

The American College of Radiology BI-RADS® ATLAS 5th Edition: Frequently Asked Questions

(Revised 1/17/17; updated questions in red)

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General

Q. When was the latest edition of BI-RADS® published?

A. The hardcopy BI-RADS® Atlas 5th Edition was published in January 2014 and is available for order online (<http://www.acr.org/Education/Education-Catalog>) or by telephone at (800) 227-7762.

Q. When was the digital edition of BI-RADS® published?

A. The BI-RADS® Atlas 5th Edition e-book was published in September 2014 and is available for order online (<http://www.acr.org/Education/Education-Catalog>) or by telephone at (800) 227-7762.

Q. Where are the rest of the BI-RADS® Frequently Asked Questions?

A. Many of the FAQs have been included within the text of the atlas; these are also available on the ACR website's [BI-RADS® page](#):

- [Mammography FAQs](#)
- [Breast Ultrasound FAQs](#)
- [Breast MRI FAQs](#)
- [Follow-up and Outcome Monitoring FAQs](#)

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Q. Is the Fifth Edition of BI-RADS® available in other languages?

A. Yes. The BI-RADS® Atlas 5th Edition has been translated into the following languages:

- Spanish - Visit Ediciones Journal S.A., of Buenos Aires, Argentina at <http://www.edicionesjournal.com/> for more information.
- German - Visit Springer Publishing at <http://www.springer.com/us/book/9783662488171> for more information.
- Portuguese –Visit the Colégio Brasileiro de Radiologia e Diagnóstico por Imagem (CBR) at <http://cbr.org.br/material-didatico/> for more information.
- Mandarin – Available soon. Visit Peking University Press at <http://pumpress.bjmu.edu.cn/en-abus.html> for more information.
- Japanese – Available soon. Visit the Japanese College of Radiology at <http://www.jcr.or.jp/index.html> for more information.

Corrections to ACR BI-RADS® Atlas 5th Edition

Q. If we have purchased the BI-RADS® Atlas and there are corrections, how can we find out what corrections were made?

A. Any significant corrections to the BI-RADS® Atlas 5th Edition will be published here in the BI-RADS® Frequently Asked Questions. Minor corrections, such as typos, will be made in future printings of the hardcopy.

Front Material

Date	1 st /2 nd Printing Page #	3 rd Printing Page #	Section	Description of Revisions
12/31/2013	-			Original issue
06/10/2014	v.	v.		Corrected fax # to (703) 648-9176 and added e-mail contact (BI-RADS@acr.org) to the Permission Agreement .

Mammography

Date	1 st /2 nd Printing Page #	3 rd Printing Page #	Section	Description of Revisions
12/31/2013	-		-	Original issue
07/23/2015	135	135	II.	The table referenced in the first paragraph is changed from Table 9 (see page 168) to Table 8 (see page 159)

Date	1 st /2 nd Printing Page #	3 rd Printing Page #	Section	Description of Revisions
07/23/2015	163	163	Guidance	The first sentence in the answer to FAQ #9 should be corrected to: In the absence of a known infectious or inflammatory cause, isolated unilateral axillary adenopathy should receive a category 0, with additional text indicating that if there is no explanation for the axillary adenopathy at diagnostic breast imaging (including obtaining a more complete medical history), then the diagnostic assessment should be category 4.

Ultrasound

Date	1 st /2 nd Printing Page #	3 rd Printing Page #	Section	Description of Revisions
12/31/2013	-			Original issue
02/28/2014	73	73	II.	Removed second paragraph from Calcifications description .

Magnetic Resonance Imaging

Date	1 st /2 nd Printing Page #	3 rd Printing Page #	Section	Description of Revisions
12/31/2013				Original issue
11/14/2014	120	120	II.	Figure 252 is an axial image: caption is incorrect Figure 253 is a sagittal image: caption is incorrect.
05/11/2015	24	24	II. - Overview	Add 3 subcategories to Lumen type: i. Single, ii. Double, iii. Other.
05/11/2015	172	172	Appendix	Provide the 'select one' option for both Implant Material and Lumen Type and Add 3 subcategories to Lumen type: i. Single, ii. Double, iii. Other.
07/23/2015	33	33	II.	Last sentence of C. Focus modified to read, "If what otherwise might be classified as a focus has an irregular shape, a margin that is not circumscribed, or internal enhancement characteristics, then the finding should be described as a mass."
07/23/2015	137	137	III.	For category 3, the range for the Likelihood of Cancer should be > 0% but ≤ 2% (not ≥ 0%).

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Follow-up and Outcome Monitoring

Date	1 st /2 nd Printing Page #	3 rd Printing Page #	Section	Description of Revisions
12/31/2013	-		-	Original issue
06/10/2014	43	43	IV.	Last two sentences of item #10 corrected to read, "Because no breast cancer is 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 indeed is diagnosed within 1 year of the second (6-month) examination and the last (13-month) examination, these are classified as false-negative (FN) and true-positive (TP), respectively."
06/24/2014	67-72	NA	VII.	Sample Forms and Example for Basic Clinically Relevant Audit Data Collection and Calculations – removed since manual audits are no longer performed and to eliminate inconsistencies with text.

Data Dictionary

Please contact BI-RADS @acr.org for the most current Data Dictionary.

Date	1 st /2 nd Printing Page #	3 rd Printing Page #	Section	Description of Revisions
12/31/2013				Original issue
02/28/2014	87	89	Data Dictionary	"PDP - Peripheral duct papillomas" added to High Risk.
03/14/2014	75	77	Data Dictionary	Field Number 107, Management – Left breast. The text for Use changed to: "Required if audit data are reported at breast level, and management for the right breast is not reported."
03/14/2014	76	78	Data Dictionary	Field Number 108, Management – Right breast. The text for Use changed to: "Required if audit data are reported at breast level, and management for the left breast is not reported."
04/17/2014	10	10	Data Dictionary	New Field Number 8.1 added.
04/17/2014	10	11	Data Dictionary	New Field Number 8.2 added.
04/17/2014	29	30	Data Dictionary	Field Number 39, Additional imaging - modified to insert 'Screening' before 'mammography and ultrasound only.'

