BI-RADS Update – 6th Edition: Audit and Outcomes Monitoring

Edward A. Sickles, MD

SBI
IN AFFILIATION WITH CSBI

No disclosures

ACR BI-RADS® Atlas

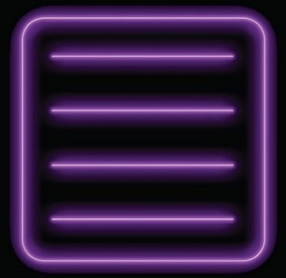
Breast Imaging Reporting and Data System

5th Edition

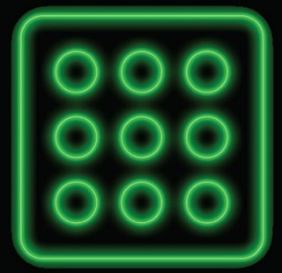
Mammography

Ultrasound

Magnetic Resonance Imaging



Follow-up and Outcome Monitoring



Data Dictionary

ACR BI-RADS® Atlas

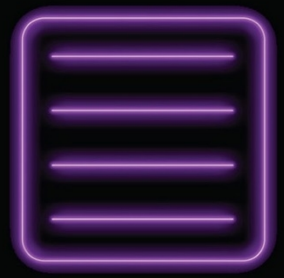
Breast Imaging Reporting and Data System

6th Edition

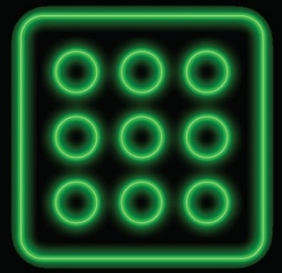
Mammography

Ultrasound

Magnetic Resonance Imaging



Auditing and Outcome Monitoring



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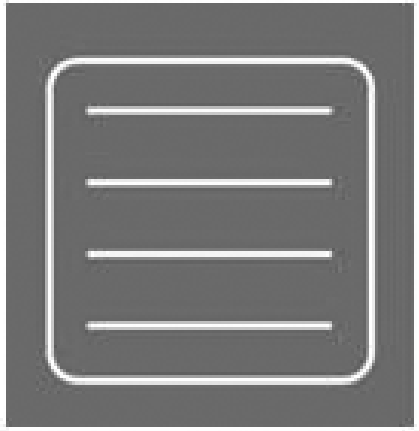

ACR BI-RADS®
Auditing and Outcomes Monitoring 202?

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Donna Plecha, MD

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BI-RADS 6th Edition Audit Changes

