

### III. FOLLOW-UP AND OUTCOME MONITORING

TO MAKE SURE THAT THESE DATA ARE PROTECTED AS PEER REVIEW INFORMATION, RADIOLOGISTS SHOULD CONSULT APPLICABLE STATE LAW AND REGULATIONS.

#### GLOSSARY OF STATISTICAL TERMS

Following is a glossary of statistical terms that are used for the basic and comprehensive audit of a mammography practice, both of which are described in detail following the glossary:

1. A **screening mammographic examination** is one performed on an asymptomatic woman to detect early, clinically unsuspected breast cancer.
2. A **diagnostic mammographic examination** is performed on a woman with *clinical signs or symptoms* that suggest breast cancer. A second type of diagnostic examination is that performed on a woman for whom further mammographic evaluation has been requested because of an abnormal screening mammographic examination. Two other types of special screening examinations, those performed in a woman with a personal history of breast cancer treated with breast conservations and those performed in a woman with breast augmentation, are often defined as diagnostic, but for *audit* purpose should be included in the *screening* group.
3. **Tissue diagnosis:** A pathologic diagnosis rendered after any type of interventional procedure (fine-needle aspiration cytology, core biopsy, incisional biopsy, excisional biopsy).
4. A **positive screening examination** is one for which a recall is initiated (BI-RADS® Category 0), or one that requires a tissue diagnosis (BI-RADS® Categories 4 and 5).

*Note: This definition of a positive screening examination is different from that used in the MQSA final rules, for which “positive” examinations are limited to only those that recommend tissue diagnosis. The ACR believes that a meaningful audit of screening examinations requires that the recommendation for recall imaging (BI-RADS® Category 0) also be considered “positive.”*

5. A **positive diagnostic examination** is one that requires a tissue diagnosis (BI-RADS® Categories 4 and 5).
6. A **negative screening examination** is one that is negative or has benign findings (BI-RADS® Category 1 or 2).  
*Note: Although BI-RADS® Category 3 is negative, it is not included among screening examinations because this assignment should be made only after appropriate workup of a finding detected at a screening examination, and would be included under negative diagnostic examination.*
7. A **negative diagnostic examination** is one that is negative, with a benign or probably benign finding (BI-RADS® Category 1, 2 or 3).
8. **Cancer:** Tissue diagnosis of either ductal carcinoma in situ (DCIS) or any type of primary (not metastatic) invasive breast carcinoma.

9. **True-Positive (TP)**: Tissue diagnosis of cancer within 1 year after a positive examination (BI-RADS® Category 0, 4 or 5 for screening; BI-RADS® Category 4 or 5 for diagnostic).
10. **True-Negative (TN)**: No known tissue diagnosis of cancer within 1 year of a negative examination (BI-RADS® Category 1 or 2 for screening, BI-RADS® Category 1, 2 or 3 for diagnostic).
11. **False-Negative (FN)**: Tissue diagnosis of cancer within 1 year of a negative examination (BI-RADS® Category 1 or 2 for screening, BI-RADS® Category 1, 2 or 3 for diagnostic).
12. **False-Positive (FP)**: Three separate definitions:
  - a. (**FP<sub>1</sub>**): No known tissue diagnosis of cancer within 1 year of a positive screening examination (BI-RADS® Category 0, 4, or 5).
  - b. (**FP<sub>2</sub>**): No known tissue diagnosis of cancer within 1 year after *recommendation* for biopsy or surgical consultation on the basis of a positive examination (BI-RADS® Category 4 or 5).
  - c. (**FP<sub>3</sub>**): Benign tissue diagnosis within 1 year after recommendation for biopsy on the basis of a positive examination (BI-RADS® Category 4 or 5).

*Note: TP + TN + FP + FN = Total number of examinations.*

This note refers to definitions 9, 10, 11, and 12.

13. **Positive Predictive Value (PPV)**: Three separate definitions:
  - a. (**PPV<sub>1</sub>**) (abnormal findings at screening): The percentage of all positive screening examinations (BI-RADS® Categories 0, 4 and 5) that result in a tissue diagnosis of cancer within 1 year. An initial screening assessment of Category 4 or 5 is unusual, but is possible.  

$$PPV_1 = TP / (\text{number of positive screening examinations})$$

**OR**

$$PPV_1 = TP / (TP + FP_1) \quad [FP_1 = \text{see 12a in glossary of statistical terms}]$$
  - b. (**PPV<sub>2</sub>**) (biopsy recommended): The percentage of all screening or diagnostic examinations *recommended* for biopsy or surgical consultation (BI-RADS® Categories 4 and 5) that resulted in a tissue diagnosis of cancer within one year.  

$$PPV_2 = TP / (\text{number of screening or diagnostic examinations } \textit{recommended} \text{ for biopsy})$$

**OR**

$$PPV_2 = TP / (TP + FP_2) \quad [FP_2 = \text{see 12b in glossary of statistical terms}]$$
  - c. (**PPV<sub>3</sub>**) (biopsy performed): The percentage of all known biopsies done as a result of positive screening or diagnostic examinations or additional imaging evaluations of positive screening examinations (BI-RADS® Categories 4 and 5) that resulted in a tissue diagnosis of cancer within 1 year. PPV<sub>3</sub> is also known as the Biopsy Yield of Malignancy or the Positive Biopsy Rate (PBR).

$$PPV_3 = TP / (\text{number of biopsies})$$

OR

$$PPV_3 = TP / (TP + FP_3) \quad [FP_3 = \text{see 12c in glossary of statistical terms}]$$

14. **Sensitivity:** The probability of detecting a cancer when a cancer exists or the number of cancers diagnosed after being identified at mammography in a population within 1 year of the imaging examination, divided by all cancers present in that population in the same time period.

$$\text{Sensitivity} = TP / (TP + FN) \quad [\text{Remember that FN is actually a cancer case}]$$

15. **Specificity:** The probability of interpreting an examination as negative when cancer does not exist; or the number of true-negative mammograms in a population divided by all actual negative cases (those for which there is no tissue diagnosis of cancer within 1 year of the mammogram) in the population.

$$\text{Specificity} = TN / (TN + FP)$$

16. **Cancer Detection Rate:** The number of cancers correctly detected at mammography per 1,000 patients examined at mammography.

a. This is of greatest value when calculated for *screening examinations* only or when calculated separately for screening and diagnostic examinations.

b. May also be calculated separately for PREVALENT cancers (those found at first-time mammographic examination) and for INCIDENT cancers (those found at subsequent screening examinations performed at or close to the recommended screening interval).

c. May also be calculated by AGE GROUP (40–49 years, 50–59 years, etc.).

