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CDR Contemporary Diagnostic Radiology

Volume 44 • Number 8
April 15, 2021

A BIWEEKLY REVIEW OF CLINICAL RADIOLOGIC PRACTICE

The Breast Imaging Medical Audit: What the Radiologist Needs to Know

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This module meets the American Board of Radiology's (ABR's) criteria for self-assessment toward the purpose of fulfilling requirements in the ABR Maintenance of Certification (MOC) program.

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After participating in this educational activity, the radiologist will be better able to identify the components of a breast imaging medical audit, explain the associated key statistical terms, and describe the benefits to improved imaging interpretation and patient care.

Category: Quality, Safety, Best Practices, and Noninterpreting Skills
Subcategory: Breast Imaging
Modality: Multiple

Key Words: Breast Imaging Medical Audit, Medical Audit

The purpose of a medical audit is to ensure that there is consistency in the quality of patient care. The components of a medical audit include evaluation of treatment, comparison of care with established standards, and examining added changes to assess improvement.[1] *The medical audit not only helps improve patient outcomes, but also helps physicians assess their own performance and clinical practice, by comparing their patient outcomes to accepted standards. In turn, medical audits help close the gap between patient outcomes in practice and established standards.*[2]

The use of a clinically relevant medical audit in breast imaging centers is a requirement under the Mammography Quality Standards Act (MQSA). This federal legislation was implemented in 1992 to ensure high-quality mammography and earliest detection of breast cancer.[3] It functions through the use of a medical audit to maintain a high level of quality control, self-improvement, and lifelong learning through continuous feedback and comparison to accepted benchmarks. In radiology, a breast imaging medical audit is a requirement of the American College of Radiology (ACR) Breast Imaging Data and Reporting System (BI-RADS) Atlas *(ACR BI-RADS® Atlas, 5th edition)*[4] and has shown to improve the quality of breast imaging interpretative performance. It has led to improving screening and diagnostic breast imaging programs as a result of the medical audit.[1]

Several elements should be included in a breast imaging medical audit. First is to keep track of all positive screening and positive diagnostic mammograms. A positive screening mammogram is when additional diagnostic imaging is recommended (BI-RADS 0). Much less frequently (use discouraged), a positive screening mammogram is one for which tissue diagnosis is recommended (BI-RADS 4 or 5), or contrary to recommended practice, a short-term follow-up imaging is recommended (BI-RADS 3) before the next routine screening examination. A positive diagnostic mammogram examination is where a tissue diagnosis is recommended (BI-RADS 4 or 5).[4] The next element of a breast imaging medical audit involves tracking the pathology results of examinations for

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The authors, faculty, and all staff in a position to control the content of this CME activity have disclosed that they have no relationships with, or financial interests in, any commercial organizations relevant to this educational activity.

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which a tissue diagnosis was recommended. The last task is to analyze all false-negatives that are found within 12 months of the mammography examination.[1]

According to the *ACR BI-RADS® Atlas, 5th edition*, several issues should be taken into account when conducting a breast imaging audit. In order for an audit to be clinically useful, it should use the same set of rules to facilitate cross-modality comparisons of clinically representative benchmarks so that an individual mammography facility (or individual interpreting physician) may reliably compare observed outcomes with these benchmarks.[4] According to the *ACR BI-RADS® Atlas, 5th edition*, a clinically useful breast imaging audit is relevant to the extent that it provides meaningful indicators of interpretive performance. One may gain a better understanding about underlying interpretive performance if more data are collected and studied. For example, looking at the recall rate alone would give us little valuable information. The recall rate alone simply would indicate the percentage of screened women in which additional imaging evaluation is recommended. However, from the recall rate alone, we would not be able to gather information regarding the likelihood of cancer, the frequency of cancer detection, or the severity of cancer.[4]

The *ACR BI-RADS® Atlas, 5th edition* states that more complete and complex auditing is necessary for a breast imaging practice to improve the performance of the interpreting physicians. Understanding the process and purpose of the medical audit will help in recognizing deficiencies, enabling research, and will be of practical value in reducing adverse medicolegal consequences.[4] Additionally, according to the *ACR BI-RADS® Atlas, 5th edition*, the outcomes data observed for all breast imaging practices should be comparable. Therefore, auditing must be based on objective and reproducible rules. To facilitate cross-modality comparisons, the same set of rules should be used for the various breast imaging modalities, unless a different approach is justified.[4] Specific data should be collected and used to calculate important derived data.