Modality-neutral auditing of all exams

2019 (Resolution 34)*

ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF WHOLE-BREAST ULTRASOUND FOR SCREENING AND STAGING

VI. DOCUMENTATION

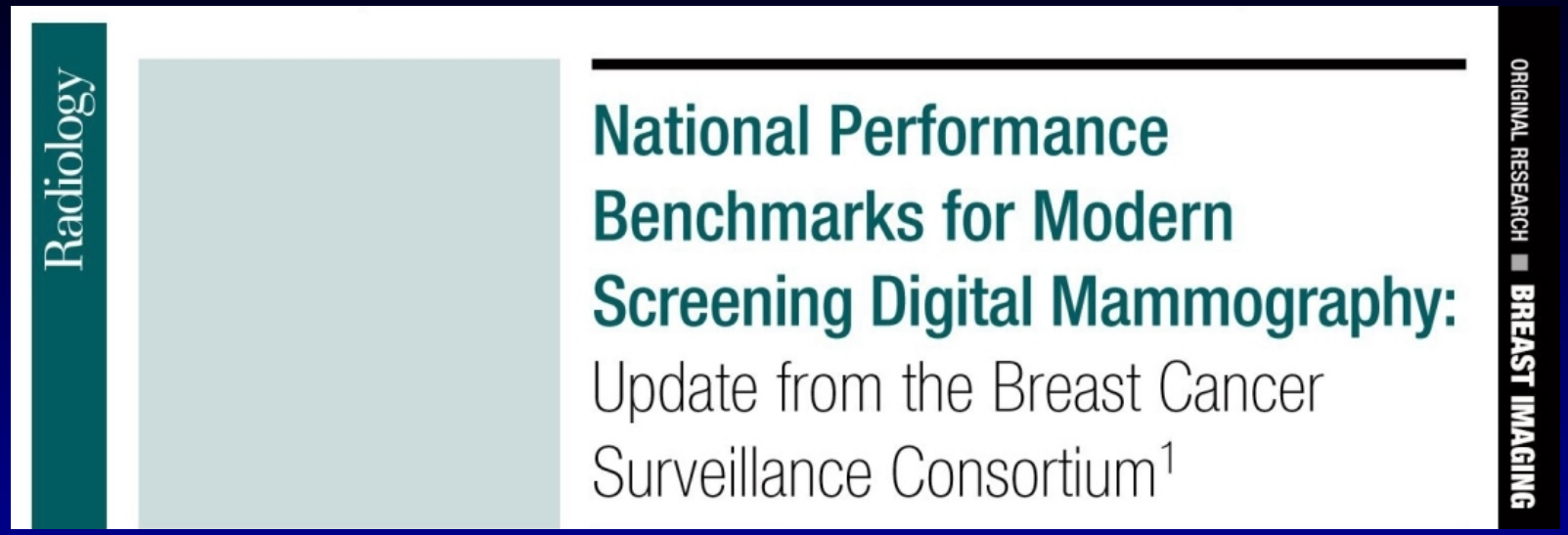
Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Images should be recorded in a retrievable and reviewable image storage format. Retention of the ultrasound examination images should be based on clinical need and in accordance with relevant legal and local health care facility requirements.

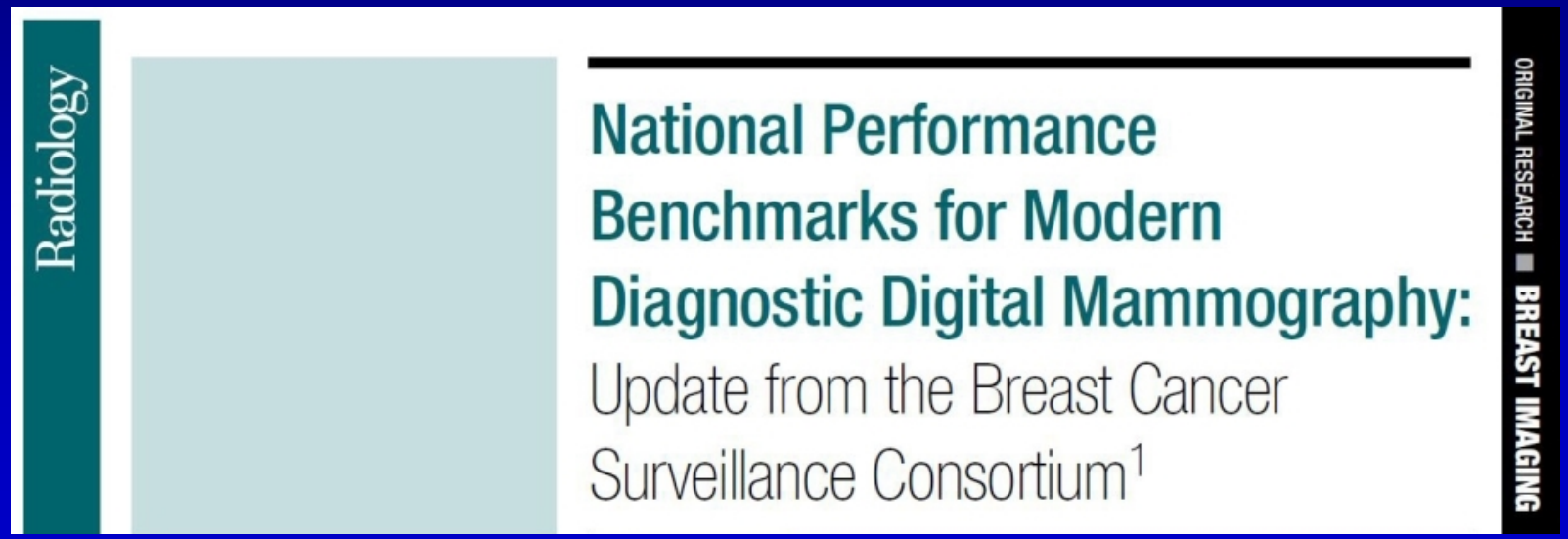
A whole-breast handheld ultrasound screening examination should document at minimum each of the four quadrants and the subareolar region [11]. The axilla may be included per facility practice and as per exam indication.