17. **Abnormal Interpretation Rate:** The percentage of examinations interpreted as positive. For screening mammography, positive examinations include BI-RADS® Categories 0, 4 and 5 assessments. For diagnostic mammography positive examinations include BI-RADS® Category 4 and 5 assessments.

$$\text{Abnormal Interpretation Rate} = (\text{positive examinations}) / (\text{all examinations})$$

*Note that in many scientific publications concerning screening mammography, a **Recall Rate** is reported as being equivalent to the **Abnormal Interpretation Rate**, even though some screening examinations occasionally are given BI-RADS® Category 4 or 5 assessments. This is done because prompt further imaging evaluation with mammography and/or ultrasound (to assess for extent of disease and to plan for imaging-guided biopsy) is also recommended in addition to tissue diagnosis for almost all (if not all) screening examinations that are given BI-RADS® Category 4 or 5 assessments.*

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# THE BASIC CLINICAL RELEVANT MAMMOGRAPHY AUDIT

Certain minimum raw data should be collected and utilized to calculate important derived data that allow each radiologist to assess his or her overall performance in mammography interpretation. Some of these are now required under the MQSA.\*

**Table 1. The Basic Clinical Relevant Mammography Audit: The Core Data to be Collected and Calculated**

## A. Raw Data

1. Dates of audit period and total number of examinations in that period.
2. Number of screening examinations; number of diagnostic examinations (separate audit statistics should be maintained for each).
3. Number of recommendations for further imaging evaluation (recalls) (BI-RADS® Category 0 – “Need Additional Imaging Evaluation”).
4. Number of recommendations for biopsy or surgical consultation (BI-RADS® Category 4 – “Suspicious” and Category 5 – “Highly Suggestive of Malignancy”).\*
5. Biopsy results: malignant or benign (ACR suggests that you keep separate data for fine-needle aspiration/core biopsy cases and for surgical biopsy cases).
6. Cancer staging: histologic type, size, nodal status and grade.
7. MQSA final rules also require analysis of any **known** false-negative examinations by obtaining follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of malignancy.\*

## B. Derived Data (Calculated from Raw Data)

1. True-positives (TP).
2. False-positives ( $FP_1, FP_2, FP_3$ ).
3. Positive predictive value ( $PPV_1, PPV_2, PPV_3$ ).
  - a) In a screening/diagnostic facility, PPV can be defined any of three ways:
    1.  $PPV_1$  – based on abnormal findings (“positive” cases) at screening examination (recommendation for recall or biopsy) (BI-RADS® Category 0, 4, 5).
    2.  $PPV_2$  – based on recommendation for biopsy or surgical consultation (BI-RADS® Category 4, 5) .
    3.  $PPV_3$  – based on results of biopsy (otherwise known as biopsy yield of malignancy or positive biopsy rate [PBR]).
  - b) If screening exclusively, can define only one way:
    1.  $PPV_1$  – based on abnormal findings (“positive” cases) at screening examination (recommendation for recall or biopsy) (BI-RADS® Category 0, 4, 5).
4. Cancer detection rate for screening examinations.
5. Percentage of minimal cancers found (Minimal cancer is defined as invasive cancer  $\leq 1$  cm, or ductal carcinoma in situ [DCIS]).
6. Percentage of node-negative invasive cancers found.
7. Abnormal interpretation (recall) rate for screening cases.

\* Collection of these data is required under MQSA final rules.

Collection of these data requires proper coding of the data elements for efficient retrieval, often requiring considerable effort. However, once collected and calculated, these data allow measurement of one's practice outcomes by providing quantifiable evidence in pursuit of the three major goals of screening mammography:

1. Find a high percentage of the cancers that exist in a screening population (measurement: cancer detection rate, sensitivity [if calculable]).
2. Find these cancers within an acceptable range of recommendations for recall and recommendations for biopsy in an effort to minimize cost and morbidity (measurement: abnormal interpretation [recall] rate, positive predictive value).
3. Find a high percentage of small and node-negative cancers, which are more likely to be curable (measurement: rates of minimal cancers found, axillary lymph node negativity).

The numbers obtained for each of the data elements above can be compared to desirable goals recommended in *Quality Determinants of Mammography Guidelines* published in 1994 by the Agency for Healthcare Policy and Research (see Table 2), or other published recommendations.

**Table 2. Analysis of Medical Audit Data: Desirable Goals**

PPV <sub>1</sub> based on abnormal screening examination	5-10%
PPV <sub>2</sub> when biopsy (surgical, FNA, or core) recommended	25-40%
Tumors found - Stage 0 or 1	>50%
Tumors found - Minimal cancer <sup>1</sup>	>30%
Node positivity	<25%
Cancers found per 1,000 cases	2-10
Prevalent cancers found per 1,000 first-time examinations	6-10
Incident cancers found per 1,000 follow-up examinations	2-4
Recall rate	<10%
Sensitivity (if measurable)	>85%
Specificity (if measurable)	>90%

<sup>1</sup> Minimal cancer is invasive cancer  $\leq 1$  cm or ductal carcinoma in situ.

(From Bassett LW, Hendrick RE, Bassford TL, et al. Quality determinants of mammography. Clinical Practice Guideline No. 13. AHCPR Publication No. 95-0632. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, October 1994: 83, with permission).

However, due to the statistical variation in the comparatively small numbers collected in any individual practice audit and the demographic differences in patient populations served by individual practices, such comparison is generally less valid than assessing the trend of one's own performance over time or assessing this trend in comparison to that of other members of the same practice.

Whether data are being collected for the basic clinically relevant audit or for the more complete audit as outlined in the next portion of this section, separate audit statistics should be maintained for screening and diagnostic examinations, as many of the audit data (e.g., cancer detection rate) are significantly different for screening and diagnostic examinations.

Biopsy data for FNA/core biopsy may be collected separately from surgical biopsy data, but should be included with surgical biopsy data for statistical calculations.

Whether data are being collected for the basic clinically relevant audit, or for the more complete audit as outlined in the next portion of this section, all audit data should be monitored for each radiologist and in the aggregate for the entire mammography facility.

