BCSC Glossary of Terms

(Last updated 09/16/2009)

DEFINITIONS

Screening mammography – scrmam_c

The radiologist's indication for exam is the primary determinant of whether a mammogram is screening or diagnostic. However, the BCSC typically applies additional criteria to examinations indicated to be screening to eliminate possible non-screening exams. The "working" definition for a screening mammogram must meet all of conditions 1-4 and conditions 5-8 are applied to select a screening population:

1. We start with examinations indicated to be for "screening" by the radiologist (inclusion criteria #1 in computed variables (scrcrit_c1), based on variable in Radiology file II.13 indicate=1), and which are known to be mammograms (scrcrit_c12), based on variable in Radiology file II.15 mammtype in (1,2,3).
2. Because there may be multiple exams on the same day, we only include the first exam in the sequence (inclusion criteria #2 in computed variables (scrcrit_c2), based on variable in Radiology file II.5 examseq=1). [Note that when the exam sequence is unknown, the SCC guidelines are to sort first by indication (ordered 1,3,4,2), then by overall assessment (ordered 0-5)].
3. We require that bilateral routine views be performed (inclusion criteria #4 in computed variables (scrcrit_c4), based on variable in Radiology file II.17 routview = 4 or 5; if routview is missing then we require II.16 mammlat = 4 or 5). Unilateral exams are excluded because this often indicates that the woman may have had a previous unilateral mastectomy or that the exam was done for diagnostic purposes.
4. We exclude screening exams that are preceded by any radiologic exam within the prior nine months based on examinations in the database, (inclusion criteria #7 (scrcrit_c7), based on the Radiology and Additional imaging files), woman's self-report of a previous mammogram (Patient file I.20 lastdate), radiologist's report of a previous mammogram (Radiology file II.12 prevdate), or a comparison film date (Radiology file II.27 compdate). The combination of these last three sources of a radiologic exam within the prior nine months is inclusion criteria #8 in the computed variables (scrcrit_c8).
5. We exclude exams on women with a history of breast cancer based on either self-report (inclusion criteria #5 in computed variables (scrcrit_c5), based on variables in Patient file I.23 bchist = 1-5 or I.25 ageatdx = age given or I.26 dxdate = date given) or breast cancer diagnosis found in the cancer registry or pathology file (inclusion criteria #6 in computed variables (scrcrit_c6, based on **newdxdt** (date of first breast cancer from cancer registry or pathology) prior to exam date).
6. We exclude exams on women with a prior mastectomy (scrcrit_c11) based on either self-report (Patient file I.31 mastect) or found in the cancer registry or pathology file.
7. We exclude women who report breast implants at the time of that exam (inclusion criteria #9 in computed variables, based on Patient information file I.35 brstaugm = 1-5).
8. We exclude exams with a left, right, or overall assessment of '6' (known biopsy – proven malignancy). This assessment code was added in the ACR BI-RADS® – Mammography, 4th Edition Atlas.

The above describes the BCSC "standard" definition of a screening mammogram which has been used in many papers (though criteria 6 is a new addition starting with the 0609

submission), including a paper describing screening performance by time since last mammogram by Yankaskas et al. (*Radiology*, 2005). However, the definition of a screening mammogram may vary depending on the analysis. For example, an analysis may also require that there be no self-report of breast symptoms. The SCC has a computed variable for symptoms (**symp_c** ordered by level of concern: lump, nipple discharge, other not including pain, pain, other not specified, and none), so that any level of symptoms can easily be excluded. Alternatively, when an analysis includes both screening and diagnostic mammograms, one may prefer to only use a radiologist's indication for the exam to categorize the mammogram type.

Diagnostic mammography – dxmam_c

The definition of a diagnostic mammogram may differ among analyses. For example, in a paper by Sickles et al. (*Radiology*, 2005), diagnostic mammograms were defined as those where the radiologist's indication for exam is additional work-up of an abnormality detected at screening examination, short-interval follow-up, or evaluation of a breast problem, and results were shown separately for these different types of diagnostic mammograms. However, in papers by Barlow et al. (*JNCI*, 2002) and Geller et al. (*Radiology*, 2002), diagnostic mammograms only included those where the radiologist's indication for exam is evaluation of breast problem. It is important to stress that the performance characteristics are different for the different types of diagnostic mammograms, so we do not recommend combining results across the different types of diagnostic mammograms.

If a diagnostic mammogram is within 90 days after a previous diagnostic mammogram then it is not considered a diagnostic mammogram for the purposes of this computed variable.