According to the *ACR BI-RADS® Atlas, 5th edition*, this data is necessary for physicians to evaluate their performance in breast imaging analysis.[4]

Summary of Key Definitions of the Breast Imaging Medical Audit

Table 1 lists key definitions.[4]

Positive Predictive Value

The *ACR BI-RADS® Atlas, 5th edition* specifies three different definitions, as follows:

1. *Positive predictive value 1 (PPV1)* is the percentage of all positive screening examinations (BI-RADS categories 0, 3, 4, and 5) that result in a tissue diagnosis of cancer within 1 year. The calculation of PPV1 is:

PPV1 = TP/(number of positive screening examinations) = TP/(TP + FP1)

TP = true-positive. A TP is when there is a tissue diagnosis of cancer within 1 year after a positive examination. BI-RADS 3 category assessments made at screening examination are considered positive examinations.

FP1 = false-positive 1. An FP1 is when there is no known tissue diagnosis of cancer within 1 year of a positive mammogram—includes BI-RADS category 3 assessments made at screening.

Positive screening examination = when additional diagnostic imaging is recommended (BI-RADS 0). Much less frequently (use discouraged), a positive screening

The continuing education activity in *Contemporary Diagnostic Radiology* is intended for radiologists.

Contemporary Diagnostic Radiology (ISSN 0149-9009) is published bi-weekly by Wolters Kluwer Health, Inc. at 14700 Citicorp Drive, Bldg 3, Hagerstown, MD 21742. **Customer Service: Phone (800) 638-3030; Fax (301) 223-2400; E-mail: customerservice@lww.com.** Visit our website at LWW.com. Publisher, Stella Bebos.

Table 1. Key Definitions or Terms of the Breast Imaging Medical Audit

Term	Definition/Formulas
True-positive (TP)	Tissue diagnosis of cancer within 1 yr after a positive examination. BI-RADS category 3 assessments made at screening examination are considered positive examinations
True-negative (TN)	No known tissue diagnosis of cancer within 1 yr of a negative examination (BI-RADS categories 1 or 2 for screening; BI-RADS categories 1, 2, or 3 for diagnostic)
False-negative (FN)	Tissue diagnosis of cancer within 1 yr of a negative examination (BI-RADS categories 1 or 2 for screening; BI-RADS categories 1, 2, or 3 for diagnostic)
False-positive 1 (FP1)	No known tissue diagnosis of cancer within 1 yr of a positive mammogram—includes BI-RADS category 3 assessments made at screening
False-positive 2 (FP2)	No known tissue diagnosis of cancer within 1 yr after recommendation for tissue diagnosis or surgical consultation on the basis of a positive examination (BI-RADS category 4 or 5)
False-positive 3 (FP3)	Concordant benign breast tissue diagnosis (or discordant benign breast tissue and no known diagnosis of cancer) within 1 yr after recommendation of a positive examination (BI-RADS category 4 or 5)
Positive predictive value 1 (PPV1) (abnormal finding at screening)	The percentage of all screening examinations (BI-RADS categories 0, 3, 4, and 5) that result in a tissue diagnosis of cancer within 1 yr *PPV1 = TP/(number of positive screening examinations) = TP/(TP + FP1)*
Positive predictive value 2 (PPV2) (biopsy recommended)	The percentage of all diagnostic (or rarely, screening) examinations recommended for tissue diagnosis or surgical consultation (BI-RADS categories 4 and 5) that result in a tissue diagnosis of cancer within 1 yr *PPV2 = TP/(number of screening or diagnostic examinations recommended for tissue diagnosis) = TP/(TP + FP2)*
Positive predictive value 3 (PPV3) (biopsy performed)	The percentage of all known biopsies done as a result of positive diagnostic examinations (BI-RADS categories 4 and 5) that resulted in a tissue diagnosis of cancer within 1 yr—also known as biopsy yield of malignancy or the positive biopsy rate (PBR) *PPV3 = TP/(number of biopsies) = TP/(TP + FP3)*
Sensitivity	The probability of interpreting an examination as positive when cancer exists. This is measured as the number of positive examinations for which there is a tissue diagnosis of cancer within 1 yr of imaging examination, divided by all cancers present in the population examined in the same period. *Sensitivity = TP/(TP + FN)*
Specificity	The probability of interpreting an examination as negative when cancer does not exist. This is measured as the number of negative examinations for which there is no tissue diagnosis of cancer within 1 yr of examination, divided by all examinations for which there is no tissue diagnosis of cancer within the same period. *Specificity = TN/(TN + FP)*
Cancer detection rate	The number of cancers detected at imaging per 1000 patients examined
Abnormal interpretation rate	The percentage of examinations interpreted as positive. For screening, positive examinations usually involve BI-RADS category 0 assessments for mammography and (for auditing purposes) breast US, but BI-RADS categories 4 and 5 for breast MRI. This also includes BI-RADS category 3 assessments made at screening for all imaging modalities. For diagnostic imaging, positive examinations involved BI-RADS category 4 and 5 assessments. Abnormal interpretation rate = (positive examinations)/all examinations