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Figure 1. The Basic Clinical Relevant Mammography Audit: The Core Data to be Collected and Calculated

		BIOPSY RESULTS	
		Positive (biopsy demonstrated malignancy within one year)	Negative (biopsy is benign or no cancer discovered within one year)
SCREENING MAMMOGRAPHY	Mammogram positive (BI-RADS® Categories 0, 4, 5)	<b>TP</b>	<b>FP</b>
	Mammogram negative (BI-RADS® Categories 1, 2)	<b>FN</b>	<b>TN</b>

$$\text{Sensitivity} = \text{TP} / (\text{TP} + \text{FN})$$

$$\text{Specificity} = \text{TN} / (\text{TN} + \text{FP})$$

$$\text{PPV} = \text{TP} / (\text{TP} + \text{FP})$$

		BIOPSY RESULTS	
		Positive (biopsy demonstrated malignancy within one year)	Negative (biopsy is benign or no cancer discovered within one year)
DIAGNOSTIC MAMMOGRAPHY	Mammogram positive (BI-RADS® Categories 4, 5)	<b>TP</b>	<b>FP</b>
	Mammogram negative (BI-RADS® Categories 1, 2, 3)	<b>FN</b>	<b>TN</b>

$$\text{Sensitivity} = \text{TP} / (\text{TP} + \text{FN})$$

$$\text{Specificity} = \text{TN} / (\text{TN} + \text{FP})$$

$$\text{PPV} = \text{TP} / (\text{TP} + \text{FP})$$

# THE MORE COMPLETE MAMMOGRAPHY AUDIT

Although the basic clinical relevant audit provides nearly all the data needed to assess one's progress in reaching the previously stated goals, certain additional audit data may also be collected and utilized to calculate derived data that provide further important information regarding mammographic performance. The following comprise the data for such a comprehensive audit:

**Table 3. The More Complete Mammography Audit: Data to be Collected**

1. **Dates of audit period and total number of examinations in that period (usually a 12-month period).**
2. Risk factors:
  - Patient's age at the time of the examination
  - Breast cancer history: personal or family (especially premenopausal cancer in first-degree relative—mother, sister or daughter)
  - Hormone replacement therapy
  - Previous biopsy-proved hyperplasia with cellular atypia or lobular carcinoma in situ (LCIS)
3. **Number and type of mammograms: screening (asymptomatic) examination, diagnostic (evaluation of symptoms or clinical/screening mammographic signs of breast cancer) examination or 6-month follow-up examination.\*\***
4. First-time examination or repeat (routine follow-up or 6-month follow-up) examination
5. Mammographic assessment and recommendation (BI-RADS® categories)
  - **Further imaging evaluation (recall) (BI-RADS® Category 0 = "Need Additional Imaging Evaluation")**
  - Routine follow-up (BI-RADS® Category 1 = "Negative" and Category 2 = "Benign")
  - Short-interval follow-up (BI-RADS® Category 3 = "Probably Benign")
  - **Biopsy should be considered (BI-RADS® Category 4 = "Suspicious")\***
  - **Appropriate action should be taken (BI-RADS® Category 5 = "Highly Suggestive of Malignancy")\***
6. **Biopsy results: benign or malignant (keep separate data for fine-needle aspiration, core biopsy and surgical biopsy cases)\***
7. Cancer data:
  - Mammographic findings: mass, calcifications, indirect signs of malignancy, no mammographic signs of malignancy
  - Palpable or nonpalpable
  - **Cancer staging: histologic type (ductal [in situ or invasive] or lobular [invasive only]), size, nodal status and grade (when available)**
8. **MQSA final rules also require analysis of any *known* false-negative examinations by obtaining follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of malignancy.\***

Note: **Bolded** items indicate data desired for the basic clinically relevant mammography audit.

\* Collection of these data required under the MQSA.

\*\* Separate audit statistics should be maintained for screening examinations, diagnostic examinations and 6-month follow-up examinations.

**Table 4. The More Complete Mammography Audit: Derived Data to be Calculated**

1. **True-positives, false-positives (three sub-definitions:  $FP_1$ ,  $FP_2$ ,  $FP_3$ ), true-negatives, false-negatives**
2. Sensitivity
3. Positive Predictive Value
  - **PPV<sub>1</sub>** – based on abnormal findings (“positive” exams) at screening examination (recommendation for recall or biopsy) (BI-RADS® Category 0, 4, 5)
  - **PPV<sub>2</sub>** – based on recommendation for biopsy or surgical consultation (BI-RADS® Category 4, 5)
  - **PPV<sub>3</sub>** – based on results of biopsy (otherwise known as biopsy yield of malignancy or positive biopsy rate [PBR])
4. Specificity
5. Cancer detection rate
  - **Cancer detection rate for screening examinations**
  - Prevalent vs. incident cancer detection rates for screening examinations
  - Cancer detection rate for diagnostic examinations
  - Rates within various age groups
6. **Percentage of nonpalpable cancers found**—separately for screening and diagnostic examinations
7. **Percentage of minimal cancers found** (minimal cancers are invasive cancers  $\leq 1$  cm or ductal carcinoma in situ [DCIS])—separately for screening and diagnostic examinations
8. **Percentage of node-negative invasive cancers found**—separately for screening and diagnostic examinations
9. **Abnormal interpretation (recall) rate for screening examinations**
10. Abnormal interpretation rate for diagnostic examinations

Note: **Bolded** items indicate data desired for the basic clinically relevant mammography audit.

## EXAMPLES OF HOW TO CLASSIFY LESIONS AS TRUE-POSITIVE, TRUE-NEGATIVE, FALSE-POSITIVE, AND FALSE-NEGATIVE

**Remember:** BI-RADS® Categories 0, 4 and 5 are positive assessments, whereas BI-RADS® Categories 1, 2 and 3 are negative assessments. True or false final outcomes depend on whether there is a tissue diagnosis of breast cancer within 1 year of mammographic examination.

1. A woman has a screening mammographic examination that is read as negative and no breast cancer is diagnosed within 1 year of the examination. The interpretation is negative and because no cancer is diagnosed within the year, the examination is classified as true-negative (TN).
2. A woman has a screening mammographic examination and is recalled for a finding. The diagnostic mammographic examination leads to a biopsy. The biopsy is benign, and breast cancer is not diagnosed within 1 year of examination. The screening interpretation is positive (BI-RADS® Category 0). The diagnostic interpretation also is positive (BI-RADS® Category 4 or 5). Both the screening and diagnostic examinations are classified as false-positive (FP) because no breast cancer is diagnosed within the year.
3. A woman has a screening mammographic examination for which a benign calcified fibroadenoma is described (BI-RADS® Category 2). A palpable mass develops within a year of examination, is biopsied and is found to be malignant. The screening interpretation is negative. However, because malignancy is diagnosed within the year, the examination is classified as false-negative (FN).
4. A woman has a diagnostic mammographic examination because of a clinically suspicious area. The examination is read as probably benign (BI-RADS® Category 3). The area of clinical suspicion is biopsied within 1 year and is found to be malignant. For diagnostic mammography, BI-RADS® Category 3 is considered a negative interpretation. Because malignancy was diagnosed within the year, the examination is classified as false-negative (FN). Note that the scientific literature that justifies mammographic surveillance for “probably benign” lesions, excludes palpable lesions from being considered for this assessment category.
5. A woman has a screening mammographic examination and is recalled for a finding (BI-RADS® Category 0). The diagnostic mammographic examination is read as probably benign, short-interval follow-up recommended (BI-RADS® Category 3). At 6 months, the second diagnostic mammographic examination shows a change and the area is biopsied (BI-RADS® Category 4). Malignancy is found. The screening interpretation is positive (BI-RADS® Category 0). The first diagnostic interpretation is negative (BI-RADS® Category 3). The second (6-month diagnostic interpretation is positive (BI-RADS® Category 4). Breast cancer is diagnosed within a year of all three examinations. Thus the screening examination is classified as true-positive (TP), the first diagnostic examination is classified as false-negative (FN), and the second diagnostic examination is classified as true-positive (TP).

