **Have Li-Fraumeni syndrome, Cowden syndrome, or Bannayan- Riley-Ruvalcaba syndrome, or have first-degree relatives with one of these syndromes** **The American Cancer Society recommends against MRI screening for women whose lifetime risk of breast cancer is less than 15%.**
American College of Radiology / Society of Breast Imaging[52]	**Same as ACS for ≥20% risk PLUS:** **Breast MRI is recommended for women with personal histories of breast cancer and dense tissue, or those diagnosed by age 50.** **All women, especially black women and those of Ashkenazi Jewish decent, should be evaluated for breast cancer risk no later than age 30 so that the need for supplemental screening in those of higher risk can be identified.**

Increased parenchymal enhancement on screening breast MRI has been observed during the secretory phase of the menstrual cycle. This normal enhancement may give rise to false positive and false negative MRI scans. It is recommended that breast MRI scans be performed during the second week of the menstrual cycle for patients undergoing screening examinations in order to reduce the background enhancement.

Gadolinium contrast enhancement is required for the evaluation of breast parenchyma, as this contrast agent increases the conspicuity of diseased tissues. Gadolinium-based contrast agents (GBCAs) are not administered to patients with acute kidney injury and/or severe chronic kidney disease because of the increased risk of nephrogenic systemic fibrosis. In terms of adverse reactions, GBCAs are extremely well tolerated by most patients, and acute adverse reaction events are low ranging from 0.07% to 2.4%. Nevertheless, appropriate emergency equipment with medications should be immediately available to treat adverse reactions associated with administered medications.

Recently, residual gadolinium deposits have been found within the brain tissue of patients who received multiple doses of GBCAs over their lifetimes, most notably in the dentate nuclei and globus pallidus.[54] The gadolinium deposition in the brain may be dose dependent and can occur in patients with no clinically evident kidney or liver disease. To date, however, no adverse health effects have been uncovered, but the radiology community continues investigations in the area to explore the mechanisms of gadolinium deposition as well as its clinical and biological significance.

Accreditation and Documentation

Unlike mammography, breast MRI accreditation is voluntary. However, in order to achieve Breast Imaging Center of Excellence (BICOE – see below) status,[55] breast MRI accreditation is necessary. Through the American College of Radiology (ACR), the Breast MRI Accreditation Program provides facilities performing breast MRI procedures with peer review and constructive feedback on staff qualifications, equipment, quality control, quality assurance, MR safety policies, and image quality.

Documentation and reporting of screening breast MR examinations are standardized in accordance with ACR BI-RADS lexicon for Breast MRI, including BI-RADS final assessment codes and terminology for reporting and tracking outcomes.[56] Examinations are systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Evaluation includes technical adequacy of the examination, as well as accuracy of interpretation and appropriateness of indications for the examinations. Each facility should also establish and maintain a medical outcome audit program to follow up positive assessments and to correlate radiology and pathology outcomes for concordance.

Pitfalls and Other Considerations with Breast MRI

As with screening mammography, false-positive results occur with breast MRI. These non-malignant abnormalities detected on breast MRI may result in follow-up examinations or recommendations for biopsy, resulting in patient anxiety or post-biopsy complication such as hematoma – which is more common following MRI-guided biopsy than stereotactic or ultrasound-guided breast biopsies. In addition, currently used imaging protocols for screening breast MRI are time-consuming and expensive. There are studies evaluating abbreviated (fast) MRI protocols, which would make contrast-enhanced MRI a more cost-effective screening tool. Preliminary studies have reported these abbreviated MRI protocols to have similar sensitivities and specificities compared to full MRI protocol.[57-59]