BI-RADS 6th Edition Audit Changes

Modality-neutral auditing of all exams

Updated performance benchmarks





Radiology 2017; 283(1):49-58 and 59-69

REVIEWS AND COMMENTARY ■ EDITORIAL

2017 Breast Cancer Surveillance Consortium Reports on Interpretive Performance at Screening and Diagnostic Mammography: Welcome New Data, But Not as Benchmarks for Practice[1]

Radiology 2017; 283(1):7-9

BCSC vs. NMD Benchmarks – Screening

	BCSC
Years	2007-2013
Exams	1,682,504
CDR	5.07 per K
PPV_1	4.38%
PPV_2	25.62%
PPV_3	28.63%

BCSC: Radiology 2017; 283:49-58.

BCSC vs. NMD Benchmarks – Screening

	BCSC	NMD
Years	2007-2013	2009-2015
Exams	1,682,504	9,832,036
CDR	5.07 per K	
PPV_1	4.38%	
PPV_2	25.62%	
PPV_3	28.63%	

BCSC: Radiology 2017; 283:49-58.

NMD: acr.org/Quality-Safety/Resources/BIRADS (select BI-RADS FAQs)

BCSC vs. NMD Benchmarks – Screening

	BCSC	NMD	B>N Diff
Years	2007-2013	2009-2015	
Exams	1,682,504	9,832,036	
CDR	5.07 per K	3.75 per K	+ 35.2%
PPV_1	4.38%	3.77%	+ 16.2%
PPV_2	25.62%	19.80%	+ 29.4%
PPV_3	28.63%	24.03%	+ 19.2%

BCSC: Radiology 2017; 283:49-58.

NMD: acr.org/Quality-Safety/Resources/BIRADS (select BI-RADS FAQs)

BI-RADS 6th Edition Audit Changes

Modality-neutral auditing of all exams

Updated performance benchmarks

BI-RADS 3 auditing added to Basic Audit

BI-RADS Category 3 Auditing

Added to the Basic Audit to increase the appropriate use of category 3 assessments

Robust literature documents that there is:

- Some incorrect use of cat. 3 assessments
- Adherence to strict category-3 imaging criteria is critical to patient safety

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Jay A. Baker, MD
Mary Scott Soo, MD

Malignant Lesions Initially Subjected to Short-term Mammographic Follow-up[1]

Index terms:
Breast, 00.13
Breast, biopsy, 00.1261
Breast neoplasms, diagnosis, 00.31
Breast neoplasms, radiography, 00.113, 00.114,
Breast radiography, utilization, 00.113, 00.114

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10.1148/radiol.2231011355
Radiology 2002; 223:221–228

Abbreviations:
BI-RADS = Breast Imaging Reporting and Data System
DCIS = ductal carcinoma in situ
UCSF = University of California at San Francisco

[1] From the Department of Radiology, Breast Imaging Division, Duke University Medical Center, Hospital South, Rm 24254, Box 3808, Durham, NC 27710. From the 2000 RSNA scientific assembly. Received August 13, 2001; revision requested September 19; revision received October 15; accepted October 31. **Address correspondence to** E.L.R. (e-mail: *rosen017@mc.duke.edu*).

PURPOSE: To determine whether systematically evaluated criteria for probably benign lesions were actually applied to lesions placed into that category.