This is our current definition of diagnostic mammograms, but other definitions may have been used in earlier papers.

Previously, there could be more than one diagnostic mammogram on the same day. However, we required diagnostic mammograms be at least 180 days apart if they both had a BI-RADS® assessment '0' and there were no Radiology exams with a non-zero assessment or Additional Imaging Follow-up exams with a resolved result between them. We assumed any unresolved exams within the follow-up period were from the same work-up period.

Overall assessment of mammogram – assmtot_c

The BI-RADS® assessments range from 0-6 where:

- BI-RADS® 0 indicates additional imaging evaluation is needed
- B-IRADS® 1-5 indicates the level of suspicion for malignancy
- BI-RADS® 6 indicates there is a known malignancy from a biopsy

Each record in the Radiology record contains a field for the left assessment, right assessment, and overall assessment. The overall assessment reflects the most serious assessment between the left and right breast. If the left and right assessments are different, the overall assessment is the 'highest' assessment in the following list ordered from the least to most concern: 1, 2, 3, 0, 4, 5 and 6. For exams where the laterality is unknown, the left and right assessments are missing, but an overall assessment is given. The SCC also computes the overall assessment as a data check and the SCC variable is used in all analyses.

The following abbreviations will be used in the definitions of initial and final assessment to represent certain combinations of recommendations:

n = recommendation of normal f/u, short interval f/u, no recommendations or recommendations are missing

w = recommendation for immediate work-up other than biopsy (additional views, ultrasound, MRI, nuclear medicine, clinical work-up, unspecified work-up)

b = recommendation for biopsy, surgical consult, or FNA

Initial (before work-up) assessment of mammogram - assminit_c

The initial assessment for screening mammograms is the assessment made before any additional imaging is performed. The use of additional imaging is determined from the screening exam record using variables II.18 diagview = 1-5, II.20 useaddv = 1, II.21 ultrasnd = 1-5, and II.22 useultra = 1 and checking whether other imaging examinations (mammogram or ultrasound) are performed on the same day from both the Radiology and Additional Imaging Follow-up files.

If additional imaging is done on the same day as the screening mammogram, the initial assessment is set to BI-RADS® 0. Otherwise, the initial assessment is considered the first recorded assessment in that imaging series. This definition was used in the paper by Yankaskas, et al. (*Radiology*, 2005) which looked at screening performance by time since last mammogram.

We do not typically use the initial assessment for diagnostic mammograms because they are performed to resolve a problem and should only result in a BI-RADS® assessment of 1-5 at the end of all imaging work-up. In addition, since the initial assessment variable is recoded to 0 if diagnostic views are performed, the recoded initial assessment (**assminit_c**) should never be used for diagnostic mammography.

Final (end of work-up) assessment of mammogram - assmfnl_c

All exams with an overall assessment of BI-RADS® 1w, BI-RADS® 2w, BI-RADS® 3w, BI-RADS® 0n, or BI-RADS® 0w are followed up for a final assessment. For all other exams the final assessment is taken to be the overall assessment (**assmtot_c**).

We look up to 90 days from the initial exam to determine the final assessment. The follow-up period is truncated at the time of biopsy if a biopsy occurs before 90 days. If there is no breast biopsy or surgery and there is a cancer diagnosis, the follow-up period is truncated at the cancer diagnosis date if it occurs before 90 days. Imaging records (from the Radiology and Additional Imaging Follow-up file) within 90 days of the original exam are considered potential follow-up records. The first follow-up record with an assessment of 1n, 2n, 3n, 1b, 2b, 3b, 0b, 4, or 5 (from the Radiology file) or with a positive/negative result (from the Additional Imaging Follow-up file) will be considered the final result. If multiple records exist on the same day then the record with the highest assessment is chosen. If there are no follow-up records that satisfy the above conditions, then the last record with an assessment of 1w, 2w, 3w, 0n, 0w (from the Radiology file), or with a recommendation of additional evaluation (from the Additional Imaging follow-up file) will be used. If the assessment is missing for all follow-up records, then the last record with a missing assessment will be used. This definition was modified after the April 2008 BCSC meeting. Prior to the meeting we continued to look for follow-up records even if a 3b or 0b was found. The definition was modified again following the December 2008 steering committee call. The change was to follow-up 1w or 2w records; whereas before, all 1s and 2s regardless of recommendation were taken to be 1 or 2 for the final assessment.