Supplemental Screening with Ultrasound for Women with Dense Breast Tissue

With many states enacting legislation requiring that the screening mammography report to patients and their healthcare providers include information on the woman’s breast density, many screening centers now offer supplemental breast ultrasound (US) screening examination to women with dense breasts or at elevated risk for developing breast cancer. Screening US examinations are performed by either a technologist or a radiologist using a standard hand-held ultrasound probe to scan the entirety of both breasts or using an automated system to perform the examination in a standardized fashion. In the majority of cases screening US is performed in conjunction with screening 2D mammography or DBT. The most noted U.S. prospective clinical trial evaluating this approach was the ACRIN 6666 Trial.[60] In this study, 2,809 women at elevated risk for breast cancer, with heterogeneous or extreme density breast tissue in at least one quadrant were evaluated with both mammography and screening US, in randomized order. 41 breast cancers were diagnosed: 8 suspicious on both US and mammography, 12 on US alone, 12 on mammography alone, and 9 were interval cancers. The diagnostic accuracy for mammography was 7.6 cancers/1000 screened and increased to 11.8/1000 when combined with supplemental ultrasound. DCIS were only seen by mammography. The false positive rate for mammography alone was 4.4%, for US alone was 8.1% and for combined mammography plus US was 10.4%. Thus, if a higher false positive rate is acceptable for women with dense breasts, combined mammography plus US screening will diagnose more cancers in this population.

In the same study, when Berg et al. compared the value of supplemental US vs supplemental breast MRI to screening mammography, both US and MRI increased the yield of breast cancers diagnosed (US: 3.7 cancers/1000 screened; MRI: 14.7/1000 screened), but both were associated with increases in false-positive findings in terms of increased recall rates and increased recommendations for biopsies that were found not to be cancer.[61]

In addition to concerns about high recall and false positive biopsy recommendation when ultrasound is used in conjunction with screening mammography, variation in the performance and interpretation of the exams has been a concern. In two other studies that evaluated interobserver variation in the interpretation of automated whole breast screening ultrasound, agreement between radiologists was found to be moderate (lesion detection) to good (lesion characterization).[62,63]

Assuring Patient Safety for Screening Ultrasound

Because US does not use ionizing radiation or require intravenous contrast, it is a safe technology for breast cancer screening. However, its high recall and false positive biopsy recommendation rates are areas of focus for improving its performance. When a potential lesion identified on a screening exam is performed by an automated system, an additional “diagnostic” study, using a hand-held transducer is performed to characterize the lesion, which adds complexity to the overall screening process.

Accreditation and Documentation

Like breast MRI, breast ultrasound accreditation is voluntary, but required for BICOE certification.[55] The ACR Ultrasound Accreditation Program provides facilities performing breast ultrasound and ultrasound-guided breast biopsies peer review and constructive feedback on staff qualifications, equipment, quality control, quality assurance, accuracy of needle placement and image quality.[64] The program accredits facilities providing services by radiologists, breast surgeons and other practitioners meeting the program’s qualifications.

To ensure uniformity in describing lesions evaluated by ultrasound, the ACR BIRADS Atlas has a section devoted to ultrasound image acquisition, image quality, transducer frequency, labeling and correct lesion measurement. Standardized terminology for describing lesions and wording reports and providing a final assessment with management recommendations is also provided.[65] The Altas focuses on ultrasound characterization of mammographic and palpable abnormalities and does not address screening ultrasound. Though the ACR has developed practice parameters for the performance of a diagnostic breast ultrasound examination, the document does not address ultrasound examinations performed as supplemental screening for breast cancer detection.[66]

Breast Imaging Centers of Excellence

Centralized breast cancer screening programs with extensive quality assurance activities are currently operated by national health care systems in several countries outside of the U.S. While adapting such programs to the diverse and somewhat fragmented U.S. health care delivery systems may not be fully feasible, programs like the NCI BCSC have shown the value of and improvements realized by quality and safety mandates, data registries and performance benchmarks. Similarly, interdisciplinary breast centers of excellence can optimize the broad range of techniques, therapies and management practices to address breast cancer screening, diagnosis and treatment. The ACR Breast Imaging Center of Excellence (BICOE) accreditation program[55] and the American College of Surgeons National Accreditation Program for

Breast Centers (NAPBC)[67] are two recognized national programs that accredit centers of excellence. To receive designation as an ACR Breast Imaging Center of Excellence, a mammography facility must be fully accredited by the ACR in mammography, stereotactic breast biopsy, breast ultrasound, ultrasound-guided breast biopsy and breast MRI. ACR BICOE accreditation is voluntary and renewable every three years.