MATERIALS AND METHODS: A search of the mammography database yielded 295 cases that were initially followed up with short-term interval mammography but eventually received a biopsy recommendation for the same breast. Of the 83 malignancies (81 patients) for which mammograms and pathology reports were available for review, 51 malignancies corresponded to the lesions for which short-term follow-up was recommended. Each case was retrospectively reviewed to determine whether the lesion followed up represented the subsequently diagnosed malignancy. Each lesion was characterized with appropriate Breast Imaging Reporting and Data System descriptors, based on the mammographic imaging available when short-term follow-up was first recommended. These characteristics were then used to determine if, in retrospect, the mammographic appearance met previously published criteria for probably benign lesions.

RESULTS: Of the 51 malignancies, 23 (45%) appeared mammographically as microcalcifications, 12 (24%) as masses, four (8%) as architectural distortion, and 12 (24%) as developing densities. None fulfilled strict criteria for a probably benign lesion when reviewed in retrospect. Forty-seven (92%) of 51 lesions had already demonstrated progression at the time of follow-up recommendation.

CONCLUSION: Short-term mammographic follow-up is often recommended for lesions that, in retrospect, do not fulfill established diagnostic criteria for probably benign lesions.

Radiology 2002; 223(1):221-228

Lesion and Patient Characteristics Associated with Malignancy After a Probably Benign Finding on Community Practice Mammography

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Keywords: BI-RADS, breast cancer, mammography, probably benign finding

DOI:10.2214/AJR.07.2153

Received March 1, 2007; accepted after revision September 4, 2007.

OBJECTIVE. The purpose of this study was to identify patient and lesion characteristics associated with a diagnosis of breast malignancy within 3 years of having a probably benign finding (BI-RADS category 3) on a mammogram obtained in a community radiology practice.

MATERIALS AND METHODS. The subjects were women 30 years old and older without breast implants or previous breast cancer who received notice of a probably benign finding on a bilateral screening mammogram between January 1, 1996, and June 30, 1999, in a community-based practice. From 82,898 mammograms, we identified 129 breast lesions designated probably benign that progressed to malignancy within 3 years of an index examination (cases) and matched them to 129 lesions designated probably benign that did not progress to malignancy within 3 years (controls). A breast imaging specialist blinded to case–control status interpreted all examinations and recorded detailed lesion descriptors according to the BI-RADS lexicon.

RESULTS. Case lesions were more likely in patients who were older, postmenopausal, or had a strong family history of breast cancer or previous biopsy. The lesions were more likely masses with obscured, indistinct, or spiculated margins compared with control lesions (84.6% vs 66%, $p = 0.03$). Case lesions were more likely calcifications (29.5% vs 17.8%, $p = 0.03$). No cases were encountered among calcifications considered typically benign in the BI-RADS lexicon (vascular or coarse), and no controls were encountered among calcifications considered suspicious or highly suggestive of malignancy in the BI-RADS lexicon (amorphous, pleomorphic, branching, and fine linear) ($p < 0.0001$).

CONCLUSION. In community practice, patient and lesion mammographic characteristics can be predictive of the likelihood of a subsequent cancer diagnosis of mammographic lesions designated as probably benign. Careful evaluation of mass margins and of the morphologic features of calcifications can help distinguish a malignant lesion from a probably benign finding.

AJR Am J Roentgenol 2008; 180(2):511-515

Breast Cancer Yield for Screening Mammographic Examinations with Recommendation for Short-Interval Follow-up[1]

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10.1148/radiol.2343031976
Radiology 2005; 234:684–692

Abbreviations:
BI-RADS = Breast Imaging Reporting and Data System
PBF = probably benign finding

[1] From the Depts of Medicine and Epidemiology and Biostatistics (K.K.) and Radiology (R.S.B., E.A.S.), Univ of California, San Francisco; General Internal Medicine Section, San Francisco Veterans Affairs Medical Ctr, 111A1, 4150 Clement St, San Francisco, CA 94121 (K.K.); Ctr for Health Studies, Group Health Cooperative, Seattle, Wash (L.A., C.L., W.E.B.); Dept of Radiology, Univ of Washington Medical Ctr, Seattle Cancer Care Alliance, Seattle, Wash (C.L.); Dept of Radiology, Univ of North Carolina, Chapel Hill (B.C.Y.); Applied Research Program, DCCPS, National Cancer Institute, Bethesda, Md (R.B.B.); Dept of Biostatistics, Univ of Washington, Seattle (W.E.B.); Cancer Research and Biostatistics, Seattle, Wash (W.E.B.); Ctr for Research Methods and Biometry, The Cooper Institute, Denver, Colo (J.H.V.); Health Promotion Research, Univ of Vermont, College of Medicine, Burlington (B.M.G.); and Norris Cotton Cancer Ctr/Dartmouth-Hitchcock Medical Ctr/Dept of Community and Family Medicine, Dartmouth Medical School, Lebanon, NH (P.A.C.). Received Dec 17, 2003; revision requested Feb 23, 2004; final revision received May 11; accepted Jun 18.