6. A woman has a screening mammographic examination and is recalled for a finding (BI-RADS® Category 0). The diagnostic mammographic examination is read as probably benign, short-interval follow-up recommended (BI-RADS® Category 3). At 6 months, the second diagnostic mammographic examination shows a change (BI-RADS® Category 4). Biopsy shows no evidence of malignancy, and no breast cancer is found within a year of the follow-up examination. Thus the screening interpretation is positive, the first diagnostic interpretation is negative, and the second (6-month follow-up) diagnostic interpretation is positive. Because no breast cancer is found within 1 year of any of the examinations, the screening interpretation is classified as false-positive (FP), the first diagnostic interpretation is classified as true-negative (TN), and the second diagnostic interpretation is classified as false-positive (FP).
7. A woman has a screening mammographic examination and is recalled for a finding (BI-RADS® Category 0). The diagnostic mammographic examination is read as probably benign, short-interval follow-up recommended (BI-RADS® Category 3). At 6 months, the second diagnostic mammographic examination shows no change, and again is read as probably benign, short-interval follow-up recommended (BI-RADS® Category 3). The woman returns for her next mammographic examination 7 months later, at which a change is seen, biopsy is recommended (BI-RADS® Category 4) and malignancy is found. Thus the screening interpretation is positive, the first diagnostic interpretation is negative, the second (6-month follow-up) diagnostic examination is negative and the last (13-month follow-up) interpretation is positive. Because no breast cancer was found within 1 year of the screening examination and the first diagnostic examination, these are classified as false-positive (FP) and true-negative (TN), respectively. Because breast cancer was diagnosed within 1 year of the second (6-month follow-up) examination and the last (13-month follow-up) examination, these are classified as false-negative (FN) and true-positive (TP), respectively.
8. A woman has a screening mammographic examination at a facility in which the examination is interpreted before the woman leaves the premises, so that additional imaging can be performed immediately if needed. A noncalcified density is seen in one breast, only on the craniocaudal view. The interpreting physician obtains a second craniocaudal view to clarify the significance of this density. The examination is then interpreted as negative because the density (judged to represent a summation artifact) is not visible on the repeated craniocaudal view. No breast cancer is found within 1 year of examination. This single examination in effect represents a positive screening examination (BI-RADS® Category 0), for which the woman was “recalled” for additional diagnostic imaging that resulted in a negative (BI-RADS® Category 1) assessment. Thus the screening component of this examination should be classified as false-positive (FP) and the diagnostic component of the examination should be classified as true-negative (TN). Whenever a screening examination is interpreted before a woman leaves the premises, and the examination is converted to a diagnostic examination to clarify a mammographic finding identified on standard screening views, this single examination should be considered to have a positive screening interpretation (BI-RADS® Category 0) and also a positive or negative diagnostic interpretation depending on the final assessment.
9. A woman presents with a palpable mass in the left breast. The diagnostic mammographic examination is read as suspicious lesion in the right breast, with a recommendation for biopsy. Both the palpable mass and the mammographic lesion are biopsied. The palpable mass is found to be

benign, and the mammographic lesion is found to be malignant. The diagnostic interpretation is positive (BI-RADS® Category 4) and malignancy indeed is diagnosed within the year on the side of mammographic abnormality. Thus the diagnostic interpretation is classified as true-positive (TP).

10. A woman presents with a palpable mass in the left breast. The diagnostic mammographic examination is read as suspicious lesion in the right breast, with a recommendation for biopsy. The palpable mass is biopsied and is found to be malignant. The mammographic lesion is biopsied, is found to be benign, and no breast cancer is diagnosed in this breast within a year of examination. The diagnostic interpretation is positive in the breast in which no breast cancer was found within a year of examination, and the interpretation also is negative in the breast in which breast cancer indeed was diagnosed within the year. Thus the diagnostic interpretation is

classified as false-positive (FP) for the right breast and as false-negative (FN) for the left breast.

*Note that for all previous examples, one assumes a classification of true-negative (TN) for the breast contralateral to the side of the mammographic lesion, even though it is not stated explicitly. This parallels the practice of most mammography facilities, including those performing more complete mammography audits, which adopt the practice of classifying by examination rather than by breast. Thus for almost all cases, as with those cited for all previous examples, the resultant classification by the mammographically more relevant breast also represents classification by the clinically more relevant breast. However, for this particular uncommon example, in which the proper classification for the breast contralateral to the side of the mammographic lesion is false-negative, the classification by breast (rather than by examination) produces a more meaningful clinical assessment.*

## AREAS OF CONFUSION IN THE DATA COLLECTION PROCESS

### 1. Double reading:

Which reader gets “credit” for interpreted cases?

For the facility-wide audit, the most practical approach is the simplest: count each examination once, based on the final assessment after double reading is completed. However, in attributing assessments to the individual radiologists who participate in double reading, the method of assigning responsibility should depend on the type of double reading used.

- a. If the first radiologist performs thorough interpretations and the second radiologist performs “quick reads,” with knowledge of the interpretations made by the first radiologist, looking only to change negative assessments to positive (or alternatively, to change positive assessments to negative), the first radiologist will assume responsibility for all examinations based on his or her individual assessments, but the second radiologist will assume separate responsibility only for those examinations for which he or she changes the final assessment.
- b. If the two radiologists interpret examinations independently and consensus is determined by predefined rules (for example, an examination is given a positive final assessment if either radiologist makes a positive individual assessment, or alternatively, an examination is given a positive final assessment only if both radiologists make positive individual assessments), then each radiologist will

assume separate responsibility for examinations based on his/her individual assessments.

