CDI QUALITY INSTITUTE

CLINICAL GUIDELINES

Breast Density and Breast Screening Guidelines

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This document provides more in depth reference materials to support the Breast Density Webinar given on 6/10/2014 and summary distributed on 7/1/2014. Some of this material can also be found in the new Bi-RADS Atlas 2013 (released in 2014). [20]

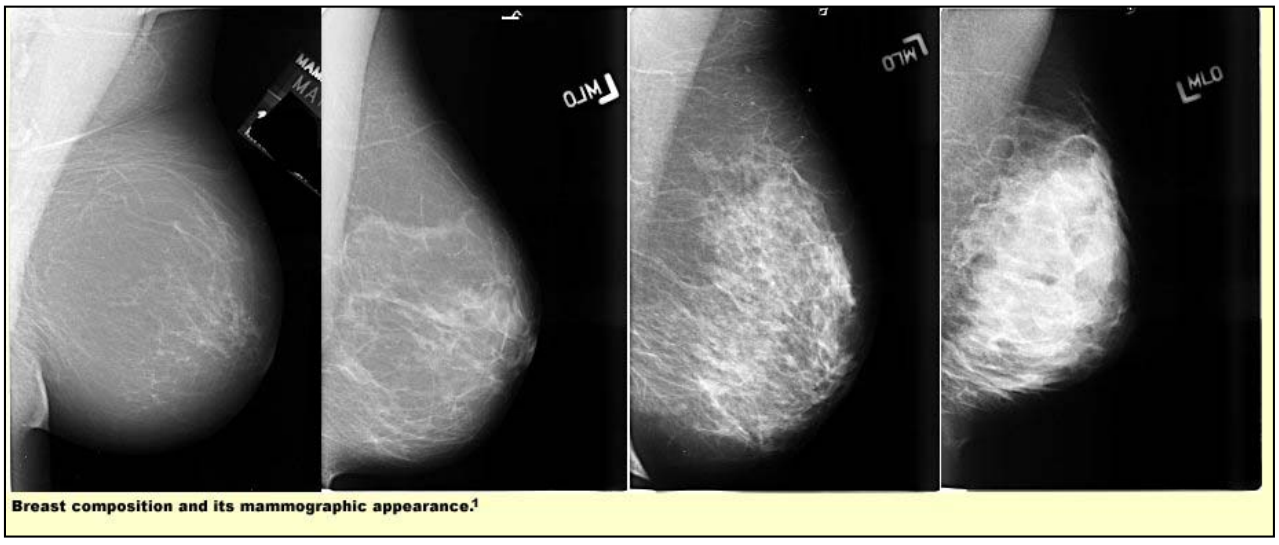
Definition of Breast Density and Density Categories on Mammography

Breasts are made up of varying amounts of fat, fibrous, and glandular tissue. Based upon the ratio of fat to fibroglandular tissue, 4 different breast density categories are assigned on mammography, ranging from the most fatty (less dense) to the least fatty (more dense). The 4 categories (see Figure 1) and the preferred language for their description from the new Bi-RADS 2013 edition are as follows:

Category A – The breasts are almost entirely fatty.
Category B – There are areas of scattered fibroglandular density.
Category C – The breasts are heterogeneously dense, which may obscure small masses.
Category D – The breasts are extremely dense, which lowers the sensitivity of mammography.

Figure 1: Breast Density on Mammography

A B C D



Breast composition and its mammographic appearance.[1]

Note that the wording for these categories has changed slightly from the prior 2003 Bi-RADs

version and also, the names of the categories have changed from 1, 2, 3, 4, to A, B, C, D, so as not to be confused with the Bi-RADS assessment categories.

The new 2013 edition also eliminates reporting the percentage of breast density, as was used in the 2003 edition. Automated quantitative density assessment software products are available to assist the radiologist in determining the density category (e.g. Volpara). Use of these products is optional, however, as visual inspection by the interpreting radiologist is felt sufficient in determining breast density, according to the ACR Bi-RADs lexicon and committee.

Assigning breast density may at times be difficult and the 2013 Bi-RADS book acknowledges that by stating, "there is considerable intra- and inter-observer variation in visually estimating breast density between any two adjacent density categories. Furthermore, there is only a minimal and insignificant difference in the sensitivity of mammography between the densest breast in a lower-density category (i.e., B) and the least dense breast in the next-higher category (i.e., C). These factors limit the clinical relevance of breast density categorization for individual woman." Thus, if the radiologist cannot decide between a category B and C density, they may choose to classify the density as category C. In borderline cases, one may choose to review the density given on the previous mammogram and if one agrees, use this category for consistency. The only real potential clinical management change would be in deciding between a category B and C density, i.e., will the mammogram be classified as not dense or as dense.

If the breasts are not of equal density, the denser breast should be used to determine the density category.

It is important to remember that breast density is a mammographic term and does not correlate with the look or feel of the breast. In some women, breast density does not change significantly with age while in others it may, typically decreasing with age.