If the final exam is taken from the Additional Imaging Follow-up file, the BI-RADS® assessment will be missing but the mammogram result may still be classified as positive or negative based on the imaging recommendation (**imgrec**). If recommendation is missing then imaging result (**imgrslt**) will be used. If no follow-up records are found then the final assessment is the same

as the original assessment (**assmtot_c**). It is possible that some of these mammograms will not be resolved and will have a final assessment of BI-RADS® 1w, 2w, 3w, 0n, or 0w.

Prior to June 2007 we had separate final assessment variables for screening and diagnostic mammograms (**scrassmfnl_c** and **dxassmfnl_c**). Diagnostic mammograms with an assessment of 0 were followed up and different definitions were used each of these variables.

In June 2007 we decided to create only one final assessment variable instead of separate assessment variables for screening and diagnostic mammograms. This means that diagnostic mammograms with an assessment of 3w or 3b, in addition to those with an assessment of 0, would now be followed up to determine a final assessment. (This changed in April 2008 and again in Decemeber 2008 – see above for more details)

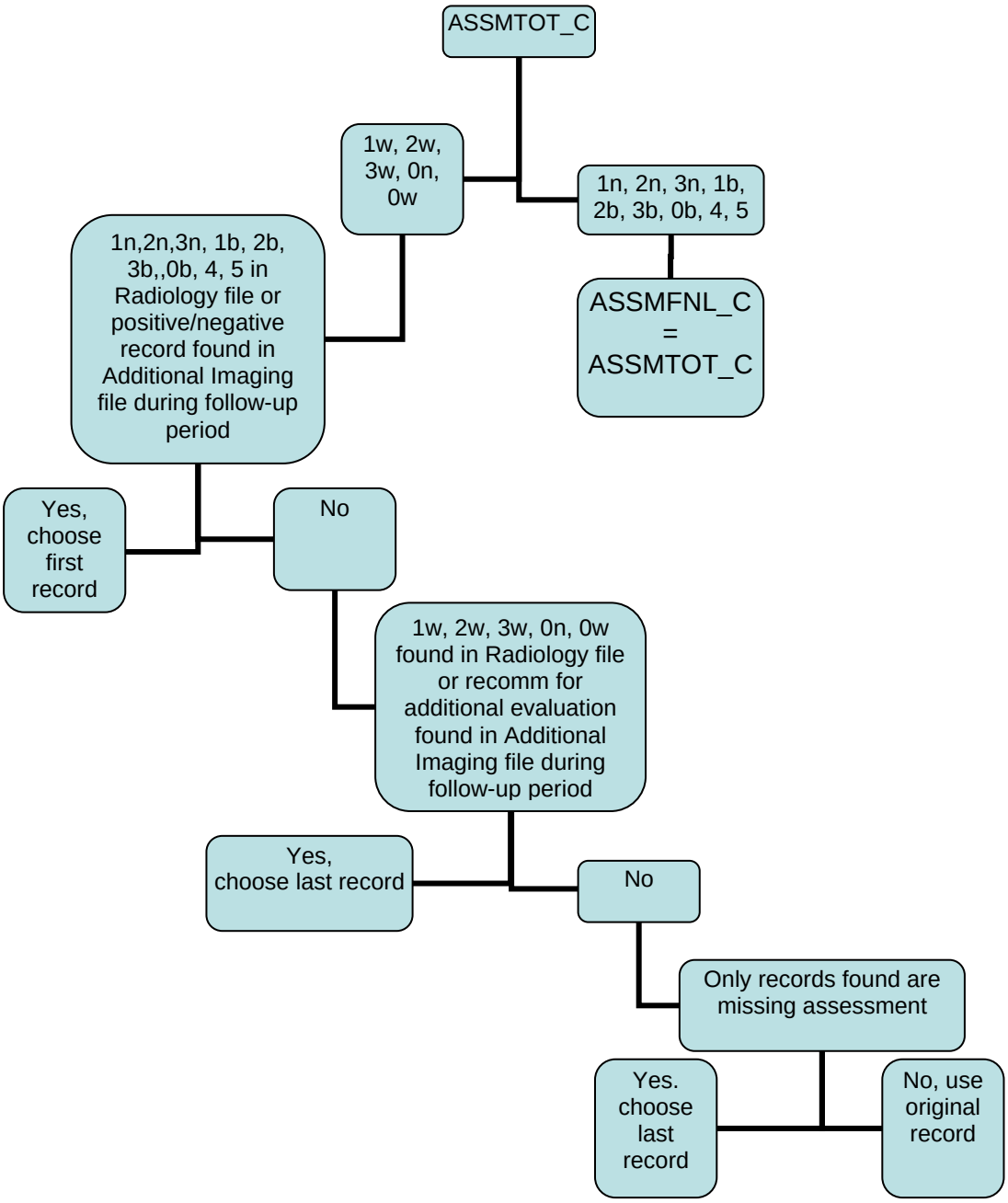
In May 2008 the Steering Committee decided to decrease the follow-up period from 180 to 90 days since the longer follow-up period did not resolve many more exams.