- c. If the two radiologists interpret examinations independently but then arrive at consensus by rereviewing examinations and coming to a joint decision, then each radiologist will assume separate responsibility for examinations based on the final assessment after double reading is completed.
- d. If the two radiologists interpret examinations together (simultaneously), then each radiologist will assume separate responsibility for examinations based on the joint assessment that they make.
- e. If the two radiologists interpret examinations independently but consensus is made by a third radiologist, then all three radiologists will assume separate responsibility for examinations, the first two readers based on their individual assessments and the consensus reader based on the final assessment that he or she makes.

*Note that for all previous examples, the “assignment of responsibility” relates only to the performance of individual radiologists at audit, for quality assurance purposes. The mammography facility that utilizes double reading may choose to adopt different approaches in deciding which radiologist(s) to name on double-read mammography reports.*

2. The “screener” versus the “diagnostic workup” radiologist:

If two different radiologists in a mammography facility interpret screening and diagnostic mammographic examinations for the same case, who gets “credit” for finding a cancer when it is correctly identified?

The answer to this question is analogous to that provided in the previous discussion concerning double reading. When two different radiologists interpret one or more mammographic examinations for the same case, each radiologist should assume separate responsibility for the examination(s) that he or she interprets. If a screening and a diagnostic mammographic examination are each interpreted as positive, and there is a subsequent diagnosis of breast cancer within the year, then both the screening and diagnostic examinations are classified as true-positive (TP), and each radiologist gets “credit” for his or her interpretation.

3. Cancer found on routine subsequent screening examination with cancer diagnosis LESS THAN 1 YEAR since the last normal screening examination:

Is the person who “missed” it on the last normal examination charged with an FN, or is the person who detected it at the “early” routine screening examination credited with a TP?

Because the first screening examination was read as negative but breast cancer was diagnosed within a year, this examination is classified as FN. Because the second screening examination was read as positive and breast cancer was diagnosed shortly thereafter, this examination is classified as TP.

For purposes of the audits of the two individual radiologists, each will assume responsibility for his or her individual assessment, the first radiologist for an FN interpretation, and the second radiologist for a TP interpretation.

It may appear to be “unfair” that the first radiologist is assigned a FN outcome when the only reason for this outcome is that the woman returned for mammographic screening sufficiently early for a breast cancer diagnosis to be made less than 1 year after her previous examination. However, for auditing to produce meaningful overall results, consistent and uniformly applied rules must be utilized. Therefore, all subjectivity such as allowing one to decide whether what appears to be a FN outcome is actually the result of “early” subsequent screening, must be eliminated from the process of determining outcomes. One would then need to examine the previous examination to decide whether it should or should not have been interpreted as negative.

There are two reasons why this scenario is encountered infrequently. First, true or false final outcomes depend on whether there is a *tissue diagnosis* of breast cancer within one year of examination. It often is several weeks after the detection of an abnormality at “early” subsequent mammographic screening until a tissue diagnosis of breast cancer is actually obtained, thus allowing the 1-year anniversary of the previous screening examination to be passed. Second, insurance reimbursement often is denied when a woman undergoes screening less than 1 year after her most recent screening examination, so that most mammography facilities establish a

policy that discourages or prevents the scheduling of “early” screening examinations.

4. Should patients returning for short-interval follow-up mammography after having been given BI-RADS® Category 3 (“Probably Benign”) assessments on previous examination be audited separately?

If these data are available, as in the more complete audit (see Table 3), then short-interval (6-month) follow-up examinations should be evaluated separately from routine screening examinations and from diagnostic examinations performed to evaluate clinical problems. It would be of great value to establish how frequently cases placed in the “probably benign” category continue to demonstrate benign findings. If too many (i.e., > 2%) of these cases are found to represent breast cancer, this would indicate incorrect assignment of truly suspicious findings as being probably benign. Such an outcome could be easily identified only through a separate “Category 3” audit. This separate audit would

encourage radiologist(s) to modify the interpretive criteria they used to categorize lesions as “probably benign.”

5. Should examinations interpreted as BI-RADS® Category 6 (Known Malignancy) be audited separately?

A typical example would involve a woman with known breast cancer (proved at recent core biopsy, not yet excised) who has a diagnostic mammographic examination to assess tumor response to neoadjuvant chemotherapy, if this examination were read as showing residual malignancy (BI-RADS® Category 6). All such interpretations should be audited separately, because of the extremely high likelihood that breast cancer will be diagnosed within one year of examination. Inclusion of such examinations amongst the (large majority of) other examinations would inappropriately skew the overall audit results of a mammography facility, rendering selected outcomes (cancer detection rate, PPV<sub>2</sub>, PPV<sub>3</sub>, sensitivity, etc.) very difficult to assess.

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## SAMPLE FORMS TO SIMPLIFY THE AUDIT DATA COLLECTION AND CALCULATION PROCESS

Form A (“Sample data collection: basic clinical relevant audit, screening cases only”) and Form B (“Sample calculation [derived data]: basic clinical relevant audit screening cases only”) have been designed to render the basic audit more “user-friendly.” By collecting and recording the numbers on Form A, one will be able to calculate all the parameters on Form B by simply “filling in the blanks.”

One will note that three different PPV’s (and three different FP’s) are listed on Form B. If these listings are too complex, one might choose to calculate only the  $PPV_3$  (derived from  $FP_3$ ), since this number simply represents the Positive Biopsy Rate (PBR), or the number of cancers found on all cases biopsied at the request of the radiologist, and is the PPV derived from the data now required

under the MQSA. The other calculations of Form B should be self-explanatory. A sample set of collected data is also provided from which one can practice the performance of Form B calculations.

The templates of Forms A and B are designed for the basic clinical relevant audit of screening examinations, but can be easily modified for other components or subgroups of the basic audit such as diagnostic examinations, core and FNA biopsy cases, or surgical biopsy cases. For the performance of the more complete audit, one must collect the additional data elements listed in Table 3, but one can construct expanded versions of Forms A and B by following the same format as well.