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Date	1 st /2 nd Printing Page #	3 rd Printing Page #	Section	Description of Revisions
11/5/2014	71	73	Data Dictionary	Field Number 101 Overall assessment – Left breast: change text for Use from ‘Optional’ to ‘Required if component of combination examination; optional otherwise.’
11/5/2014	72	74	Data Dictionary	Field Number 103 Overall assessment – Right breast: change text for Use from ‘Optional’ to ‘Required if component of combination examination; optional otherwise.’
11/5/2014	74	76	Data Dictionary	Field Number 105 Overall assessment – Patient: change text for Use from ‘Optional’ to ‘Required if component of combination examination; optional otherwise.’
4/21/2015	35	36	Data Dictionary	Field Number 49 Change “Use: Required” to “Use: Required if audit data are reported at breast level, and BPE for the right breast is not reported; optional otherwise.
4/21/2015	35	36	Data Dictionary	Field Number 50 Change “Use: Required” to “Use: Required if audit data are reported at breast level, and BPE for the left breast is not reported; optional otherwise.
4/21/2015	36	37	Data Dictionary	Field Number 51 Change “Use: Required” to “Use: Required if audit data are reported at patient level; optional otherwise.
4/21/2015	63	65	Data Dictionary	Field Number 88 Implants: Implant material – references to lumen type removed
4/21/2015	63	65	Data Dictionary	New Field Number 88.1 Implants: Lumen type added
10/21/2015	87	89	Data Dictionary	Added: AH Atypical hyperplasia FEA Flat epithelial atypia DCS Ductal carcinoma in situ DCL Ductal carcinoma in situ low nuclear grade DCI Ductal carcinoma in situ intermediate nuclear grade DCH Ductal carcinoma in situ high nuclear grade Deleted: DCC Ductal carcinoma in situ, comedo type DCM Ductal carcinoma in situ, micropapillary type DCR Ductal carcinoma in situ, cribriform type DCS Ductal carcinoma in situ, solid type MCA Microcalcifications associated with ductal carcinoma in situ

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Date	1 st /2 nd Printing Page #	3 rd Printing Page #	Section	Description of Revisions
12/7/2015	60	62	Data Dictionary	Add new value to Field Number 81. Location of lesion: Quadrant or region: 88 Other
1/20/17	59	61	Data Dictionary	Field Number 80 Location of lesion: Laterality Remove " Mammography and MRI only " from the element
1/20/17	60	62	Data Dictionary	Field Number 82 Location of lesion: Clock-face location Remove " Mammography and MRI only " from the element
1/20/17	61	63	Data Dictionary	Field Number 84 Location of lesion: Distance Remove " Mammography and MRI only " from the element

Appendix – Sample Lay Letters

Date	1 st /2 nd Printing Page #	3 rd Printing Page #	Section	Description of Revisions
12/31/2013				Original issue
02/28/2014	8	9	Sample Lay Letters	Second page of Sample Lay Letter for Negative or Benign Finding(s) and Patient has Physical Findings, Signs or Symptoms (to be used with BI-RADS® 1-2) - added (signature block & ACS Guidelines text box).
02/28/2014	9	11	Sample Lay Letters	Second page of Sample Lay Letter for Negative or Benign Finding(s) (to be used with BI-RADS® 1-2) - added (signature block & ACS Guidelines text box).
02/28/2014	13	16	Sample Lay Letters	Second page of Sample Lay Checklist Letter to be Handed to Patient if On-Line, Same Day Reading Is Done - added (last 3 paragraphs, signature block, & ACS text box).
02/28/2014	14	18	Sample Lay Letters	Second page of Sample Lay Letter for Review of Previous Mammograms if Not Available at time of Current Mammogram - added (ACS text box).
10/26/2015	9	9	Sample Lay Letters	Second page of Sample Lay Letter for Negative or Benign Finding(s) and Patient has Physical Findings, Signs or Symptoms (to be used with BI-RADS® 1-2) - revised box to be consistent with ACR Screening Recommendations
10/26/2015	11	11	Sample Lay Letters	Second page of Sample Lay Letter for Negative or Benign Finding(s) (to be used with BI-RADS® 1-2) - revised box to be consistent with ACR Screening Recommendations.

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Date	1 st /2 nd Printing Page #	3 rd Printing Page #	Section	Description of Revisions
10/26/2015	12	12	Sample Lay Letters	Second page of Sample Lay Letter for Probably Benign Finding, but Initial 6-Month Follow-up Recommended (to be used with BI-RADS® 3) - revised box to be consistent with ACR Screening Recommendations.
10/26/2015	16	16	Sample Lay Letters	Second page of Sample Lay Checklist Letter to be Handed to Patient if Online, Same Day Reading Is Done - revised box to be consistent with ACR Screening Recommendations.
10/26/2015	18	18	Sample Lay Letters	Second page of Sample Lay Letter for Review of Previous Mammograms if Not Available at time of Current Mammogram - revised box to be consistent with ACR Screening Recommendations.

Mammography

Q. There is confusion at my facility among the radiologists and the technologists regarding the exact wording of breast density under the findings section of the report. The density categories used to be numbered (1, 2, 3, and 4); it now appears that they are lettered (a, b, c, and d). Most of our radiologists have been using the written descriptions for breast density, specifically: almost entirely fatty, scattered areas of fibroglandular density, heterogeneously dense, extremely dense as descriptors alone. My specific question is: Are we to drop the word descriptors and replace the words with a, b, c, or d? Is it a requirement for reporting that letters be used? It seems redundant to use the word descriptors and adds a layer of unnecessary confusion if so.

A. The verbal descriptors of breast density should be used in the report, neither letters nor numbers. The reason that the lists of the assessment categories and densities were given numbers and letters, respectively, was to minimize confusion in their shorthand use.

Q. I'd like to know which BI-RADS® category is appropriate for the following subset of our patients. We commonly receive scripts requesting "screening mammogram with ultrasound if indicated", or "screening mammogram with ultrasound if needed", or "screening mammogram with ultrasound if medically necessary", or some other similar iteration. Many of these patients will have heterogeneously dense tissue or extremely dense tissue and be otherwise negative or negative with benign finding. With the script worded as such, is it appropriate to assess these cases as category 0 since the referring physicians seem to be requesting both exams, and we would have to schedule and bring the patient back another day for a follow-up screening whole breast ultrasound?