There may be variations of this definition depending on the analysis being done and the time it was performed.

Points to keep in mind are the following:

- Even though the initial mammogram is coded 1-5, the assessment may change during the work-up period. While the BCSC would not change the initial assessment in this case, some argue that the final assessment and initial assessment can differ even when the initial assessment was not 1w, 2w, 3w, 0n, 0w .
- Some cancer registries define the date of diagnosis as the first evidence of breast cancer. Therefore, if an abnormality is noted on a screening mammogram and the radiologist gives it an assessment of zero, that screening mammogram date may be taken as the diagnosis date even if additional imaging is performed on a different day. Therefore, we may be truncating the follow-up period too soon. This will only occur if we have no record of a biopsy being performed within 90 days.

FIGURE 1: Determining Final Assessment



n = recommendation of normal f/u, short interval f/u, no recommendations or recommendations are missing

w = recommendation for immediate work-up other than biopsy (additional views, ultrasound, MRI, nuclear medicine, clinical work-up, unspecified work-up)

b = recommendation for biopsy, surgical consult, or FNA

Positive and negative mammography result – resinit_c, resfnl_c

A mammogram result is determined to be positive or negative based on the BI-RADS® assessment and recommendations given.

For initial result (**resinit_c**), 1, 2, and 3n are considered negative while 3w, 3b, 0, 4, 5 are positive.

Prior to June 2007 we had two separate final result variables for screening (**scrresfnl_c**) and diagnostic exams (**dxresfnl_c**). For screening final result, assessments of 1, 2, and 3n were considered negative and 3w, 3b, 0, 4, and 5 were considered positive. For diagnostic final result, assessments of 1, 2, 3, and 0n, 0w were considered negative and 0b, 4, and 5 were considered positive.

In June 2007 the BCSC/SCC decided to create only one final result variable (**resfnl_c**) for screening and diagnostic exams. We decided to designate assessments of 3b and 0b to be positive. All other assessments of 3 and 0 were considered negative. In January 2008 the steering committee decided that exams with a final assessment of 0 and with a recommendation of non-specified work-up or additional imaging or missing recommendation would be missing final result.

To summarize the current coding for final result: 1 and 2 are considered negative; assessments of 3 without a recommendation for biopsy, FNA, or surgical consult are negative; assessments of 3 with a recommendation for biopsy, FNA, or surgical consult are positive; assessments of 0 with no recommendations or a recommendation for normal follow-up, short interval follow-up, or clinical exam are negative; assessments of 0 with a recommendation for biopsy, FNA, or surgical consult are positive; assessments of 4 or 5 are positive.

If the final result is based on a record from the Additional Imaging Follow-up file, the result is classified as positive if the recommendation (**imgrec**) is 'Surgical consult or biopsy' and negative if the recommendation is 'Normal interval screen' or 'Short interval follow-up'. If the recommendation is missing, then imaging result (**imgrslt**) is used to classify the mammogram as positive or negative. An imaging result of 'Abnormal' is positive and 'Normal' is negative. The following table summarizes how the initial and final results are defined based on the assessment and recommendation variables. The table also highlights changes between the new and old definitions.

Changes in classification of positive and negative exams based on BI-RADS assessment and recommendation.

BI-RADS assessment & recommendation	Initial Result (not changed) **Resinit_c**	**Final Result NEW** (created **March '08**) **Resfnl_c**	Final Result NEW (created June'07) **Resfnl_c**	Final Result screens OLD (used < June '07) **Scrresfnl_c**	Final Result diagnostic exams OLD (used < June '07) **Dxresfnl_c**
1	Negative	Negative	Negative	Negative	Negative
2	Negative	Negative	Negative	Negative	Negative
3n	Negative	Negative	Negative	Negative	Negative
3w	Positive	Negative	Negative	Positive	Negative
3b	Positive	Positive	Positive	Positive	Negative
0 with recomm of addnl imaging, non-specified work-up, or missing	Positive	Missing	Negative	Positive	Negative
0 with recomm of normal, short-interval f/u, clinical exam or no recomm	Positive	Negative	Negative	Positive	Negative
0b	Positive	Positive	Positive	Positive	Positive
4	Positive	Positive	Positive	Positive	Positive
5	Positive	Positive	Positive	Positive	Positive

For the purposes of ROC analysis we order the assessments for initial screens as 1, 2, 3n, 3w/b, 0, 4, 5.