Summary

Mammography has been the primary breast cancer screening modality for more than five decades. The quality and safety of screening mammography has been improved by requiring specific training and continuing experience and education for radiologists and technologists; standardizing the terms and descriptors used in reporting findings; providing women with their mammography results and follow-up recommendations; tracking performance and outcomes through practice audits; ensuring compliance with accreditation requirements; and performing periodic facility inspections. The future of breast cancer screening will entail tools providing a more personalized understanding of cancer risk to better guide the type and frequency of screening test performed for an individual woman. Programs and practices must be cognizant that the majority of women undergoing screening will never develop breast cancer and that patient safety, quality assurance and benchmarks for performance outcomes remain vital to the success of breast cancer screening.

References

1. Duffy SW, Tabár L, Chen HH, Holmqvist M, Yen MF, Abdsalah S, Epstein B, Frodis E, Ljungberg E, Hedborg-Melander C, Sundbom A, Tholin M, Wiege M, Akerlund A, Wu HM, Tung TS, Chiu YH, Chiu CP, Huang CC, Smith RA, Rosén M, Stenbeck M, Holmberg L. The impact of organized mammography service screening on breast carcinoma mortality in seven Swedish counties. Cancer. 2002 Aug 1;95(3):458-69. https://doi.org/10.1002/cncr.10765 PubMed PMID: 12209737.

2. Coburn NG, Chung MA, Fulton J, Cady B. Decreased breast cancer tumor size, stage, and mortality in Rhode Island: an example of a well-screened population. Cancer Control. 2004 Jul-Aug;11(4):222-30. https://doi.org/10.1177/107327480401100403 PubMed PMID: 15284713.

3. Institute of Medicine (US) and National Research Council (US) Committee on Technologies for the Early Detection of Breast Cancer; Nass SJ, Henderson IC, Lashof JC, editors. Mammography and Beyond: Developing Technologies for the Early Detection of Breast Cancer. Washington (DC): National Academies Press (US); 2001. https://doi.org/10.17226/10030 PubMed PMID: 25057542.

4. Institute of Medicine (US) Committee on New Approaches to Early Detection and Diagnosis of Breast Cancer; Herdman R, Norton L, editors. Saving Women's Lives: Strategies for Improving Breast Cancer Detection and Diagnosis: A Breast Cancer Research Foundation and Institute of Medicine Symposium. Washington (DC): National Academies Press (US); 2005. https://doi.org/10.17226/11156 PubMed PMID: 22379646.

5. Institute of Medicine (US) Committee on Improving Mammography Quality Standards; Nass S, Ball J, editors. Improving Breast Cancer Imaging Quality Standards. Washington (DC): National Academies Press (US); 2005. https://doi.org/10.17226/11308

6. Tabár L, Dean PB, Chen TH, Yen AM, Chen SL, Fann JC, Chiu SY, Ku MM, Wu WY, Hsu CY, Chen YC, Beckmann K, Smith RA, Duffy SW. The incidence of fatal breast cancer measures the increased effectiveness of therapy in women participating in mammography screening. Cancer. 2019 Feb 15;125(4):515-523. https://doi.org/10.1002/cncr.31840 Epub 2018 Nov 8. PubMed PMID: 30411328; PubMed Central PMCID: PMC6588008.

7. Myers ER, Moorman P, Gierisch JM, Havrilesky LJ, Grimm LJ, Ghate S, Davidson B, Mongtomery RC, Crowley MJ, McCrory DC, Kendrick A, Sanders GD. Benefits and Harms of Breast Cancer Screening: A Systematic Review. JAMA. 2015 Oct 20;314(15):1615-34. https://doi.org/10.1001/jama.2015.13183 Erratum in: JAMA. 2016 Apr 5;315(13):1406. PubMed PMID: 26501537.

8. ACOG The American College of Obstetricians and Gynecologists. ACOG Revises Breast Cancer Screening Guidance: OB-Gyns Promote Shared Decision Making. June 22, 2017. https://www.acog.org/About-ACOG/News-Room/News-Releases/2017/ACOG-Revises-Breast-Cancer-Screening-Guidance--ObGyns-Promote-Shared-Decision-Making?IsMobileSet=false Accessed 02/19/2019.