A. There are 2 scenarios:

- If the exam is normal, then the assessment should be category 1 or 2, depending upon whether the interpreting physician chooses to describe benign findings in the breast imaging report (category 1 for no findings described, category 2 for at least one benign finding described). That's all that is required. If the patient is asymptomatic and has no abnormal findings at clinical breast exam, but the interpreting physician identifies an abnormality that requires additional imaging evaluation, the correct BI-RADS® assessment is category 0.
- If the patient is symptomatic or has an abnormal finding at clinical breast exam, then this is a diagnostic exam. The area of concern should be appropriately worked up. If an ultrasound is

included with the workup, a combined diagnostic mammography and US report should be rendered, containing a final combined BI-RADS® assessment (category 1-5). If the diagnostic mammogram and US are done separately, for whatever reason, then the diagnostic mammogram should be given a BI-RADS® assessment with the additional recommendation for US if appropriate. If US then is done subsequently, the final BI-RADS® assessment for this exam should complete the diagnostic exam. The audit section (some material is available on the web at: <http://www.acr.org/Quality-Safety/Resources/BIRADS/Monitoring>) and FAQs from the mammography section (<http://www.acr.org/~media/ACR/Documents/PDF/QualitySafety/Resources/BIRADS/01%20Mammography/03%20%20BIRADS%20Mammography%20FAQs.pdf>) provide more detailed information on this topic.

Note that it is **not** appropriate to assess a normal screening mammography exam as category 0 simply because one is recommending downstream supplementary screening with MRI or US (whether for high-risk status or dense breasts). In this scenario, assess the screening mammography exam as category 1 or 2, provide the concordant management recommendation (routine screening), and add a “However, ...” sentence stating that because of the patient’s high-risk status or because she has dense breasts, supplementary screening with MRI or US is recommended.

Q. On a screening mammogram, when referring to a very dense breast that had no mammographic evidence of cancer, I would include in my report a recommendation for breast MRI. However, the insurers (and Medicare) are declining payment because of the BI-RADS® category 1 assessment. The assessment must be based on what I see on the mammogram, in this case, category 1 (Negative). Yet, should I also give a recommendation to do an MRI that may find small cancers in a dense breast?

A. BI-RADS® does not provide guidance on specific clinical situations in which supplementary screening should or should not be performed. But it does require that assessment be based on imaging findings, so a normal screening mammogram should be assessed as category 1 or 2. As stated previously, the interpreting physician has the option to recommend supplementary screening, but patients who choose to undergo supplementary screening should be prepared to pay out-of-pocket if their insurance declines payment.

Probably the most comprehensive review of indications for supplementary screening examinations based on breast density comes from the California Breast Density Information Group. We recommend visiting the CBDIG web site (www.breastdensity.info) or reading its recent publication in Radiology. ([The California Breast Density Information Group: A Collaborative Response to the Issues of Breast Density, Breast Cancer Risk, and Breast Density Notification Legislation](#). Price ER, Hargreaves J, Lipson JA, et al. Radiology 2013, 269[3]:887-892.)

Q. Please explain why we should not use an of assessment category 3 in screening. In particular, what is wrong in using category 3 when dealing with calcifications in screening mammography?

A. Use of a probably benign (category 3) assessment at screening essentially defers diagnostic work-up for 6 months. **It is strongly recommended that category 3 assessments be issued only after appropriate workup.** This modification has been made based on recent studies (see below) indicating that full diagnostic imaging evaluation will identify both benign and malignant lesions promptly instead of waiting for 6 months.

There are two major advantages to the recommended approach.

- The first is more prompt identification of truly benign findings (simple cysts, some intramammary lymph nodes, some cases of grouped skin calcifications, etc.). A large-scale BCSC study, involving more than 1 million mammograms, has shown that recall imaging significantly increases the identification of characteristically benign lesions, thus promptly establishing a benign

diagnosis, eliminating 6 months of potential anxiety, and obviating short-interval follow-up examination. (Kerlikowske K, Smith-Bindman R, Abraham LA, et al. [Breast cancer yield for screening mammographic examinations with recommendation for short-interval follow-up](#). *Radiology* 2005; 234(3):684–692.)

- The second is more prompt identification of some rapidly growing cancers (the same BCSC study also suggested that recall imaging leads to the prompt diagnosis of some aggressively growing cancers by identifying these tumors when they are smaller and more likely to be node-negative, rather than 6 months later at initial short-interval follow-up examination.)

Discouraging the use of category 3 assessments at screening mammography is not limited to BI-RADS® recommendations. The first pay-for-performance initiative within [Medicare's Physician Quality Reporting System \(PQRS\)](#) that concerns breast imaging involves reporting the percentage of screening mammography examinations that are assessed as category 3, with the stated goal of reducing this to “approaching 0%” in clinical practice.

Also, note that a category 3 assessment rendered from a screening exam, without prompt diagnostic workup, is considered a positive screening exam. The rationale for making category 3 at screening positive is that it recommends additional imaging evaluation prior to routine screening in 1 year. Use of category 3 assessment at screening is no longer a strategy to reduce recall rate.

Q. The category 3 Lay Letter for patients (as well as the BI-RADS® category 3 description) states: Probably Benign, however, in 6 months, you should have a follow-up mammogram. According to the surveillance imaging (BI-RADS® category 3), after two consecutive category 3, six-month follow-ups, the radiologist wants to monitor this benign finding in one year. The radiologist codes it as a BI-RADS® category 3 (Lesion stability and no findings; Bilateral Mammography in 12 months to further follow the probably benign finding and for screening of the rest of both breasts). Is it permissible to implement a second category 3 patient Lay Letter, stating category 3, return in 12 months for mammogram?

A. Note that the Lay Letters provided in the BI-RADS® appendix are samples. In the introduction to this section, facilities are encouraged to “use as is, modify them, or create your own lay reports.” For the situation you describe, you may very well want to create a second category 3 patient Lay Letter, tailoring it to the request for a 12-month follow-up exam after two consecutive 6-month follow-up exams are performed. Probably benign assessments continue for the full duration of surveillance imaging, whether the recommended interval is 6 months or 1 year. This is done to inform the referring clinician and patient that the next breast imaging exam is required for surveillance of a finding that cannot yet be considered benign, to maximize compliance with the surveillance protocol.

Q. Should a post-lumpectomy patient who has (apparently) had the tumor completely excised automatically be assigned a category 3?