# SAMPLE DATA COLLECTION:

## BASIC CLINICAL RELEVANT AUDIT, SCREENING CASES ONLY

### FORM A

DATA ITEM	RESULTS
1. Total screening cases	
2. Total screening cases, BI-RADS® assessment Category 0, (needs additional imaging evaluation) and screening cases given BI-RADS® Assessment Category 4 or 5, without further evaluation	
3. Total screening cases, Final Assessment BI-RADS® Category 4	
4. Total screening cases, Final Assessment BI-RADS® Category 5	
5. Total cases from Final Assessment BI-RADS® Categories 4 and 5 that underwent core biopsy/FNA	
5a. Number of these that were malignant	
5b. Number of these that were benign	
6. Total cases from Final Assessment BI-RADS® Categories 4 and 5 that underwent surgical biopsy	
6a. Number of these that were malignant	
6b. Number of these that were benign	
7. Total cases from Final Assessment BI-RADS® Categories 4 and 5 that were lost to follow-up, refused biopsy, or surgeon elected to follow rather than biopsy	
8. Total cancers found that were ductal carcinoma in situ	
9. Total cancers found that were invasive ductal carcinoma or invasive lobular carcinoma	
10. Total cancers found that were invasive ductal carcinoma or invasive lobular carcinoma for which axillary sampling was performed	
11. Total number of invasive cancers that were $\leq 1$ cm in size	
12. Total number of invasive cancers that showed negative axillary lymph nodes at surgery	

*Note: BI-RADS® Category 3 cases are not listed here because they are considered negative.*

# SAMPLE CALCULATION (DERIVED DATA):

BASIC CLINICAL RELEVANT AUDIT, SCREENING CASES ONLY

FORM B

PARAMETER TO BE CALCULATED	CALCULATION*	RESULT
Number of True Positives (TP)	$5a + 6a$	
Number of False Positives (FP) Three Definitions:		
FP <sub>1</sub>	$2 - TP$	
FP <sub>2</sub>	$5b + 6b + 7$	
FP <sub>3</sub>	$5b + 6b$	
Positive Predictive Value Three Definitions:		
PPV <sub>1</sub> (how often abnormal screens are cancer)	$[TP] / 2$	
PPV <sub>2</sub> (how often biopsies recommended are cancer)	$[TP] / [TP + FP_2]$	
PPV <sub>3</sub> (how often biopsies done are cancer)	$[TP] / [TP + FP_3]$	
Cancer Detection Rate	$([TP] / [1]) \times 1000$	
Percent Minimal Cancers (Invasive Cancers $\leq 1$ cm, or Ductal Carcinoma in Situ) Found	$([8 + 11] / [TP]) \times 100$	
Percent Axillary Node-Negative Invasive Cancer Found	$([12] / [10]) \times 100$	
Percent Recall (i.e., recall rate)	$([2] / [1]) \times 100$	

\* Numbers refer to data items on Form A.

# PRACTICE DATA SET FOR FORMS A AND B

Please use the following hypothetical data set for Form A as a practice exercise for performing the requisite calculations of Form B for the basic audit.

1.	5,000
2.	450
3.	50
4.	40
5.	43
5a.	15
5b.	28
6.	42
6a.	15
6b.	27
7.	5
8.	6
9.	24
10.	23
11.	9
12.	19

Answers to categories on Form B:

$$TP = 30$$

$$FP_1 = 420$$

$$FP_2 = 60$$

$$FP_3 = 55$$

$$PPV_1 = 0.07 \text{ (7\%)}$$

$$PPV_2 = 0.33 \text{ (33\%)}$$

$$PPV_3 = 0.35 \text{ (35\%)}$$

$$\text{Cancer Detection Rate} = 6/1,000$$

$$\% \text{ Minimal Cancers} = 50\%$$

$$\% \text{ Node-Negative Invasive Cancers} = 83\%$$

$$\text{Recall Rate} = 9\%$$

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## IV. GUIDANCE CHAPTER

**W**ith the Fourth Edition of BI-RADS®, the committee includes this chapter on guidance in response to user comments. Many substantive changes have been incorporated in this edition to improve the clinical utility and to supply a unified base for research involving breast imaging. This chapter will expand on these changes as they appear in each section of BI-RADS® and provide explanations for the change. **What follows is intended for guidance and is not meant to imply required standards of practice.**

### Breast Imaging Lexicon

#### Masses

A mass is a three-dimensional structure demonstrating convex outward borders, usually evident on two orthogonal views. Due to confusion with the term “density,” which describes attenuation characteristics of masses, the term “density” which describes a finding other than a mass has been replaced with “asymmetry.” An asymmetry lacks convex outward borders and the conspicuity of a mass as discussed below.

#### Calcifications

It is confusing to have both “round” and “punctate” as separate descriptions unless each has characteristic features. The difference relates to size, with “punctate” defined as smaller than 0.5 mm and “round” as greater than or equal to 0.5 mm. The phrase “coarse heterogeneous” was added to describe calcifications of intermediate concern which are larger than 0.5 mm and variable in size and shape, but are smaller than those that usually occur in response to injury. When present as multiple bilateral groupings, coarse heterogeneous

calcifications are often due to fibrosis or fibroadenomas and follow-up may be appropriate. These tend to coalesce into typically benign calcifications. As an isolated cluster, “coarse heterogeneous” calcifications, however, have a small but significant likelihood of malignancy, especially when occurring together with smaller pleomorphic calcifications. Further data is needed on this issue. As with any calcifications, distribution must also be considered. Coarse heterogeneous calcifications in a linear or segmental distribution may be due to malignancy. To summarize, “coarse heterogeneous” was added and “fine pleomorphic” should be used to describe calcifications smaller than 0.5 mm that are variable in shape and have a higher probability of indicating malignancy.

#### Special Cases

Several questions were received by the BI-RADS® committee reflecting confusion distinguishing the terms “mass,” “focal asymmetry” and “asymmetry.” A mass should demonstrate completely or partially visualized convex outward borders and is usually depicted on orthogonal views.

Asymmetries are planar, lack convex borders, usually contain interspersed fat and lack the conspicuity of a three-dimensional mass. In order to clarify asymmetry, the term “global asymmetry” was introduced with this edition to underscore the difference between generalized and focal asymmetry. “Global asymmetry” involves a large portion of the breast (at least a quadrant). In the absence of a palpable correlate, a “global asymmetry” is usually due to normal variations or hormonal influence. A “focal asymmetry” differs from a mass since it usually lacks convex outward borders and differs from “global asymmetry” only in

the size of the area of the breast involved. A focal asymmetry is of more concern than a global asymmetry. Comparison to prior films is critical in evaluating asymmetries. A developing density requires additional evaluation in the absence of a history of surgery, trauma or infection at the site. What appears to be a focal asymmetry seen on screening, when further evaluated with spot compression views and/or ultrasound, may prove to be due to an indistinctly marginated mass.

### Report Organization

Many of the suggestions and questions received by the BI-RADS® committee concerned the assessment categories. We have responded and hopefully made changes that allow more flexibility and mirror what occurs in clinical practice.

BI-RADS® was designed as a mammographic tool. With the Fourth Edition, BI-RADS® for mammography has been combined with BI-RADS®–Ultrasound and BI-RADS®–MRI. Where appropriate, these two new lexicons are arranged in a similar manner. Both Ultrasound and MRI have features that are unique to each modality but, wherever applicable, terms having been developed for mammography are used. Assessment categories are the same for all BI-RADS® lexicons.