9. Committee on Practice Bulletins—Gynecology. Practice Bulletin Number 179: Breast Cancer Risk Assessment and Screening in Average-Risk Women. Obstet Gynecol. 2017 Jul;130(1):e1-e16. https://doi.org/10.1097/AOG.0000000000002158 PubMed PMID: 28644335.

10. Oeffinger KC, Fontham ET, Etzioni R, Herzig A, Michaelson JS, Shih YC, Walter LC, Church TR, Flowers CR, LaMonte SJ, Wolf AM, DeSantis C, Lortet-Tieulent J, Andrews K, Manassaram-Baptiste D, Saslow D, Smith RA, Brawley OW, Wender R;American Cancer Society. Breast Cancer Screening for Women at Average Risk: 2015 Guideline Update From the American Cancer Society. JAMA. 2015 Oct 20;314(15):1599-614. https://doi.org/10.1001/jama.2015.12783 . Erratum in: JAMA. 2016 Apr 5;315(13):1406. PubMed PMID: 26501536; PubMed Central PMCID: PMC4831582.

11. Monticciolo DL, Newell MS, Hendrick RE, Helvie MA, Moy L, Monsees B, Kopans DB, Eby PR, Sickles EA. Breast Cancer Screening for Average-Risk Women: Recommendations From the ACR Commission on Breast Imaging. J Am Coll Radiol. 2017 Sep;14(9):1137-1143. https://doi.org/10.1016/j.jacr.2017.06.001 Epub 2017 Jun 22. PubMed PMID: 28648873.

12. Systematic Review of Cancer Screening Literature for Updating American Cancer Society Breast Cancer Screening Guidelines. Durham, NC: Duke Evidence Synthesis Group, 2014. https://www.cancer.org/content/dam/cancer-org/cancer-control/en/reports/complete-systematic-evidence-review-acs-breast-cancer-screening-guideline.pdf Accessed 02/19/2019.

13. *BreastDensity.Info* [Internet]. California Breast Density Information Group (CBDIG). http://www.breastdensity.info/index.html Accessed 02/15/2019.

14. Breast Density, Breast Cancer Risk, and California Breast Density Notification Law SB 1538: Scenarios for Clinicians. California Breast Density Information Group (CBDIG); March 2013. http://www.breastdensity.info/docs/DENSITY-SCENARIOS-FOR-CLINICIANS.pdf Accessed 02/15/2019.

15. McLelland R. Mammography 1984: challenge to radiology. AJR Am J Roentgenol. 1984 Jul;143(1):1-4. https://doi.org/10.2214/ajr.143.1.1 PubMed PMID: 6428201.

16. Galkin BM, Feig SA, Muir HD. The technical quality of mammography in centers participating in a regional breast cancer awareness program. Radiographics. 1988 Jan;8(1):133-45. https://doi.org/10.1148/radiographics.8.1.3353530 PubMed PMID: 3353530.

17. Conway BJ, McCrohan JL, Rueter FG, Suleiman OH. Mammography in the eighties. Radiology. 1990 Nov;177(2):335-9. https://doi.org/10.1148/radiology.177.2.2217765 PubMed PMID: 2217765.

18. Hendrick RE, Chrvala CA, Plott CM, Cutter GR, Jessop NW, Wilcox-Buchalla P. Improvement in mammography quality control: 1987-1995. Radiology. 1998 Jun;207(3):663-8. https://doi.org/10.1148/radiology.207.3.9609888 PubMed PMID: 9609888.

19. Spelic D, Kaczmarek R, Hilohi M, Belella S. United States radiological health activities: inspection results of mammography facilities. Biomed Imaging Interv J. 2007 Apr;3(2):e35. https://doi.org/10.2349/biij.3.2.e35 Epub 2007 Apr 1. PubMed PMID: 21614276; PubMed Central PMCID: PMC3097660.

20. Beam CA, Layde PM, Sullivan DC. Variability in the interpretation of screening mammograms by US radiologists. Findings from a national sample. Arch Intern Med. 1996 Jan 22;156(2):209-13. https://doi.org/10.1001/archinte.1996.00440020119016 PubMed PMID: 8546556.