A. No, one should not automatically make a category 3 assessment because of a recent surgical procedure.

- After lumpectomy, the usual mammographic appearance is interval appearance of architectural distortion caused by the surgery. Assuming that the interpreting physician interprets the mammographic findings to be post-surgical rather than suspicious for malignancy, a benign (category 2) assessment is correct if the post-surgical findings are described in the mammography report. Most radiologists are comfortable accepting interval architectural distortion at the known surgical site to be benign at initial post-lumpectomy mammography, especially if the exam is performed within 6 months of surgery.
- A category 3 assessment should be assigned in the post-lumpectomy setting only in rare cases, if ever. Remember that category 3 assessments should not be made when one is “not sure”

whether a finding is benign or suspicious. In this scenario, one should choose between a category 2 and category 4 assessment.

- During the post-lumpectomy period, a category 4 assessment is appropriate in the uncommon event that a subsequent mammogram shows increased architectural distortion (instead of anticipated stabilization or decreased distortion).

Many radiologists never use category 3 in the setting of post-lumpectomy mammography, preferring to classify the great majority of exams as category 2 and the few for which there is concern as category 4.

Q. We are recently seeing several patients for whom we recommended surgical consult for excision of high risk lesions 6 months previously (particularly radial scars). The patient and surgeon decide to follow rather than excise and say “any decision will be made on imaging change.” We get a follow-up mammogram at 6 months post biopsy that shows post-biopsy change (i.e., distortion usually larger than the area of distortion in the first place). While I do feel that the decision to not excise is likely still appropriate (we sample with a 10 gauge vacuum-assisted needle under tomosynthesis guidance and take 12 or more samples), I am concerned that decisions regarding subsequent surgery should not be based on imaging as it is limited by the post biopsy change.

a. Given the circumstances described above, if a patient has percutaneous biopsy of a high-risk lesion but the patient/surgeon decides not to do the surgical excision recommended by the radiologist, opting instead for short-interval follow-up imaging of the area of abnormality, what BI-RADS[®] assessment category should be chosen?

b. For this situation, which follow-up should be recommended: surgical consult, clinical follow-up, return to screening, continued diagnostic follow-up (if so, for how long, or MRI)?

A. Because one cannot be certain that architectural distortion represents residual pre-core-biopsy mammographic finding, post-core-biopsy change, or both, and because the core biopsy diagnosis of a high-risk lesion indicates a substantial likelihood of underlying malignancy due to under-sampling, the appropriate assessment category is Suspicious (category 4). However, because the patient/surgeon may again decide to decline the continuing radiology recommendation for surgical excision, it would be prudent to add a sentence stating that if the patient and surgeon once more choose to decline this recommendation, opting instead for continued short-interval follow-up, repeat diagnostic mammography should be obtained in 6 months.

Q. A Probably Benign (category 3) finding given for a diagnostic mammogram is assessed as Negative (category 1) six months later on short-interval follow-up (see chart below).

Date	Indication	Left Breast	Right Breast
Jan. 1, 2014	Screening mammogram	Category 0 (needs additional imaging)	Category 1 (negative)
Jan. 2, 2014	Diagnostic mammogram – evaluation of abnormal finding at screening	Category 3 (probably benign)	
Jul. 1, 2014	Diagnostic mammogram – surveillance imaging for a probably benign finding	Category 1 (negative)	
Jul. 1, 2015	Screening mammogram		1½ years has passed since the right breast was screened

Should there be a screening mammogram in January 2015 to keep the right breast on an annual cycle?

A. Unusual in this scenario is that the category 3 assessment made on January 2, 2014 was changed back to category 1 by the radiologist who read the July 1, 2014 examination. This effectively ended the period of surveillance. Most radiologists would recommend repeat mammography in January 2015 which would keep the opposite breast on an annual screening schedule. However, there is some variability in doing this, and BI-RADS® does not provide specific guidance; so, anything is allowed.

Q. The current mammography lexicon includes the available documentation options for quadrant as upper outer, upper inner, lower outer, and lower inner. These options seem to be insufficient to describe an asymmetry that is seen only from one view. How should the findings seen in only one view be described?

A. The most accurate way to describe findings seen on only one view is to say “lateral (or medial) aspect of the breast as depicted on the CC view” for CC-only asymmetries, and “superior (or inferior) aspect of the breast as depicted on the MLO view” for MLO-only asymmetries. One can determine inner versus outer on the CC view, but not upper/lower/inner/outer on MLO view. Note that the asymmetry descriptor applies only to mammography.

Q. Is there BI-RADS® guidance concerning the standardization of breast skin markers in the 5th Edition?

A. No – this is because there has been no consensus in establishing the use of specific-shaped markers to represent palpable versus skin lesions; however, the following two practices are recommended:

1. To properly inform interpreting physicians within a given mammography facility, the facility should adopt a policy requiring consistent use of two different shapes of radiopaque devices for palpable and skin lesions, respectively.
2. To properly inform interpreting physicians outside the facility, there should be an indication of the type of underlying lesion marked by every radiopaque device (palpable versus skin lesion), either as a permanent annotation on the appropriate mammographic image(s) or as a description in the mammography report.

Ultrasound (US)

Q. Which BI-RADS® category is appropriate in a breast mass bigger than 5 cm and in a mass suspected to be juvenile papillomatosis? (Biopsy is recommended in both.)

A. If biopsy is recommended based on the imaging, the appropriate assessment is category 4 (Suspicious). This is true regardless of the patient’s age.

Q. Since it is not technically a breast study, should a unilateral “ultrasound examination of the axilla only” performed after a diagnosis of breast cancer require a BI-RADS® assessment?

A - Even though a BI-RADS® assessment is not mandatory, it would be good practice to include one because the examination described could have an impact on the management recommendation and treatment of the breast cancer.

Q. I have always described a cyst with thin septations as a complicated cyst, however I was re-reading the BI-RADS® lexicon and it states the only difference between a simple cyst and

complicated cyst should be internal debris, so how should a cyst with thin septations be characterized?

A. A septated cyst can be called a simple cyst with a septation; it does not need to be followed.

Q. We have a busy practice and I feel we are following too many complicated cysts with ultrasound (BI-RADS® category 3). I know multiple complicated cysts bilaterally can be given a BI-RADS® category 2, but what about multiple complicated cysts unilaterally? If we are working up a finding in one breast and discover multiple complicated cysts, should we look with ultrasound in the contralateral breast for complicated cysts so we can render a BI-RADS® 2?