Breast cancer cases

The first diagnosis of breast cancer, invasive or ductal carcinoma *in situ* (DCIS), for each woman is identified through the cancer registry and pathology files. If there are diagnoses of both invasive cancer and DCIS, the earliest result is taken if the two diagnoses are more than 60 days apart. If the two diagnoses are within 60 days of each other, the invasive result is taken but the earliest date is retained as the diagnosis date. For cancer characteristics (e.g., size, stage, nodal status), we take the most severe result from all records with the same cancer type (invasive or DCIS) within 60 days of diagnosis.

Only invasive and DCIS breast cancer cases are included as breast cancer. Sarcomas (including cystosarcoma phyllodes), lymphomas, and LCIS are excluded.

Follow-up period post-mammogram for cancer diagnosis

Both screening and diagnostic mammograms are followed for one year (365 days) for cancer diagnosis. For screening mammograms, the follow-up period is truncated at the next screening exam if the screening exam is 270-365 days after the mammogram. This definition was adopted based on a paper by Rosenberg et al (*Acad Radiol*, 2000). However, non-screening mammograms occurring less than 270 days after the exam do not terminate the follow-up period. Note that this definition is different from the definition described in the ACR BI-RADS® manual that uses a strict 365-day follow-up period.

For diagnostic mammograms the follow-up period in which cancer is diagnosed includes 30 days prior to and one year after the exam. If multiple cancer diagnoses exist during follow-up then one is chosen using the following hierarchy:

1) If one or more cancers are diagnosed within 0-60 days after the exam then the cancer closest to the exam is chosen
2) Otherwise if one or more cancers are diagnosed within 1-30 days prior to the exam then the cancer closest to the exam is chosen
3) Otherwise if one or more cancers are diagnosed within 61-365 days after the exam then the cancer closest to the exam is chosen

For both screening and diagnostic mammograms, a diagnosis of cancer is determined within 365 days of the initial mammogram (not the mammogram used for final assessment).

To determine if a cancer was diagnosed within 1 year after:

a screening mammogram use: **cancscrfu1yr_c**

a diagnostic mammogram use: **cancdxfu1yr_c**

To determine if a cancer was diagnosed within 1 year after an exam, without truncation for screening mammograms within that year, use **cancfu1yr_c**. This variable does not include cancers diagnosed within 30 days prior to the exam.

PERFORMANCE MEASURES

Below are definitions for performance measures that are often used in BCSC papers. Note, that the BCSC definitions of positive and negative mammogram and cancer in the follow-up period may be different from those used by the American College of Radiology.

False positive: positive mammogram with no breast cancer diagnosed by the end of the follow-up period.

True positive: positive mammogram with DCIS or invasive breast cancer diagnosed by the end of the follow-up period.

False negative: negative mammogram with DCIS or invasive breast cancer diagnosed by the end of the follow-up period.

True negative: negative mammogram with no breast cancer diagnosed by the end of the follow-up period.

2x2 table:

Outcome	Positive mammogram	Negative mammogram	Total
Cancer diagnosis by end of follow-up	A (true positive)	C (false negative)	A+C
No cancer diagnosis by end of follow-up	B (false positive)	D (true negative)	B+D
Total	A+B	C+D	A+B+C+D

Sensitivity is the proportion of cancers within the follow-up period of the mammogram that had a positive mammography assessment

$$\text{Sensitivity} = \frac{A}{A+C}$$

Specificity is the proportion of non-cancers within the follow-up period of the mammogram that had a negative mammography assessment

$$\text{Specificity} = \frac{D}{B+D}$$

Positive Predictive Value (PPV) has three separate definitions:

PPV_1 is the proportion of exams with a positive assessment that had a cancer diagnosis in the follow-up period (referred to as PPV if no other definitions are used)

$$PPV_1 = \frac{A}{A+B}$$

PPV_1 should only be computed using initial assessment.

PPV_2 is the proportion of exams with a recommendation for biopsy or surgical consult (based on recommendation alone or combination of assessment and recommendation) that had a cancer diagnosis in the follow-up period.