21. Beam CA, Conant EF, Sickles EA. Factors affecting radiologist inconsistency in screening mammography. Acad Radiol. 2002 May;9(5):531-40. https://doi.org/10.1016/S1076-6332(03)80330-6 PubMed PMID: 12458879.

22. Beam CA, Conant EF, Sickles EA. Association of volume and volume-independent factors with accuracy in screening mammogram interpretation. J Natl Cancer Inst. 2003 Feb 19;95(4):282-90. https://doi.org/10.1093/jnci/95.4.282 PubMed PMID: 12591984.

23. Smith-Bindman R, Chu P, Miglioretti DL, Quale C, Rosenberg RD, Cutter G, Geller B, Bacchetti P, Sickles EA, Kerlikowske K. Physician predictors of mammographic accuracy. J Natl Cancer Inst. 2005 Mar 2;97(5):358-67. https://doi.org/10.1093/jnci/dji060 PubMed PMID: 15741572.

24. Elmore JG, Wells CK, Lee CH, Howard DH, Feinstein AR. Variability in radiologists' interpretations of mammograms. N Engl J Med. 1994 Dec 1;331(22):1493-9. https://doi.org/10.1056/NEJM199412013312206 PubMed PMID: 7969300.

25. Elmore JG, Miglioretti DL, Reisch LM, Barton MB, Kreuter W, Christiansen CL, Fletcher SW. Screening mammograms by community radiologists: variability in false-positive rates. J Natl Cancer Inst. 2002 Sep 18;94(18):1373-80. https://doi.org/10.1093/jnci/94.18.1373 PubMed PMID: 12237283; PubMed Central PMCID: PMC3142994.

26. D'Orsi CJ, Sickles EA, Mendelson EB, Morris EA, et al. ACR BI-RADS© Atlas, Breast Imaging Reporting and Data System. Reston, VA, American College of Radiology; 2013.

27. Sickles EA, D'Orsi CJ, Bassett LW et al. ACR BI-RADS® Mammography. In: ACR BI- RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA, American College of Radiology; 2013

28. Sickles EA, D'Orsi CJ. ACR BI-RADS© Follow-up and Outcome Monitoring. In: ACR BI- RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA, American College of Radiology; 2013.

29. Improving the Interpretive Performance of Mammography, Chapter 2. In: Nass S, Ball J, editors. Improving Breast Imaging Quality Standards. Institute of Medicine and National Research Council. Washington, DC: The National Academies Press; 2005. P. 24-81. https://doi.org/10.17226/11308.

30. Smith-Bindman R, Chu P, Miglioretti DL, Quale C, Rosenberg RD, Cutter G, Geller B, Bacchetti P, Sickles EA, Kerlikowske K. Physician predictors of mammographic accuracy. J Natl Cancer Inst. 2005 Mar 2;97(5):358-67. https://doi.org/10.1093/jnci/dji060 PubMed PMID: 15741572.

31. Esserman L, Cowley H, Eberle C, Kirkpatrick A, Chang S, Berbaum K, Gale A. Improving the accuracy of mammography: volume and outcome relationships. J Natl Cancer Inst. 2002 Mar 6;94(5):369-75. https://doi.org/10.1093/jnci/94.5.369 PubMed PMID: 11880475.

32. Destounis SV, DiNitto P, Logan-Young W, Bonaccio E, Zuley ML, Willison KM. Can computer-aided detection with double reading of screening mammograms help decrease the false-negative rate? Initial experience. Radiology. 2004 Aug;232(2):578-84. Epub 2004 Jun 30. https://doi.org/10.1148/radiol.2322030034 PubMed PMID: 15229350.

33. Frankel SD, Sickles EA, Curpen BN, Sollitto RA, Ominsky SH, Galvin HB. Initial versus subsequent screening mammography: comparison of findings and their prognostic significance. AJR Am J Roentgenol. 1995 May;164(5):1107-9. https://doi.org/10.2214/ajr.164.5.7717214 PubMed PMID: 7717214.