PURPOSE: To compare cancer yield for screening examinations with recommendation for short-interval follow-up after diagnostic imaging work-up versus after screening mammography only.

MATERIALS AND METHODS: From January 1996 to December 1999, Breast Imaging Reporting and Data System assessments and recommendations were collected prospectively for 1171792 screening examinations in 758 015 women aged 40–89 years at seven mammography registries in Breast Cancer Surveillance Consortium. Registries obtained waiver of signed consent or collected signed consent in accordance with institutional review boards at each location. Diagnosis of invasive cancer or ductal carcinoma in situ within 24 months of screening examination and tumor stage and size for invasive cancer were determined through linkage to pathology database or tumor registry. χ^2 test was used to determine significant differences between groups.

RESULTS: Overall, 5.2% of first and 1.7% of subsequent screens included recommendation for short-interval follow-up, which was similar to likelihood of recommendation for diagnostic evaluation (first screens, 4.6%; subsequent, 2.6%). Most recommendations for short-interval follow-up were based on screening mammography alone (86.2% of first screens, 77.5% of subsequent). Yield of cancer for screening examinations with probably benign finding (PBF) and recommendation for short-interval follow-up based on screening mammography alone tended to be lower than in those with PBF and recommendation for short-interval follow-up after additional work-up (first screens: 0.54% vs 0.96%, $P = .10$; subsequent: 1.50% vs 1.73%, $P = .26$). Proportion of stage II and higher disease tended to be higher for examinations with PBF and recommendation for short-interval follow-up based on screening mammography alone compared with those recommended for short-interval follow-up after additional work-up (first screens: 34.7% vs 24.4%, $P = .43$; subsequent: 27.5% vs 19.2%, $P = .13$).

CONCLUSION: Many first screening examinations include recommendation for short-interval follow-up based on screening mammography alone. Cancer yield for these examinations is low and is lower than that with diagnostic work-up prior to short-interval follow-up recommendation. Absence of diagnostic work-up prior to short-interval follow-up recommendation may result in periodic surveillance of a high proportion of benign lesions.

Radiology 2005; 234(3):684-692

Cancer Yield and Patterns of Follow-up for BI-RADS Category 3 after Screening Mammography Recall in the National Mammography Database

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From the Departments of Radiology (W.A.B., M.L.Z.) and Computational and Systems Biology (J.M.B.), University of Pittsburgh School of Medicine, Pittsburgh, Pa; Magee-Women's Hospital of University of Pittsburgh Medical Center, 300 Halket St, Pittsburgh, PA 15213 (W.A.B., M.L.Z.); Department of Radiology and Biomedical Imaging, University of California San Francisco, San Francisco, Calif (E.A.S.); Department of Radiology, University of Wisconsin-Madison School of Medicine and Public Health, Madison, Wis (E.S.B.); Radiology Associates of Albuquerque, Albuquerque, NM (R.D.R.); and Department of Radiology, New York University Langone Medical Center, New York, NY (C.S.L.). Received November 30, 2019; revision requested January 2, 2020; revision received March 12; accepted March 25. **Address correspondence to** W.A.B. (e-mail: *wendieberg@gmail.com*).

The views expressed in this article represent those of the author(s), and do not necessarily represent the official views of the American College of Radiology's National Radiology Data Registry or the American College of Radiology.

Conflicts of interest are listed at the end of this article.

See also the editorial by Moy in this issue.

