

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. (**FP₁**): No known tissue diagnosis of cancer within 1 year of a positive screening examination (BI-RADS® Category 0, 4, or 5).
 - b. (**FP₂**): 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. (**FP₃**): 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. (**PPV₁**) (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. (**PPV₂**) (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.

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

OR

$$PPV_2 = TP / (TP + FP_2) \quad [FP_2 = \text{see 12b in glossary of statistical terms}]$$
 - c. (**PPV₃**) (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. PPV₃ 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.*