34. Baker JA, Rosen EL, Lo JY, Gimenez EI, Walsh R, Soo MS. Computer-aided detection (CAD) in screening mammography: sensitivity of commercial CAD systems for detecting architectural distortion. AJR Am J Roentgenol. 2003 Oct;181(4):1083-8. https://doi.org/10.2214/ajr.181.4.1811083 PubMed PMID: 14500236.

35. Gur D, Sumkin JH, Rockette HE, Ganott M, Hakim C, Hardesty L, Poller WR, Shah R, Wallace L. Changes in breast cancer detection and mammography recall rates after the introduction of a computer-aided detection system. J Natl Cancer Inst. 2004 Feb 4;96(3):185-90. https://doi.org/10.1093/jnci/djh067 PubMed PMID: 14759985.

36. Lehman CD, Wellman RD, Buist DS, Kerlikowske K, Tosteson AN, Miglioretti DL; Breast Cancer Surveillance Consortium. Diagnostic Accuracy of Digital Screening Mammography With and Without Computer-Aided Detection. JAMA Intern Med. 2015 Nov;175(11):1828-37. https://doi.org/10.1001/jamainternmed.2015.5231 PubMed PMID: 26414882; PubMed Central PMCID: PMC4836172.

37. Carney PA, Sickles EA, Monsees BS, Bassett LW, Brenner RJ, Feig SA, Smith RA, Rosenberg RD, Bogart TA, Browning S, Barry JW, Kelly MM, Tran KA, Miglioretti DL. Identifying minimally acceptable interpretive performance criteria for screening mammography. Radiology. 2010 May;255(2):354-61. https://doi.org/10.1148/radiol.10091636 PubMed PMID: 20413750; PubMed Central PMCID: PMC2858814.

38. National Cancer Institute Breast Cancer Surveillance Consortium. Performance Benchmarks for Screening Mammography. http://breastscreening.cancer.gov/statistics/benchmarks/screening/ Updated May 20, 2015. Accessed 02/01/2019.

39. Rosenberg RD, Yankaskas BC, Abraham LA, Sickles EA, Lehman CD, Geller BM, Carney PA, Kerlikowske K, Buist DS, Weaver DL, Barlow WE, Ballard-Barbash R. Performance benchmarks for screening mammography. Radiology. 2006 Oct;241(1):55-66. Erratum in: Radiology. 2014 May;271(2):620. https://doi.org/10.1148/radiol.2411051504 PubMed PMID: 16990671.

40. Lehman CD, Arao RF, Sprague BL, Lee JM, Buist DS, Kerlikowske K, Henderson LM, Onega T, Tosteson AN, Rauscher GH, Miglioretti DL. National Performance Benchmarks for Modern Screening Digital Mammography: Update from the Breast Cancer Surveillance Consortium. Radiology. 2017 Apr;283(1):49-58. https://doi.org/10.1148/radiol.2016161174. Epub 2016 Dec 5. PubMed PMID: 27918707; PubMed Central PMCID: PMC5375631.

41. Sickles EA, Miglioretti DL, Ballard-Barbash R, Geller BM, Leung JW, Rosenberg RD, Smith-Bindman R, Yankaskas BC. Performance benchmarks for diagnostic mammography. Radiology. 2005 Jun;235(3):775-90. https://doi.org/10.1148/radiol.2353040738 PubMed PMID: 15914475.

42. Rothschild J, Lourenco AP, Mainiero MB. Screening mammography recall rate: does practice site matter? Radiology. 2013 Nov;269(2):348-53. https://doi.org/10.1148/radiol.13121487 Epub 2013 Jul 24. PubMed PMID: 23884734.

43. Chubak J, Boudreau DM, Fishman PA, Elmore JG. Cost of breast-related care in the year following false positive screening mammograms. Med Care. 2010 Sep;48(9):815-20. https://doi.org/10.1097/MLR.0b013e3181e57918 PubMed PMID: 20706161; PubMed Central PMCID: PMC3079487.