BI-RADS, Breast Imaging Data and Reporting System; FP, false-positive; TN, true-negative; US, ultrasound.
Adapted from Sickles EA, D'Orsi CJ. ACR BI-RADS® follow-up and outcome monitoring. In: *ACR BI-RADS® Atlas, 5th edition. Breast Imaging Reporting and Data System.* Reston, VA, American College of Radiology; 2013.[4])

mammogram is one for which tissue diagnosis is recommended (BI-RADS 4 or 5), or contrary to recommended practice, a short-term follow-up imaging is recommended (BI-RADS 3) before the next routine screening examination.

Based on the *ACR BI-RADS® Atlas, 5th edition*, the acceptable range of a PPV1 for screening mammography is 3% to 8% (Table 2).

2. *Positive predictive value 2 (PPV2)* is the percentage of all diagnostic (or rarely, screening) examinations recommended for tissue diagnosis or surgical consultation (BI-RADS categories 4 and 5) that result in a tissue diagnosis of cancer within 1 year. The calculation of PPV2 is:

PPV2 = TP/(number of screening or diagnostic examinations recommended for tissue diagnosis) = TP/(TP + FP2)

FP2 = false-positive 2. An FP2 is when there is no known tissue diagnosis of cancer within 1 year after recommendation for tissue diagnosis or surgical consultation on the basis of a positive examination (BI-RADS categories 4 or 5).

Table 2. Acceptable Ranges of Screening Mammography Performance

Cancer detection rate (per 1000 examinations)	≥2.5
Abnormal interpretation (recall) rate	5%–12%
PPV1 (abnormal interpretation)	3%–8%
PPV2 (recommendation for tissue diagnosis)	20%–40%
Sensitivity (if measurable)	≥75%
Specificity (if measurable)	88%–95%

PPV1, positive predictive value 1; PPV2, positive predictive value 2. (Adapted from Sickles EA, D'Orsi CJ. ACR BI-RADS® follow-up and outcome monitoring. In: *ACR BI-RADS® Atlas, 5th edition, Breast Imaging Reporting and Data System.* Reston, VA, American College of Radiology; 2013.[4])

Based on the *ACR BI-RADS® Atlas, 5th edition*, the acceptable performance range for screening mammograms recommended for tissue diagnosis (PPV2) is 20% to 40%.

3. *Positive predictive value 3 (PPV3)* is the percentage of all known biopsies done as a result of positive diagnostic examinations (BI-RADS categories 4 and 5) that resulted in a tissue diagnosis of cancer within 1 year—also known as biopsy yield of malignancy or the positive biopsy rate (PBR). The calculation of PPV3 is:

PPV3 = TP/(number of biopsies) = TP/(TP + FP3)

FP3 = false-positive 3. An FP3 is when there is a concordant benign breast tissue diagnosis (or discordant benign breast tissue and no known diagnosis of cancer) within 1 year after recommendation of a positive examination (BI-RADS category 4 or 5).

Sensitivity

Sensitivity is defined as the probability of interpreting an examination as positive when cancer exists. This is measured as the number of positive examinations for which there is a tissue diagnosis of cancer within 1 year of imaging examination, divided by all cancers present in the population examined in the same period. The calculation for sensitivity is:

Sensitivity = TP/(TP + FN)

TP = true-positive. A TP is when there is tissue diagnosis of cancer within 1 year after a positive examination. BI-RADS category 3 assessments made at screening examination are considered positive examinations.