A. Multiple, unilateral simple and complicated cysts should be BI-RADS® category 2.

Magnetic Resonance Imaging (MRI)

Q. A patient has a lumpectomy with positive margins and an MRI is ordered to check for residual. The plan is to re-excise regardless, but the surgeon wants to be sure there isn't bulky residual or one particular area that needs to be excised. The MRI shows only post-operative changes. Would this be assigned a category 6 or a category 2? If it shows findings suspicious for residual should it be a category 4?

A. Remember that the assessment rendered should match the imaging findings, not the plan for clinical management. If planned management does not match the imaging findings (a so-called discordance scenario), the report should include a final "However, ..." sentence that describes the discordance as well as why planned management is different than usual.

First, you describe one of the "discordance" scenarios, in which the assessment does not match the appropriate management. If the MRI exam shows only benign (post-surgical) findings in a patient who has had lumpectomy with positive resection margins, the correct assessment is benign (category 2). However, the recommended management should be surgical excision when clinically appropriate.

Second, you describe a scenario in which MRI shows findings suspicious for residual cancer in a patient who has had lumpectomy with positive resection margins. This should be assessed as category 6 if the suspicious findings are contiguous with or nearby the lumpectomy site (residual as opposed to second primary cancer), with recommended management being surgical excision when clinically appropriate.

However, if the suspicious findings are in a different location than the site of lumpectomy (for example, in a different quadrant, very distant from the lumpectomy site, or in the contralateral breast), then you may be dealing with a second primary cancer, and the correct assessment is suspicious (category 4), management being prompt tissue diagnosis.

Q. If an MRI is done to monitor response to neoadjuvant chemotherapy and shows no abnormal enhancement (complete imaging response), should the MRI be given a BI-RADS® category 1 or 2 or should it receive a BI-RADS® category 6?

A. A central principle in BI-RADS® is that the final assessment category should be assigned based on the imaging findings. Cases of known malignancy in which definitive treatment has not yet been performed represent an exception to this rule. In this clinical setting, unlike the usual situation, it would be most appropriate to give an assessment of known, biopsy proven malignancy (BI-RADS® 6) rather than negative or benign (BI-RADS® 1 or 2) despite the fact that there are no abnormalities on the imaging study. There are several reasons for this. First, current practice dictates that the patient will go on to have further surgical treatment, either mastectomy or lumpectomy, despite negative

imaging. Second, assigning a negative or benign assessment can cause confusion among clinicians and even patients themselves, who are increasingly accessing actual reports from their imaging studies. Finally, assigning a BI-RADS® category 6 appropriately takes the case out of the audit. In cases such as these, it is known that the patient has an incompletely treated cancer and the BI-RADS® assessment is being made based on a combination of imaging AND clinical factors. An analogous situation would be a patient who on imaging has a suspicious appearing mass but who has already had a biopsy showing the mass to be benign. In that case, a benign assessment (BI-RADS® 2) rather than suspicious (BI-RADS® 4) would be appropriate.

Multi-Modality

Q. Given this patient history:

- **Mother had breast cancer at age 45**
- **Patient's current age is 38**
- **Patient started imaging in 2007 with diagnostic mammography and ultrasound**
- **Screening mammogram in 2008**
- **Diagnostic ultrasounds in 2010 and 2012**
- **Screening mammogram 3/13/13 – BI-RADS® category 2**
- **Screening ultrasound 3/13/13 – BI-RADS® category 3**
- **6 month follow-up ultrasound 9/23/13 – BI-RADS® category 3**
- **Breast MRI due to family hx 9/26/13 – BI-RADS® category 2**
- **Screening mammogram 4/1/14 – BI-RADS® category 2**
- **6 month follow-up ultrasound 4/1/14 – BI-RADS® category 3**

One of the coders for our radiologists' office called to say that the 4/1/14 mammogram cannot be a screening mammogram since she had a finding on her breast ultrasound. She quoted the Medicare guidelines stating that if a breast is symptomatic (in this case, the US finding) then it cannot be asymptomatic (screening mammogram).

Do all mammograms for category 3 US and MRI cases need to be diagnostic? Our doctors dictate - nothing seen on mammogram or normal mammogram – for these cases.

A. The 4/1/14 mammogram should be a screening exam because the patient is asymptomatic and the previous mammograms were normal. The same would be true for any subsequent screening MRIs. It makes sense that a probably benign US assessment causes the subsequent surveillance US exams to be diagnostic, but this does not apply to exams using other modalities at which the US finding is not visible.

The provided scenario occurs frequently due to the very high rate of false positives at US screening. This is not just limited to false positive biopsies. US screening also has a high rate of category 3 assessments (all category 3 assessments at screening are positive), and at least 98% of category 3 assessments are, by definition, false positive. As the scientific literature for US screening becomes more robust, it is hoped that fewer category 3 and category 4 assessments will be justified, bringing the FP rate of US screening closer to that of mammography screening.

Q. We are now doing a large volume of screening ultrasound exams following screening mammograms on dense-breasted women. Previously, when we did a diagnostic ultrasound exam following a diagnostic mammogram we produced one breast imaging report with two sections (one for the mammogram and one for the ultrasound) with a single BI-RADS® overall impression and recommendation. How should we report a normal screening mammogram that was followed by an abnormal screening ultrasound that identified a mammographically occult, benign appearing nodule requiring 6-month follow-up ultrasound only? We would like to continue using one report with mammography and ultrasound sections rather than separate screening mammography and ultrasound reports; however, a single screening

mammography/US report could have a category 3 assessment on the screening exam recommending 6-month follow-up ultrasound alone. Furthermore, the patient would subsequently get an automated layman's letter letting her know mammogram was normal. Does the 5th Edition of the BI-RADS[®] Atlas forbid assigning a category 3 assessment to a screening exam?

A. When two breast imaging examinations (usually mammography and ultrasound) are performed on the same patient on the same day, BI-RADS[®] encourages radiologists to produce a single report for both examinations. The report should describe the findings for each examination in separate paragraphs, with a single (combined) assessment for the two examinations. The rationale behind a combined report is that when the two examinations individually have different findings and assessments, the interpreting radiologist is much better equipped to integrate the findings and conclusions than either the referring clinician or the patient. Note that the FDA supports this approach as well.