44. Gilbert FJ, Cordiner CM, Affleck IR, Hood DB, Mathieson D, Walker LG. Breast screening: the psychological sequelae of false-positive recall in women with and without a family history of breast cancer. Eur J Cancer. 1998 Dec;34(13):2010-4. https://doi.org/10.1016/S0959-8049(98)00294-9 PubMed PMID: 10070302.

45. Brett J, Austoker J. Women who are recalled for further investigation for breast screening: psychological consequences 3 years after recall and factors affecting re-attendance. J Public Health Med. 2001 Dec;23(4):292-300. https://doi.org/10.1093/pubmed/23.4.292 PubMed PMID: 11873891.

46. Schwartz LM, Woloshin S, Sox HC, Fischhoff B, Welch HG. US women's attitudes to false-positive mammography results and detection of ductal carcinoma in situ: cross-sectional survey. West J Med. 2000 Nov;173(5):307-12. https://doi.org/10.1136/ewjm.173.5.307 PubMed PMID: 11069862; PubMed Central PMCID: PMC1071147.

47. Grabler P, Sighoko D, Wang L, Allgood K, Ansell D. Recall and Cancer Detection Rates for Screening Mammography: Finding the Sweet Spot. AJR Am J Roentgenol. 2017 Jan;208(1):208-213. https://doi.org/10.2214/AJR.15.15987 Epub 2016 Sep 28. PubMed PMID: 27680714.

48. Poor Positioning Responsible for Most Clinical Image Deficiency, Failures. U.S. Food & Drug Administration, Current as of 29 November 2017. https://www.fda.gov/radiation-emitting-products/mqsa-insights/poor-positioning-responsible-most-clinical-image-deficiencies-failures. Accessed 02/15/2019

49. EQUIP: Enhancing Quality Using the Inspection Program. U.S. Food & Drug Administration, current as of 27 November 2017. Accessed 02/15/2019.

50. Committee on Practice Bulletins–Gynecology, Committee on Genetics, Society of Gynecologic Oncology. Practice Bulletin No 182: Hereditary Breast and Ovarian Cancer Syndrome. Obstet Gynecol. 2017 Sep;130(3):e110-e126. https://doi.org/10.1097/AOG.0000000000002296 PubMed PMID: 28832484.

51. Committee opinion no. 625: management of women with dense breasts diagnosed by mammography. Obstet Gynecol. 2015 Mar;125(3):750-1. https://doi.org/10.1097/01.AOG.0000461763.77781.79. Erratum in: Obstet Gynecol. 2016 Jan;127(1):166. PubMed PMID: 25730253.

52. Saslow D, Boetes C, Burke W, Harms S, Leach MO, Lehman CD, Morris E, Pisano E, Schnall M, Sener S, Smith RA, Warner E, Yaffe M, Andrews KS, Russell CA; American Cancer Society Breast Cancer Advisory Group. American Cancer Society guidelines for breast screening with MRI as an adjunct to mammography. CA Cancer J Clin. 2007 Mar-Apr;57(2):75-89. https://doi.org/10.3322/canjclin.57.2.75 Erratum in: CA Cancer J Clin. 2007 May-Jun;57(3):185. PubMed PMID: 17392385.

53. Monticciolo DL, Newell MS, Moy L, Niell B, Monsees B, Sickles EA. Breast Cancer Screening in Women at Higher-Than-Average Risk: Recommendations From the ACR. J Am Coll Radiol. 2018 Mar;15(3 Pt A):408-414. https://doi.org/10.1016/j.jacr.2017.11.034 Epub 2018 Jan 19. PubMed PMID: 29371086.

54. Gulani V, Calamante F, Shellock FG, Kanal E, Reeder SB; International Society for Magnetic Resonance in Medicine. Gadolinium deposition in the brain: summary of evidence and recommendations. Lancet Neurol. 2017 Jul;16(7):564-570. https://doi.org/10.1016/S1474-4422(17)30158-8 Epub 2017 Jun 13.PubMed PMID: 28653648.

55. ACR-Breast Imaging Center of Excellence (BICOE) Accreditation Program. ACR American College of Radiology. https://www.acraccreditation.org/breast-imaging-center-of-excellence. Accessed 02/15/2019.