FN = false-negative. An FN is when there is tissue diagnosis of cancer within 1 year of a negative examination (BI-RADS categories 1 or 2 for screening; BI-RADS categories 1, 2, or 3 for diagnostic).

Based on the *ACR BI-RADS® Atlas, 5th edition*, the acceptable range of sensitivity for screening mammography is 75% or more.

Specificity

Specificity is defined as the probability of interpreting an examination as negative for which there is no tissue diagnosis of cancer within 1 year of examination, divided by all examinations for which there is no tissue diagnosis of cancer within the same period. The calculation for specificity is:

Specificity = TN/(TN + FP)

Based on the *ACR BI-RADS® Atlas, 5th edition*, the acceptable range of specificity for screening mammography is 88% to 95%.

Cancer Detection Rate

The cancer detection rate is defined as the number of cancers detected at imaging per 1000 patients examined. The cancer detection rate is of value when calculated only for screening examinations or when calculated separately for screening and diagnostic examinations as noted in the *ACR BI-RADS® Atlas, 5th edition*.

Based on the *ACR BI-RADS® Atlas, 5th edition*, the acceptable range of cancer detection rate for screening mammography is 2.5 or more per 1000 examinations.

Based on the *ACR BI-RADS® Atlas, 5th edition*, the acceptable range of cancer detection rate for screening mammography is 2.5 or more.

Based on the *ACR BI-RADS® Atlas, 5th edition*, the acceptable range of cancer detection rate for diagnostic mammography is 20 or more per 1000 examinations for workup of abnormal screening examinations.

Based on the *ACR BI-RADS® Atlas, 5th edition*, the acceptable range of cancer detection rate for diagnostic mammography is 40 or more per 1000 examinations for workup of palpable lump.

Abnormal Interpretation Rate

The abnormal interpretation rate is defined as the percentage of examinations interpreted as positive. For screening, positive examinations usually involve BI-RADS category 0 assessments for mammography and (for auditing purposes) breast ultrasound, but BI-RADS categories 4 and 5 for breast MRI. This also includes BI-RADS category 3 assessments made at screening for all imaging modalities. For diagnostic imaging, positive examinations involved BI-RADS category 4 and 5 assessments. The calculation for abnormal interpretation rate is:

Abnormal interpretation rate = (positive examinations)/all examinations

Based on the *ACR BI-RADS® Atlas, 5th edition*, the acceptable range of the abnormal interpretation rate for screening mammography is 5% to 12%.

Based on the *ACR BI-RADS® Atlas, 5th edition*, the acceptable range of the abnormal interpretation rate for screening mammography is 5% to 12%.

The use of a breast imaging medical audit, which is performed annually, allows for comparison between breast imaging facilities and interpreting radiologists based on accepted terms and definitions, as described previously. The continuous feedback is beneficial at the institutional level, as it ensures patients continue to receive an acceptable level of care that is not negatively deviant from other similar institutions. It allows the opportunity for early intervention

such that thorough analysis and systematic evaluation may be performed to improve the quality of mammography to a higher sustainable level. Examples of such interventions where a medical audit has initiated change are in postmammography communication, online or double reading, and standardizing image acquisition.

Continuous feedback from medical audits can also be used as a tool for self-improvement for the individual interpreting radiologist. The first issue is ensuring radiologists receive audits, as approximately 10% do not receive mammography audit reports.[5] However, of those who did receive audit reports, 87% found it to be valuable and 75% reported improved interpretation as a result of the reports.[5] These audit reports function to review previously false-negative diagnoses and reevaluate these cases to determine whether the radiologist had made an interpretive error. This can potentially shed light on any potential knowledge deficiencies, biases, or other interpretive issues that may benefit from remediation. As expected, interpreting a higher volume of cases is associated with higher-quality interpretations. Radiologists who interpret a minimum of 2500 examinations per year have a lower abnormal interpretation rate and better cancer detection rates.[6] It is important to note that this remediation should be performed in an educational, nonpunitive manner to ensure the radiologist practices within the clinically accepted practice standards of breast imaging set by the ACR BI-RADS standards.

Additional benefits of the yearly medical audit are that it allows for lifelong learning and for the interpreting radiologist to track their progress over time. As new standards of image acquisition, interpretation, and technologies become available the reported acceptable benchmarks are likely to change over time, thus requiring interpreting radiologists to adapt and maintain their skills. This is a continuous process that is implemented throughout the radiologist's career, which may be facilitated through yearly medical audits to ensure they do not fall below acceptable benchmarks that would require remediation.