We have defined "exam with a recommendation for biopsy or surgical consult" in a number of ways. In a paper by Sickles et al. looking at performance benchmarks for diagnostic mammography (*Radiology*, 2005) it was defined as an exam with a final BI-RADS assessment of 4 or 5 AND a recommendation for biopsy, surgical consult or fna within 180 days of the exam. In a paper by Rosenberg et al. (*Radiology*, 2006) looking at performance benchmarks for screening mammography, it was defined as an exam with a final BI-RADS assessment of 4 or 5 (regardless of whether or not a recommendation for biopsy was made).

The current proposal (03/17/08) is to define an "exam with a recommendation for biopsy or surgical consult" as an exam with a BI-RADS assessment of 4 or 5 or an exam with a BI-RADS assessment of 3 or 0 with a final recommendation of biopsy, surgical consult or FNA. (i.e. 4, 5, 3b, 0b)

PPV_3 is the proportion of exams with a recommendation for biopsy or surgical consult (see above) and a biopsy performed within 1 year of the exam that had a cancer diagnosis in the follow-up period.

Note: PPV_3 is based on exams with a biopsy performed. However, there are at least two sites that do not have complete biopsy data. Analysts should realize this measure could be biased since it is based on only the exams that have biopsies within one year; for the other exams it is not known whether a biopsy was NOT performed or if we are missing the biopsy record.

Negative Predictive Value (NPV) is the proportion of exams with a negative assessment that did not have a cancer diagnosis in the follow-up period

$$NPV = \frac{D}{C+D}$$

Cancer Detection Rate (CDR) is the proportion of exams with a positive assessment and cancer diagnosis in the follow-up period. It is usually computed per 1000 mammograms.

$$CDR=1000*A/(A+B+C+D)$$

False Positive Rate is the proportion of non-cancers within the follow-up period of the mammogram that had a positive mammography assessment. It is equivalent to 1-Specificity.

$$FPR= B/(B+D)$$

The consequence of shortening the follow-up period for screening mammograms must be understood. Consider the following example:

Date	Event	Assessment	Classification
Jan 1, 2000	Screening mammogram	Negative	True negative
Nov 1, 2000	Screening mammogram	Positive	True positive
Nov 1, 2000	Cancer diagnosed		

By the ACR definition, the first mammogram would be classified as false negative exam because a breast cancer was diagnosed within 365 days of a negative exam. However, based on our definitions, the follow-up period ended October 31, 2000 because of the Nov 1 screening exam so the first mammogram would be classified as a true negative exam. This would result in increasing the sensitivity. For the purpose of classification, there are two entries for this woman into the analysis.

Mode of Diagnosis (Screen Detected and Interval Detected Cancers)

(last updated by LA, 03/17/08):

"Screen-detected" and "interval-detected" cancers have been defined in a number of ways. Two methods are summarized below. These are not meant to be standardized definitions but simply examples of how mode of detection was defined for two analyses.

Method 1 (used in DR104):

(based on cancers with at least one mammogram within 6 months prior to or 1 month after the diagnosis date)

Screen detected: cancer diagnosed with a positive screen without self-reported symptoms, where the screen is within 3 months prior or 1 month after the diagnosis date.

This group will be divided further into two groups:

a) positive screens with no prior mammograms (i.e. first mammogram)

b) positive screens with a prior mammogram within 3 years

Interval detected: cancers not considered screen-detected that occur within 0 to 6 months after (or 1 month prior to) a mammogram (screening or diagnostic, with or without symptoms) that is within 3 years of a prior mammogram. (A woman with a negative screen within 3 months of diagnosis would be in this group if her prior mammogram was within 3 years).

Clinical detected: All other cancers that have a diagnostic mammogram or symptomatic screen within 6 months after (or 1 month prior) and do not have a prior mammogram within 3 years.

(positive/negative is based on final result)

Method 2 (used in AB48):

Screen: Indicate=1 & no lump

Diagnostic: Indicate=2,3,4 OR lump

Choose

1) Furthest screen within 365 days prior to diagnosis OTHERWISE

2) Furthest diagnostic within 365 days prior to diagnosis OTHERWISE

3) Closest diagnostic within 30 days *after* diagnosis

Use the final result at the time of the mammogram to define mode of diagnosis as one of the following:

screen – positive

screen – negative

diagnostic – positive

diagnostic – negative

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PRESENTATIONS

Linn Abraham and Erin Aiello. Definitions used for Performance Assessment, April 2005 BCSC meeting