56. Morris, EA, Comstock CE, Lee CH, et al. ACR BI-RADS® Magnetic Resonance Imaging. In: ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA, American College of Radiology; 2013.

57. Kuhl CK, Schrading S, Strobel K, Schild HH, Hilgers RD, Bieling HB. Abbreviated breast magnetic resonance imaging (MRI): first postcontrast subtracted images and maximum-intensity projection-a novel approach to breast cancer screening with MRI. J Clin Oncol. 2014 Aug 1;32(22):2304-10. https://doi.org/10.1200/JCO.2013.52.5386 Epub 2014 Jun 23. PubMed PMID: 24958821.

58. Oldrini G, Derraz I, Salleron J, Marchal F, Henrot P. Impact of an abbreviated protocol for breast MRI in diagnostic accuracy. Diagn Interv Radiol. 2018 Jan-Feb;24(1):12-16. https://doi.org/10.5152/dir.2018.16609 PubMed PMID: 29317373; PubMed Central PMCID: PMC5765922.

59. Kuhl CK. Abbreviated breast MRI for screening women with dense breast: the EA1141 trial. Br J Radiol. 2018 Oct;91(1090):20170441. https://doi.org/10.1259/bjr.20170441 Epub 2017 Oct 27. PubMed PMID: 28749202; PubMed Central PMCID: PMC6350487.

60. Berg WA, Zhang Z, Lehrer D, Jong RA, Pisano ED, Barr RG, Böhm-Vélez M, Mahoney MC, Evans WP 3rd, Larsen LH, Morton MJ, Mendelson EB, Farria DM, Cormack JB, Marques HS, Adams A, Yeh NM, Gabrielli G; ACRIN 6666 Investigators. Detection of breast cancer with addition of annual screening ultrasound or a single screening MRI to mammography in women with elevated breast cancer risk. JAMA. 2012 Apr 4;307(13):1394-404. https://doi.org/10.1001/jama.2012.388 PubMed PMID: 22474203; PubMed Central PMCID: PMC3891886.

61. Berg WA, Blume JD, Cormack JB, Mendelson EB, Lehrer D, Böhm-Vélez M, Pisano ED, Jong RA, Evans WP, Morton MJ, Mahoney MC, Larsen LH, Barr RG, Farria DM, Marques HS, Boparai K; ACRIN 6666 Investigators. Combined screening with ultrasound and mammography vs mammography alone in women at elevated risk of breast cancer. JAMA. 2008 May 14;299(18):2151-63. https://doi.org/10.1001/jama.299.18.2151 Erratum in: JAMA. 2010 Apr 21;303(15):1482. PubMed PMID: 18477782; PubMed Central PMCID: PMC2718688.

62. Kim EJ, Kim SH, Kang BJ, Kim YJ. Interobserver agreement on the interpretation of automated whole breast ultrasonography. Ultrasonography. 2014 Oct;33(4):252-8. https://doi.org/10.14366/usg.14015 Epub 2014 Apr 21. PubMed PMID: 25036754; PubMed Central PMCID: PMC4176111.

63. Berg WA, Blume JD, Cormack JB, Mendelson EB. Operator dependence of physician-performed whole-breast US: lesion detection and characterization. Radiology. 2006 Nov;241(2):355-65. https://doi.org/10.1148/radiol.2412051710 PubMed PMID: 17057064.

64. Breast Ultrasound Accreditation Program Requirements. ACR American College of Radiology, revised June 2019. https://www.acraccreditation.org/-/media/ACRAccreditation/Documents/Breast-Ultrasound/Requirements.pdf?la=en

65. Mendelson EB, Bohm-Velez M, Berg WA, et al. ACR BI-RADS Ultrasound. IN: ACR BI- RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA, American College of Radiology; 2013.

66. ACR Practice Parameter for the Performance of a Breast Ultrasound Examination. ACR American College of Radiology, revised 2016. https://www.acr.org/-/media/ACR/Files/Practice-Parameters/US-Breast.pdf?la=en

67. National Accreditation Program for Breast Centers (NAPBC). Chicago: American College of Surgeons; c1996-2019. https://www.facs.org/quality-programs/napbc/accreditation Accessed 02/15/2019.