This would apply to combined diagnostic mammography and ultrasound examinations performed after recall for a screening-detected abnormality, and also to combined screening mammography and ultrasound examinations. In the scenario described in the question above (a mammographically occult finding that is assessed as probably benign at ultrasound), the mammography component would be assessed as negative (category 1) and the ultrasound component would be assessed as probably benign (category 3). The combined assessment would be probably benign (category 3). Management recommendations would be for short-interval follow-up with diagnostic ultrasound (targeted at the probably benign finding, limited to a small part of one breast) and routine screening mammography in one year. The patient might receive an automated letter stating that her screening mammography was normal, recommending routine screening in one year only with mammography. However, it would be prudent to amend this letter to also describe the more abnormal (in this case, probably benign) ultrasound outcome (just as you should amend a patient letter following combined diagnostic mammography and ultrasound for which the mammography was read as normal but the ultrasound was read as suspicious). Note that even though MQSA does not require a facility to amend the patient letter for a concurrently performed ultrasound examination (MQSA applies only to mammography), when appropriate, it would be prudent to do so, not only for optimal patient care but also to reduce malpractice exposure.

The new edition of BI-RADS[®] does not forbid category 3 assessments at screening. Rather, it discourages them, recommending instead complete diagnostic imaging evaluation (usually both mammography and ultrasound) before making a final assessment (probably benign or otherwise). If a radiologist ignores this BI-RADS[®] guidance, the new rules for auditing consider any category 3 assessment at screening to be “positive” (that is, similar to recommending recall) because the recommendation is for something other than routine screening in 1 year. In the case of screening mammography, the effect would be to audit the screening examination as if it recommended recall, except that the patient would not return for her diagnostic examination until 6 months later. In the case of screening ultrasound producing a category 3 assessment, the correct BI-RADS[®] approach to *auditing* is to consider the examination as a category 0 screening ultrasound assessment immediately recalled for a category 3 diagnostic ultrasound assessment (even though there was billing only for a single ultrasound examination).

Some radiology practices may choose to record separate assessments (only for auditing purposes, not in the physician or patient report) for two concurrent examinations that have different assessments. This is not required, but it would make auditing of the two component examinations more realistic. For example, in the given scenario, if the patient did not have a breast cancer diagnosis within one year of screening, the screening mammography examination would be audited as true-negative, the screening ultrasound examination would be audited as false-positive, and the diagnostic ultrasound examination would be audited as true-negative (category 3 assessments at diagnostic imaging are “negative” assessments because biopsy is not recommended).

Q. Given the following screening and follow-up situation:

- **A patient has a screening mammogram at our facility. We give assessment 0 and recommend an MRI.**
- **The patient has the MRI at an outside facility. We receive the result, which indicates a negative exam and no need for additional follow-up.**
- **Our screening radiologist disagrees and would like to send the patient to biopsy.**

a. How should our original screening mammogram be coded?

b. As a result of the MRI, should we maintain the assessment of 0 for the mammogram but continue with the discordant management recommendation of biopsy?

c. Should we change the assessment on the screening mammogram to category 4 (which BI-RADS® does not recommend for screening exams)?

A. a. Since the recommended follow-up for the screening mammogram was a diagnostic MRI exam, the screening mammogram would be Category 0: Incomplete – Need Additional Imaging Evaluation.

b. The assessment should be based on the imaging findings (i.e., the screening mammogram assessment would be category 0 as noted above, and the MRI assessment would be category 1: Negative). If there is a reason to diverge from the concordant management recommendation, the correct approach to reporting in this scenario is to provide a negative MRI assessment with a concordant management recommendation for routine mammography screening, but to follow this with a sentence recommending surgical consultation or tissue diagnosis if clinically indicated.

c. No, the screening mammogram should remain category 0: Incomplete – Need Additional Imaging Evaluation. The results of the diagnostic MRI examination do not change the results of the screening mammography examination.

Q. Given the following screening and follow-up situation:

- **A patient has a screening mammogram at our facility. We recommend a diagnostic mammogram and give assessment 0.**
- **The patient has the diagnostic mammogram at our facility. We recommend an MRI, which is done at an outside facility.**
- **The MRI comes back with negative results, but we would like to recommend a biopsy.**

a. What assessment should be placed on the diagnostic mammogram while we are waiting for the result from the MRI?

b. Once we determine we would like to recommend a biopsy, should we replace the original assessment on the diagnostic mammogram?

A. a. The diagnostic mammogram should be given a final assessment (i.e., 1,2,3,4,5,6) based on the imaging findings at mammography. Category 0 **should not be used** for diagnostic breast imaging findings that warrant further evaluation with MRI.

b. No. The final assessment would remain, but the physician should note if the management recommendation is discordant. The correct approach to reporting is to provide a negative assessment with a concordant management recommendation for routine mammography screening, but to follow this with a sentence recommending surgical consultation or tissue diagnosis if clinically indicated.

Q. When a patient receives chemotherapy prior to surgery and the imaging done after the chemotherapy does not show the previous biopsied lesion, what assessment should be given in the case that no other lesion is seen?

A. If no lesion remains visible, the correct BI-RADS® assessment is negative (category 1). The report also should contain a sentence at the end of the management section indicating recommending surgical excision when clinically appropriate (this is the usual recommendation for category 6 lesions).

Q. When a patient with a BI-RADS® category 4 assessment at MRI later has an ultrasound examination on a different day, and the ultrasound is negative, should the ultrasound assessment be negative (BI-RADS® 1) or suspicious (BI-RADS® 4)?

A. The final BI-RADS® assessment for the ultrasound examination should be based on the imaging findings for the ultrasound examination. Therefore, if a patient has a normal study, it should be assessed as BI-RADS® category 1 or 2 BUT the management recommendation still could be for a biopsy. The 5th edition of BI-RADS® has uncoupled the management recommendation from the final assessment category to address situations such as this. For example, if the patient has a suspicious finding on MRI that has been given a BI-RADS® 4 but then has a negative ultrasound, the ultrasound should be given a BI-RADS® category 1, but a sentence should be added saying “biopsy is recommended as per the MRI report.”

Q. If a patient has examinations with multiple imaging modalities and one (or more) is suspicious (BI-RADS® 4) but the others are negative, should the same assessment be given to all of the examinations to avoid confusion among the referring clinicians? For example, if the patient has a screening MRI that is suspicious but her screening mammogram and ultrasound are negative, should the mammogram and ultrasound also be assessed as suspicious (BI-RADS® 4) to be sure the MRI finding is not ignored or overlooked?