Radiology 2020; 296:32–41 • https://doi.org/10.1148/radiol.2020192641 • Content codes: BR OI

Background: The literature supports the use of short-interval follow-up as an alternative to biopsy for lesions assessed as probably benign, Breast Imaging Reporting and Data System (BI-RADS) category 3, with an expected malignancy rate of less than 2%.

Purpose: To assess outcomes from 6-, 12-, and 24-month follow-up of probably benign findings first identified at recall from screening mammography in the National Mammography Database (NMD).

Materials and Methods: This retrospective study included women recalled from screening mammography with BI-RADS category 3 assessment at additional evaluation from January 2009 through March 2018 from 471 NMD facilities. Only the first BI-RADS category 3 occurrence for women aged 25 years or older with no personal history of breast cancer was analyzed, with biopsy or 2-year imaging follow-up. Cancer yield and positive predictive value of biopsies performed (PPV3) were determined at each follow-up.

Results: Among 45 202 women (median age, 55 years; range, 25–90 years) with a BI-RADS category 3 lesion, 1574 (3.5%) underwent biopsy at the time of lesion detection, yielding 72 cancers (cancer yield, 4.6%; 72 of 1574 women). For the remaining 43 628 women who accepted surveillance, 922 were seen within 90 days (with 78 lesions biopsied and 12 [15%] classified as malignant). The women still in surveillance (31 465 of 43 381 women [72.5%]) underwent follow-up mammography at 6 months. Of 3001 (9.5%) lesions biopsied, 456 (15.2%) were malignant (cancer yield, 1.5%; 456 of 31 465 women; 95% confidence interval [CI]: 1.3%, 1.6%). Among 18 748 of 25 997 women (72.1%) in surveillance who underwent follow-up at 12 months, 1219 (6.5%) underwent biopsy with 230 (18.9%) malignant lesions found (cancer yield, 1.2%; 230 of 18 748 women; 95% CI: 1.1%, 1.4%). Through 2-year follow-up, the biopsy rate was 11.2% (4894 of 43 628 women) with a cancer yield of 1.86% (810 malignancies found among 43 628 women; 95% CI: 1.73%, 1.98%) and a PPV3 of 16.6% (810 malignancies found among 4894 women).

Conclusion: In the National Mammography Database, Breast Imaging Reporting and Data System (BI-RADS) category 3 use is appropriate, with 1.86% cumulative cancer yield through 2-year follow-up. Of 810 malignancies, 468 (57.8%) were diagnosed at or before 6 months, validating necessity of short-interval follow-up of mammographic BI-RADS category 3 findings.

Radiology 2020; 296(1):32-41

BI-RADS Category 3 Auditing

all exams and # initial category 3 exams

If any initial category 3 assessments are made at screening instead of after recall from screening, audit them separately

Finding type (mass, calcs, focal asymmetry)

Track all surveillance exams for:

- Assessment category (1-2, 3, 4-5)
- If biopsy: benign or breast cancer

BI-RADS Category 3 Auditing

- Frequency of initial category 3 assessments
- Percentage of initial category 3 assessments that result in a breast cancer diagnosis
- Percentage of initial category 3 assessments that result in a breast cancer diagnosis from biopsy of the category 3 finding(s)
- Percentage of initial category 3 assessments downgraded to category 1 or 2 for decrease or disappearance of the category 3 finding(s)

BI-RADS 6th Edition Audit Changes

Modality-neutral auditing of all exams

Updated performance benchmarks

BI-RADS 3 auditing added to Basic Audit

MRI EOD added to More Complete Audit

Cancer Extent Using Diagnostic MRI

Cancer extent before definitive surgery

Audit approach, metrics, benchmark data

Findings separate from the known cancer

Unique auditing (all exams are Category 6)

- Linkage with tumor registry non-helpful
- Diligent internal tracking of each finding

Cancer Extent Using Diagnostic MRI

MRI EOD exams, # findings for each exam

- For each finding: ipsilat. or contralateral
- For each finding: mass or NME

EOD exams assessed as BI-RADS 4 or 5

- If biopsy: benign or breast cancer
- If breast cancer: histology, size, grade, biomarkers