### Assessment Categories

BI-RADS® assessments are divided into incomplete (Category 0) and final assessment categories (Categories 1, 2, 3, 4, 5 and 6). An incomplete assessment requires further evaluation with additional mammographic views, comparison films, ultrasound or, less commonly, MRI. When additional imaging studies are completed, a final assessment is rendered. Ideally, the report of diagnostic mammographic views and ultrasound will be included in the same report, with separate paragraphs detailing each, and one integrated final assessment that takes into consideration all breast imaging findings.

The Mammography Quality Standards Act (MQSA) requires that a single assessment be given to a mammographic study. Sites or individuals who wish to provide a BI-RADS® assessment separately for each breast may do so within the impression text or body of the report, provided that the single overall assessment for the study is clearly coded at the end of the entire report. The overall final assessment should, of course, be based on the most worrisome findings present. For example, if probably benign findings are noted in one breast and suspicious abnormalities in the opposite breast, the overall report should be coded BI-RADS® Category 4 suspicious abnormality. Similarly, if immediate additional evaluation is still needed for one breast, (as an example, the patient could not wait for an ultrasound examination at the time), and the opposite breast had probably benign findings, the overall code would be BI-RADS® Category 0, incomplete.

A great deal of confusion centers on the patient with a palpable finding and negative imaging. These reports should be coded with final assessments based on the imaging findings. When the interpretation of imaging findings is influenced by the clinical findings, the final assessment should take both into consideration and the clinical findings may be detailed in the report.

### Category 3

The use of Category 3, probably benign, is reserved for findings that are almost certainly benign. It must be emphasized that this is NOT an indeterminate category for malignancy, but one that, for mammography, has a less than 2% chance of malignancy (i.e. is almost certainly benign). Such findings are generally identified on baseline screening or on screening for which previous examinations are unavailable for comparison. Immediate evaluation with additional mammographic views and/or ultrasound is required to render a

Category 3, probably benign assessment. Lesions appropriately placed in this category include a nonpalpable, circumscribed mass on a baseline mammogram (unless it can be shown to be a cyst, an intramammary lymph node, or another benign finding), a focal asymmetry which partially thins on spot compression, and a cluster of punctate calcifications (1). The initial short-term follow-up is usually a unilateral mammogram at 6 months after the time of the initial screening examination. Assuming stability of the finding, the recommendation is then for a bilateral follow-up examination in another 6 months (corresponding to 12 months after the initial examination). If no other features of concern are noted at this bilateral second short-interval follow-up, the examination is again coded as Category 3 with recommendation typically bilateral 12-month follow-up. If the feature(s) again shows no change in the next subsequent 12-month examination (corresponding to 24 months after the initial examination), the final assessment may be Category 2, benign, or Category 3, probably benign at the discretion of the interpreting physician. According to the literature (2), after 2 to 3 years of stability, the final assessment category may be changed to a Category 2, benign, although diagnostic (rather than screening) follow-up may be appropriate if, for example, continued magnification views will be needed.

As with any interpretive examination, a less experienced reader may still perceive a minimal focal asymmetry that changes with workup to be a Category 3 finding. A more experienced reader at 6, 12 or 24 months may recognize this as a normal variant and classify it as Category 1, negative. With a properly worded report the assessment category may be then changed to one that the current reader feels is appropriate.

It is also possible that a Category 3 finding is biopsied as a result of patient and/or clinician

concern, or lack of confidence in the probably benign follow-up assessment (see Figure 1). In such instances the final assessment category should be based on risk of malignancy, rather than management provided. Lesions appropriately classified as probably benign on ultrasound include nonpalpable incidental complicated cysts. Individual centers have shown < 2% rate of malignancy for nonpalpable, oval circumscribed hypoechoic solid masses that may be indistinguishable from complicated cysts. Clustered microcysts without a discrete solid component may also be included in this category.

The proper use of a Category 3, probably benign, assessment requires auditing one's practice. The rate of malignancy for mammographic findings placed in this category should be < 2%. For ultrasound, the rate of malignancy also should be < 2%, but this has not been widely validated in the literature. For MRI, the types of findings to be placed in short interval follow-up and expected rate of malignancy require further study. It is imperative that short interval follow-up does not alter the stage distribution or the prognosis of the few patients with malignancies placed under surveillance: this information must be included in the audit.

#### Category 4

Category 4 is used for the vast majority of findings prompting breast interventional procedures ranging from aspiration of complicated cysts to biopsy of pleomorphic calcifications. Many institutions have, on an individual basis, subdivided Category 4 to account for the vast range of lesions subjected to interventional procedures and corresponding broad range of risk of malignancy. This allows a more meaningful practice audit, is useful in research involving receiver-operating characteristic (ROC) curve analysis, and is an aid for clinicians and pathologists. The **optional** division

of Category 4 into three subdivisions **internally** at the facility level helps to accomplish these goals.

#### Category 4A

Category 4A may be used for a finding needing intervention but with a *low suspicion for malignancy*. A malignant pathology report not expected and a 6-month or routine follow-up after a benign biopsy or cytology is appropriate. Examples of findings placed in this category may be a palpable, partially circumscribed solid mass with ultrasound features suggestive of a fibroadenoma, a palpable complicated cyst or probable abscess.

#### Category 4B

Category 4B includes lesions with an *intermediate suspicion of malignancy*. Findings in this category warrant close radiologic and pathologic correlation. Follow-up with a benign result, in this situation, depends on concordance. A partially circumscribed, partially indistinctly marginated mass yielding fibroadenoma or fat necrosis is acceptable, but a result of papilloma might warrant excisional biopsy.

#### Category 4C

Category 4C includes findings of *moderate concern, but not classic* (as in Category 5) for malignancy. Examples of findings placed in this category are an ill-defined, irregular solid mass or a new cluster of fine pleomorphic calcifications. A malignant result in this category is expected.

These internal divisions of Category 4 should encourage pathologists to initiate further evaluation of benign results in a Category 4C, and should allow clinicians to better understand follow-up recommendations after biopsy for findings placed in each subset of Category 4.

#### Category 5

Category 5 is used for lesions almost certainly representing breast carcinoma. In earlier editions of BI-RADS® when histopathologic or cytologic diagnoses obtained by needle biopsies were less common, this assessment category signified that a lesion might be treated definitively without prior tissue sampling. This category must be reserved for findings that are classic breast cancers, with a  $\geq 95\%$  likelihood of malignancy. A spiculated, irregular high-density mass, a segmental or linear arrangement of fine linear calcifications or an irregular spiculated mass with associated pleomorphic calcifications are examples of lesions that should be placed in Category 5. Findings that warrant biopsy but are not classic for malignancy should be placed in Category 4, ideally in one of the three subdivisions mentioned above.