A. It depends on whether the examinations are performed concurrently and are reported together. Both BI-RADS® and the FDA recommend that concurrently performed examinations using different breast imaging modalities be reported together, to reduce confusion. In this scenario, both BI-RADS® and the FDA recommend use of an integrated assessment for all reported examinations, so a suspicious (BI-RADS® 4) assessment would be rendered in the scenario described in the question, although an additional sentence could be added that indicates suspicion only on the MRI examination. However, if the examinations are reported separately, then the answer given to the previous question applies – assess the MRI examination as suspicious (BI-RADS® 4) and recommend biopsy, but assess the mammography and ultrasound examinations as negative (BI-RADS® 1) and recommend biopsy as per the MRI report.

Follow-up and Outcome Monitoring

Q. I consult regularly with a breast surgeon, before we jointly decide whether a biopsy or surveillance is the best management recommendation. The atlas does not seem to address this situation. Should these images be reported as BI-RADS® category 3, or category 4, or possibly category 0, in the interim? Category 0 specifies additional imaging, not a surgical consult. Is there a provision for “waiting for consult”?

A. The BI-RADS® assessment category is chosen **only** by the interpreting physician, who is 100% responsible for that choice. However, if the interpreting physician decides to accede to the management requests of a treating physician, that is acceptable, but this scenario should be described in the report as follows:

- Assign whatever assessment category is correct for the **imaging** findings.

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- Follow this with a concordant management recommendation for that assessment.
- Then add a sentence, beginning with "However, ..." describing why, in the particular case, a different management plan will be implemented.

One such scenario could be an imaging-justified category 3 assessment, recommending short-interval follow-up, accompanied by "However, the patient has declined mammographic surveillance and has requested prompt biopsy instead." Or, it could be "However, after discussion with the patient's surgeon, Dr. X, subsequent management will involve biopsy instead of mammographic surveillance." If the report is made before discussion with a treating physician whose input may affect subsequent management, then the report should simply be based on imaging findings with concordant management recommendation for that assessment. Subsequently, if different management is planned after discussion with the treating physician, an addendum should be issued that retains the original assessment but adds the "However, ..." sentence.

It is important to remember that neither BI-RADS[®] nor MQSA allows for use of a category 0 assessment while awaiting discussion with the treating physician.

Q. BI-RADS[®] allows for tracking outcomes of cross-modality studies both at the modality (mammography, ultrasound, MRI) level and the combined level. Does the atlas allow for separate tracking outcomes of tomosynthesis (DBT)?

A. No. BI-RADS[®] auditing does not discriminate between mammography and tomosynthesis at this time.

Q. For audit purposes, what is the most accurate interpretation of "within 1 year"? (Is it literally 365 days or could it be anytime during the 12th month?)

A. BI-RADS[®] defines one year as 365 days (See the Follow-up and Outcome Monitoring section of the BI-RADS[®] Atlas, 5th Edition – Glossary of Statistical Terms: #7. Cancer. Also, note that a 365-day year is used by the National Mammography Database, which will be used to define future national benchmarks). The cancer ascertainment interval should match the routine screening interval of your facility. This is one of the set-up questions that the facility must enter before reporting software is ready to work.

Q. Is the determination of a false-negative (FN) based on the imaging-to-imaging findings or imaging-to-pathology findings?

A. The truth (cancer versus no cancer) for a finding is determined by the pathology. (See the Follow-up and Outcome Monitoring section of the BI-RADS[®] Atlas, 5th Edition – Glossary of Statistical Terms: #3. Tissue diagnosis and #8,9,10,11 True-Positive, True-Negative, False-Positive, and False-Negative.)

Q. If a patient has screening mammography and supplementary screening with MRI or US, how are false negative outcomes determined?

A. This is a complex issue that is discussed in detail below. Briefly, BI-RADS[®] considers combined reporting good, but combined auditing of limited value.

When more than one breast imaging modality is utilized for the same patient on the same date, both BI-RADS[®] and the FDA encourage the interpreting physician to issue a single combined *report* that integrates the findings of all breast imaging examinations (a separate paragraph describing the findings at each component examination, followed by a combined assessment and management recommendations for all examinations). During the set-up of reporting software, BI-RADS[®] now requires each breast imaging facility to decide whether to *audit* only combined examinations versus *auditing* both combined examinations and the separate component examinations. The former choice

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will yield outcomes data only for the overall breast imaging examinations performed, whereas the latter choice also will yield outcomes for the component examinations, permitting a better understanding of the strengths and limitations of the different breast imaging modalities in screening and diagnostic settings at the breast imaging facility. However, acquisition of the additional outcomes data, although beneficial, requires that all interpreting physicians in the breast imaging facility must enter not only a combined assessment but also component-examination assessments for each combined examination performed. And separate-modality auditing also requires a high level of understanding of how the interplay among modalities affects outcomes data.

Given this background information, the answer to the question about false-negative (FN) screening outcomes (at mammography, US, and MRI) will depend on the type of auditing performed. Assuming (for the sake of simplicity) that combined assessments always reflect the more abnormal assessment among component examinations, combined-assessment auditing for mammography/US/MRI screening examinations will have more positive (and correspondingly fewer negative) outcomes than separate-modality auditing because imaging-detected abnormalities will count as positive whether identified only at mammography or US or MRI, at more than one modality, or at all modalities. Since some of these positive examinations will lead to cancer diagnosis, there will be more true-positive (TP) and fewer FN combined examinations. The infrequent FN outcomes from combined-modality auditing may appear to paint a rosy picture, but this picture simply indicates that fewer cancers are missed if one looks for cancer using different approaches.

Additional separate-modality auditing likely will result in the most TP outcomes for screening MRI (because MRI is the most sensitive examination), but the difference will not be as large as the benchmarks commonly reported in the breast imaging literature. This is because the limited benchmarks for screening MRI are derived from very high-risk women (the even more limited benchmarks for screening US also are derived from different mixes of high-risk women), whereas screening mammography benchmarks come from the examination of all women. Higher risk women have a greater prior probability of having detectable cancer; hence, more cancers will be detected simply due to differences in the patient populations examined. Inter-modality comparison of audit data is neither instructive nor clinically relevant unless the modalities are used to examine the same patient population. So a breast imaging facility should evaluate its separate-modality outcomes only among women who undergo combined-modality screening.