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MRI EOD added to More Complete Audit

MOD added to diagnostic exam reporting

Defining and Determining MOD

MOD identifies the first test or clinical event leading to the diagnosis of breast cancer

MOD includes screening with breast imaging exams (FFDM, DBT, CEM, US, MRI, etc), clinical exam, self-exam, symptomatic patients seeking care, and other imaging or lab tests with incidental findings

Potential Benefits of MOD Data

Relative merits of screening and treatment

Screening vs clinical detection of cancer:
Differences in staging, treatment options, disease-free survival, mortality

Supplementary vs mammography screening:
Differences in staging, treatment options, disease-free survival, mortality

Who Should Classify MOD and How

- Cancer registry abstractors use the EMR to accurately acquire most data, but not MOD
- 6th edition Audit chapter proposes MOD classified by radiologist in all diagnostic imaging reports that recommend biopsy (relevant clinical data already available, radiologist has the needed expertise, no bias because outcomes not yet known)

MOD Classification

MOD category S (image-based screening)
- Sma (2D film / FFDM, no synthetic or DBT)
- Sdbt (DBT + FFDM, synthetic, or both)
- Sus (ultrasound)
- Smri (MRI)
- Scem (contrast-enhanced mammo)
- Snuc (PEM or MIBI)
- So (other screening modality (CT, etc)

MOD Classification

MOD category P (patient / provider detected)
- Pat (patient self-exam and/or symptom)
- Pro (provider CBE of asymptomatic patient)
- Ppp (cannot determine who detected first)

MOD Category N (detected by all other means)
- Non-breast imaging test (chest CT, PET/CT)
- Prophylactic mastectomy, reduction surgery
- Search for unknown primary site

BI-RADS 6th Edition Audit Changes

Modality-neutral auditing of all exams

Updated performance benchmarks

BI-RADS 3 auditing added to Basic Audit

MRI EOD added to More Complete Audit

MOD added to diagnostic exam reporting

Addition of “What Not to Audit”

What Not to Audit

Cat. 0 – Awaiting prior exams for comparison

What Not to Audit

Cat. 0 – Awaiting prior exams for comparison

Cat. 0 – Incomplete diagnostic exam

What Not to Audit

Cat. 0 – Awaiting prior exams for comparison
Cat. 0 – Incomplete diagnostic exam
Cat. 0 – Technical repeats

What Not to Audit

Cat. 0 – Awaiting prior exams for comparison
Cat. 0 – Incomplete diagnostic exam
Cat. 0 – Technical repeats
Cat. 3 – Exams other than initial category 3 assessments (in Category 3 audit)

What Not to Audit

Cat. 0 – Awaiting prior exams for comparison
Cat. 0 – Incomplete diagnostic exam
Cat. 0 – Technical repeats
Cat. 3 – Exams other than initial category 3 assessments (in Category 3 audit)
Cat. 6 – Known biopsy-proven malignancy

What Not to Audit

Cat. 0 – Awaiting prior exams for comparison
Cat. 0 – Incomplete diagnostic exam
Cat. 0 – Technical repeats
Cat. 3 – Exams other than initial category 3 assessments (in Category 3 audit)
Cat. 6 – Known biopsy-proven malignancy
Non-contrast MRI exams

What Not to Audit

Cat. 0 – Awaiting prior exams for comparison
Cat. 0 – Incomplete diagnostic exam
Cat. 0 – Technical repeats
Cat. 3 – Exams other than initial category 3 assessments (in Category 3 audit)
Cat. 6 – Known biopsy-proven malignancy
Non-contrast MRI exams
Post-procedure mammo exams after image guided biopsy or localization

What Not to Audit

Cat. 0 – Awaiting prior exams for comparison
Cat. 0 – Incomplete diagnostic exam
Cat. 0 – Technical repeats
Cat. 3 – Exams other than initial category 3 assessments (in Category 3 audit)
Cat. 6 – Known biopsy-proven malignancy
Non-contrast MRI exams
Post-procedure mammo exams after image guided biopsy or localization
Second opinions of completed imaging