#### Category 6

This category has been added for breast findings confirmed to be malignant by biopsy *but prior to definitive therapies* such as surgical excision, radiation therapy, chemotherapy or mastectomy. Unlike BI-RADS® categories 4 and 5, there is no associated intervention required to confirm malignancy. This category is appropriate for second opinions on findings previously biopsied and shown to be malignant or for the monitoring of responses to neoadjuvant chemotherapy prior to surgical excision.

There may be scenarios where patients with biopsy-proven malignancy are sent for further imaging evaluation prior to therapeutic intervention. For example, a patient with known malignancy in one breast may be sent for outside film consultation with resulting recommendation for additional evaluation of other abnormalities in the same or opposite breast (Category 0). As in any situation, the final assessment should be based on the most immediate action required. The additional

evaluation may show a cyst in the opposite breast, a benign finding that requires no action, and the final assessment would then revert to Category 6 due to the known but as yet untreated cancer. If additional evaluation reveals a separate suspicious finding requiring biopsy, the overall assessment should be Category 4, suspicious, with biopsy recommended as that is the next action required.

If additional work-up is performed only on the opposite breast, it should be coded appropriately for the findings in that breast alone, however, it may be advisable to add a comment in the impression/recommendation that definitive treatment of the known cancer in the opposite breast is still required.

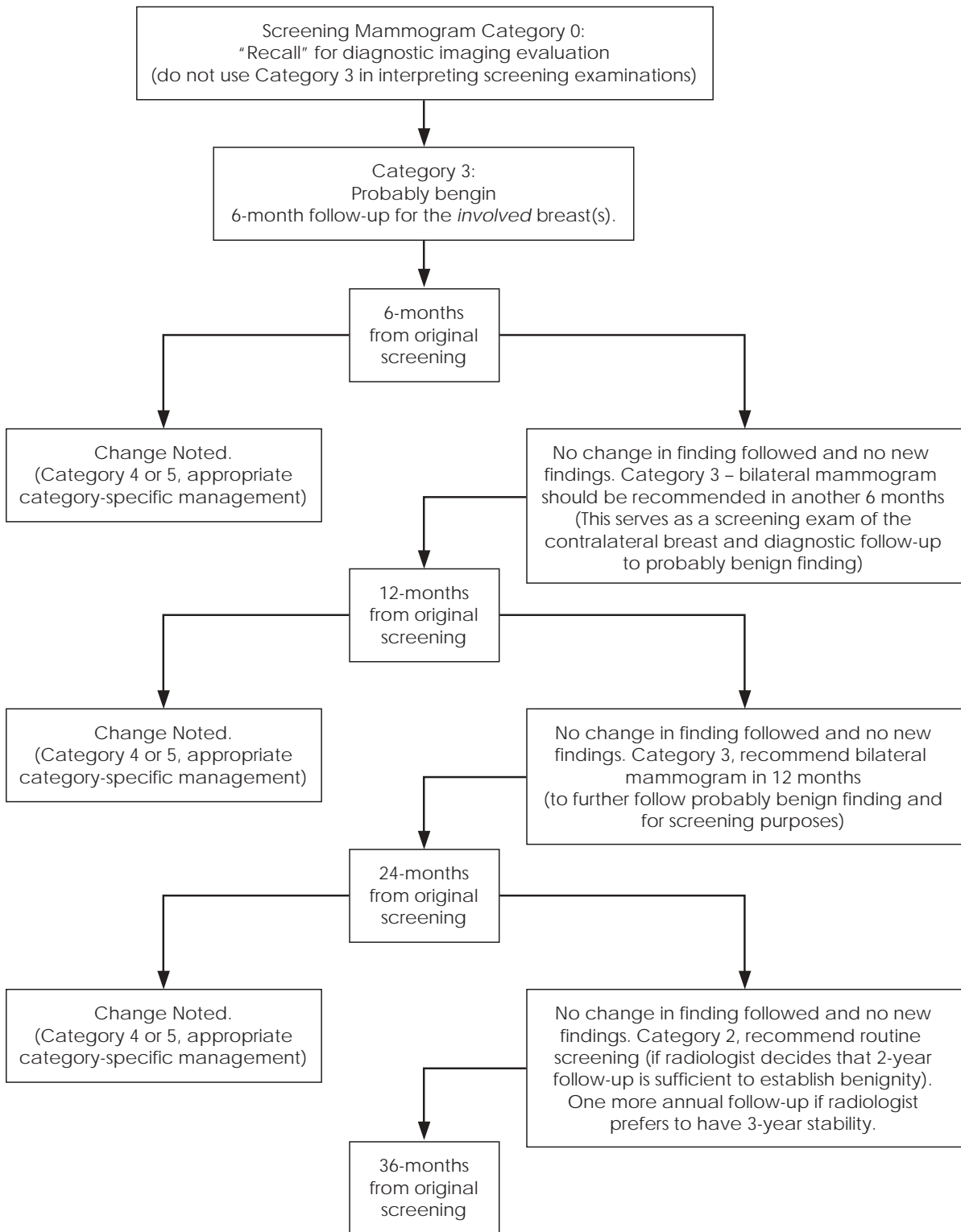
Use of Category 6 is not appropriate following excision of a malignancy (lumpectomy). After surgery, there may be no residual evidence of tumor, with final assessment of Category 3, probably benign, or Category 2, benign. There may, alternatively, be calcifications suspicious for residual tumor, with final assessment of Category 4, suspicious, or Category 5, highly suggestive of malignancy, with recommendation for biopsy or additional surgery.

A major rationale for adding Category 6 is that examinations meriting this assessment should be excluded from auditing. Auditing that includes such examinations would inappropriately indicate inflated cancer detection rates, positive predictive values, and other outcomes parameters.

### Category 0

Category 0 is utilized after a screening examination. When further imaging evaluation (e.g. additional views or ultrasound) or retrieval of prior films is required. Comparison to old films decreases the need for recall. However, comparison is not always required to interpret mammograms (3-4). In the absence of any findings of concern, it was found that prior films will be helpful in only 35/1093 (3.2%) of cases (5). Only examinations requiring prior films in order to make a valid assessment should be coded as Category 0. This would most often include cases with a focal asymmetry that could represent a normal variant or mammograms showing circumscribed mass(es) that may have been present previously. The recommendations should detail the suggested workup (e.g., additional views and/or ultrasound) needed if old films are not received.

**Figure 1. Category 3 Algorithm**



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