Specifically addressing FN outcomes in the context of separate-modality auditing, the more screening modalities that are utilized, the more FN outcomes that will be observed. This is because positive screening examinations are very likely to result in prompt tissue diagnosis, so that cancers uniquely identified at screening with one modality will be found within the cancer ascertainment period, thereby contributing to the FN count for each of the other modalities. If screening is limited to only one modality, some (probably most) of the cancers that would have been detected at another modality will not surface clinically within the cancer ascertainment period, so fewer FN outcomes will be counted. For example, let us consider screening mammography. When this is the only screening modality used, FN exams will involve only those cancers that become palpable or otherwise symptomatic within the cancer ascertainment period. Add screening with clinical breast examinations and more cancers will be found (hence more FN screening mammography exams); add screening US to the mix and still more cancers will be found (more FN screening mammography exams); and then add screening MRI and the large number of additional cancers found will further contribute to FN screening mammography exams.

Q. After a screening mammogram, the radiologist requested prior images; no images were received in 30 days; and another radiologist recommended the patient be recalled for additional imaging. In the audit, who does the recall get charged to: the original reader who asked for prior studies or the reader who recommended the recall for an addendum? Does this also mean that the call-back is counted in recall statistics against the second reader, or does it count towards the first reader who read the study?

A. When a category 0 “awaiting prior exams” assessment is updated with an assessment either with or without prior exams, the updated assessment **replaces** the initial one. Whoever makes the updated assessment takes responsibility for the exam. A screen recall awaiting prior exams or to overcome technical deficiency is not used for auditing purposes; instead, the updated assessment is what is audited.

Q. The radiologist assesses a patient’s mammography exam as Suspicious - category 4A with a recommendation for tissue diagnosis; however, the patient seeks a second opinion, and the second-opinion radiologist assesses the same finding as category 3 with a recommendation for short-interval follow-up imaging in 6 months. The patient prefers to follow the recommendation from second opinion but wants to follow-up at the facility where her imaging was done. How this should be handled?

A. When a radiologist makes an assessment (which determines whether the interpretation is positive or negative), the exam is judged to be TP/FP/TN/FN based on whether there is a cancer diagnosis within the recommended screening interval. If a patient, clinician, intervening morbidity from a different disease, or act of God causes a recommended biopsy not to be done, there will be no cancer diagnosis within the recommended screening interval. Therefore, a negative assessment will be true negative and a positive assessment will be false positive. This will apply equally to all breast imaging facilities.

BI-RADS® auditing rules must be applied uniformly according to this approach. If flexibility were allowed so that an individual mammography facility could decide how to classify an exam (TP/FP/TN/FN) when a recommended biopsy is not done, then benchmarking would become meaningless because all facilities would not be using the same approach.

Q. Why is Negative Predictive Value omitted from the more complete clinically relevant audit?

A. BI-RADS® acknowledges the limited ability of most breast imaging facilities to ascertain cancer diagnosis information on patients given negative interpretations, both true negative (TN) and false negative (FN) outcomes. Without linkage of breast imaging interpretations with data in a regional tumor registry, cancer ascertainment is limited, hence all calculations based on either TN or FN are unreliable. This is why calculations of sensitivity and specificity are reliable for very few breast imaging facilities (calculation of sensitivity involves FN and calculation of specificity involves TN). The formula to calculate negative predictive value (NPV) is:

$$\frac{TN}{TN+FN}$$

Therefore, calculation of NPV is doubly unreliable for most breast imaging facilities.

Q. How should we document a re-excision or re-excision biopsy?

A. A lumpectomy is an excisional biopsy for known biopsy-proven malignancy (diagnosis at percutaneous biopsy), or to get negative margins of resection after an initial unsuccessful attempt at clear-margin excision. All such biopsies are excisional biopsies because the intent is to completely remove the tumor. (Lumpectomies are a subset of all excisional biopsies because sometimes complete excision is performed for lesions known to be benign.) Some software might provide an additional selection for re-excision, which would allow a facility to track these counts locally. However, the lumpectomies and re-excisions would also have to be included with excisional biopsies when reporting to NMD.

Q. A tumor is generally reported by the pathologist as three dimensions. Should organizations be using the largest dimension, the sum of dimensions or a different measurement for use in breast imaging audit calculations?

A. The largest dimension should be used. The largest dimension is described in the atlas for use in measuring calcification distribution descriptors at mammography (see p144 of the Mammography section). The same should be used for reporting tumor size in imaging.

Miscellaneous

Q. In the Atlas, the Lay Letter for Probably Benign Finding (BI-RADS® 3) states: “However, in 6 months, you should have a follow-up mammogram to confirm that this area has not changed.” According to the Surveillance Imaging chart on (page 152 hardcopy), after 2 six-month follow-ups with category 3 assessments, a 12-month follow-up should be done. May we change the BI-RADS® 3 Lay Letter to indicate that a follow-up mammogram should take place in 12 months instead of 6?

A. Yes. Note that the Lay Letters provided are samples. In the Introduction to this section, we encourage facilities to “use as is, modify them, or create your own lay reports.” For the situation you describe, you certainly may want to create a 2nd category 3 patient Lay Letter, tailoring it to the request for a 12 month follow-up exam after two consecutive 6 month follow-up exams are performed.

Q. If a patient is concerned because the Lay Letter she received has a management recommendation that is not usually given for the BI-RADS® final assessment her examination received, how do I explain it to her?

A. While it is both recommended and appropriate that text be included in clinician reports to explain the rationale for discordance scenarios (when management recommendations do not “match” the assessment category), Lay Letters typically do not include the assessment or specific management recommendations. FDA regulation does not require, and the atlas does not recommend, providing such detailed reporting of complex interpretive issues directly to the patient in writing. However, if a patient expresses concern about a discordance scenario or does not understand the contents of her Lay Letter, the radiologist should discuss this with her in person, or if that is impractical, over the telephone.

Q. Several data elements in the BI-RADS® Data Dictionary 5th Edition ask about family history of breast cancer. Should breast cancer history obtained from patients refer only to female members of their family or should it include any member with breast cancer?

A. Patient family history should include breast cancer occurrences in male as well as female family members on both the maternal and paternal sides.

Q. The BI-RADS® Data Dictionary currently offers the data element options of “male”, “female”, and “unknown” for patient sex. This makes data collection specific to transgender patients problematic. What code should I use for patient sex in transgender patients?

A. The Data Dictionary uses sex rather than gender (biological sex instead of gender identity) because it is believed that sex is relevant to risk assessment and clinical performance. For transgender patients, indicate the sex at birth.