There are multiple components to a medical audit, which include treatment evaluation, comparing care to establish standards, and searching for avenues for improvement. These components function to ensure consistent high-quality patient care. In the setting of breast imaging, medical audits are a requirement by the MQSA and have been shown to improve the quality of breast imaging and interpretation, benefiting both the patient and the radiologist.

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1. A breast imaging center performs 10,000 screening mammograms per year, with 1000 mammograms requiring return for additional diagnostic evaluation. Which one of the following is the abnormal screening interpretation rate?

A. 10%
B. 20%
C. 80%
D. 90%

See Reference No. 4 for further study

2. A breast imaging center has 100 screening mammograms that are determined to be suspicious for cancer (BI-RADS 0), ultimately requiring tissue biopsy. If 75 of the mammogram cases come back positive for cancer, which one of the following is the positive predictive value 1 (PPV1)?

A. 25%
B. 50%
C. 75%
D. 90%

See Reference No. 4 for further study

3. One hundred patients undergo biopsy for suspicious findings on diagnostic mammograms. Of these, 33 come back positive for cancer within the next year. Which one of the following is the positive predictive value 2 (PPV2)?
   A. 30%
   B. 33%
   C. 66%
   D. 67%

See Reference No. 4 for further study

4. A 62-year-old woman presents for a screening mammogram, which is interpreted as negative for breast cancer. Six months later, the patient returns with a palpable lump that is determined to be a solid mass on ultrasound. A biopsy of this mass by ultrasound was obtained, and the pathology results were positive for breast cancer. This case would be considered a
   A. true-positive
   B. false-positive
   C. true-negative
   D. false-negative

See Reference No. 4 for further study

5. One thousand mammograms were performed at a breast imaging facility. Of these, 100 were called back due to a suspicious finding requiring biopsy (BI-RADS category 4). Twenty of the biopsies were positive for cancer. Which one of the following is the cancer detection rate?
   A. 2 per 1000
   B. 4 per 1000
   C. 20 per 1000
   D. 90 per 1000

See Reference No. 4 for further study

6. A 55-year-old woman presents for a screening mammogram. She is recalled for additional diagnostic imaging, which confirmed the presence of suspicious findings, and a BI-RADS category 4 assessment is given. A biopsy is performed, which comes back negative for malignancy. Follow-up mammograms the next year were negative for cancer. This case would be considered a
   A. true-positive
   B. false-positive
   C. true-negative
   D. false-negative

See Reference No. 4 for further study

7. In the medical audit of a single radiologist, it is found that this radiologist was able to detect 90% of all cancers and exclude 98% of cancers. Based on these findings, the radiologist exhibits which one of the following sensitivity and specificity characteristics compared with universal benchmarks?
   A. High sensitivity, high specificity
   B. High sensitivity, low specificity
   C. Low sensitivity, low specificity
   D. Low sensitivity, high specificity

See Reference No. 4 for further study

8. Which one of the following is the definition of positive predictive value 3 (PPV3)?
   A. The percentage of all known biopsies done as a result of positive diagnostic examinations (BI-RADS categories 4 and 5) that resulted in a tissue diagnosis of cancer within 1 year
   B. The percentage of all diagnostic (or rarely, screening) examinations recommended for tissue diagnosis or surgical consultation (BI-RADS categories 4 and 5) that result in a tissue diagnosis of cancer within 1 year
   C. The percentage of all screening examinations (BI-RADS categories 0, 3, 4, and 5) that result in a tissue diagnosis of cancer within 1 year
   D. Concordant benign breast tissue diagnosis (or discordant benign breast tissue and no known diagnosis of cancer) within 1 year after recommendation of a positive examination (BI-RADS category 4 or 5)

See Reference No. 4 for further study

9. Which one of the following is the frequency at which a medical audit should be performed?
   A. Yearly
   B. Semi-annually
   C. Quarterly
   D. Monthly

See Reference No. 4 for further study

10. MQSA stands for
   A. Multifactorial Quantitative Standard Activity
   B. Mammography Quality Standards Act
   C. Magnetic Quotient Specificity Act
   D. Michigan Qualitative Sensitivity Action

See Reference No. 4 for further study