In the U.S., the breakdown of breast density on mammography is as follows (see Figure 2):

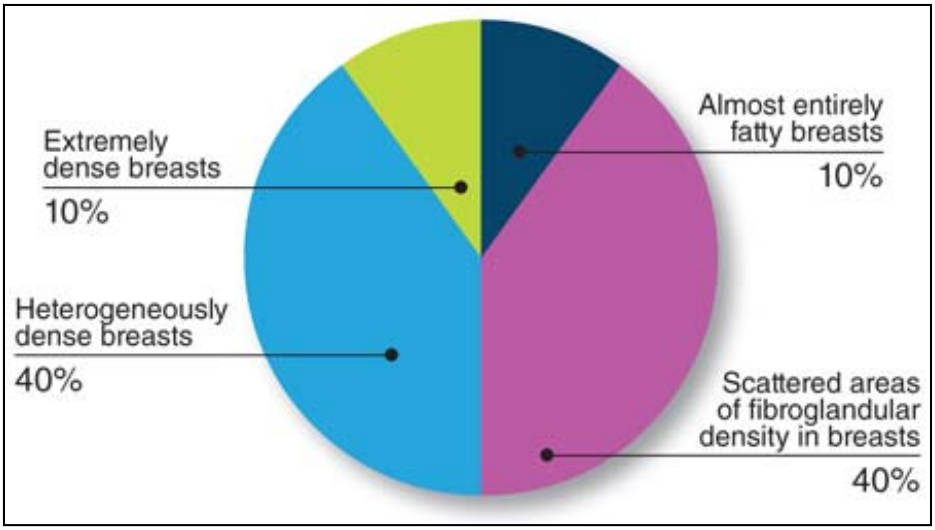
10% of women have fatty breasts (Cat A)

40% have scattered areas of fibroglandular density (Cat B)

40% have heterogeneously dense breast (Cat C)

10% have extremely dense breast (Cat D).

Figure 2: Breast Density in the U.S.



From the ACR website[1]

Categories C and D are considered dense, and thus, approximately 50% of women in the U.S. have dense breasts on mammography.[1] Breast density should be included in all mammography reports to the referring physician.

What is the Importance of Breast Density?

There are two main implications of dense breast tissue. First, and more importantly, the sensitivity of mammography for detecting breast cancer decreases as the breast density increases. In women with dense breasts, the sensitivity of mammography decreases by 7 – 26% as the breast density increases (see table 1). The most striking difference is between categories A and D, in which there is a 26% decrease in sensitivity in the denser category (See Figure 3).

Table 1: Masking Associated with Breast Density

Masking for density D vs. A: decreased sensitivity of mammography of 26%

Masking for density B vs. C: decreased sensitivity of mammography of 13%

Masking for density C vs. “avg”: decreased sensitivity of mammography of 7%

Masking for density D vs. “avg”: decreased sensitivity of mammography of 13%

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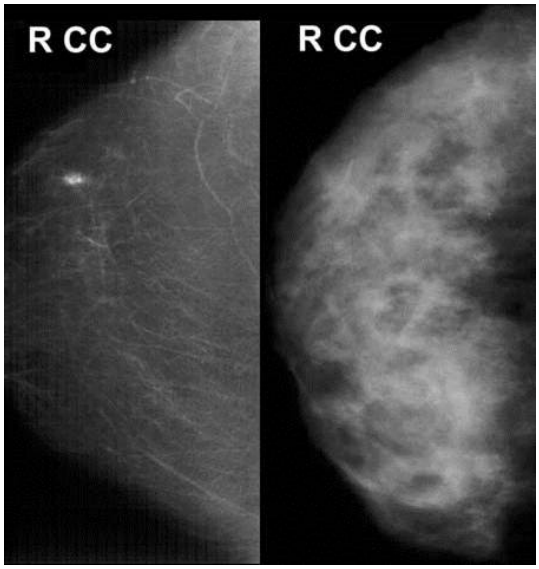
from references 2 and 3

Figure 3: Example of Masking with Category D Density vs. Category A Density Breasts



Cat A Cat D

Figure 3: Both patients have a known cancer in the lateral breasts - 5 mm mass in the patient on the left and a 1.5 cm mass in the patient on the right. The tiny cancer is clearly visible in the fatty breasts (left), but the larger cancer is not visible in the extremely dense breasts (right).

The second implication of dense breast tissue is a slightly increased risk of developing breast cancer in women with dense breasts (Table 2). In patients with heterogeneously dense breast tissue (Cat C), there is only a minimal risk above the average breast (Relative Risk =1.2 compared to average breast density) (See table 2). If the breast is extremely dense (Cat D), the relative risk of developing breast cancer is 2 fold compared with average breast density. The increased relative risk of breast cancer is most pronounced when comparing women with extremely dense breast (Cat D) with women to fatty breasts (Cat A), in which there is a 4 to 6 fold increase. [2,3]

Table 2: Relative Breast Cancer Risk Associated with Breast Density (from references 2 & 3)

Relative Risk (RR) for density D vs. A: 4 to 6

RR for density C vs. B density: < 1.5

RR for density C vs. “average”: <1.2

RR for density D vs. “average”: <2.1

Summary of Laws Being Enacted

Thus far, 21 states have passed or are in the process of passing breast density laws and 4 states have a breast density insurance law.

The wording of the breast density notification requirements varies from state to state.

Examples of Wording of Breast Density in Patient Lay Letters

Below are examples of wording for notification of breast density in patient lay letters. In some states, only patients with dense breast tissue need to be notified of their density, whereas in other states, all patients need to be notified about the limitations of dense breast tissue on mammography and told "If you have dense breasts …" We can be more consistent throughout CDI and Insight, if we notify all patients of their breast density and then add the state specific language. References to educational material can also be added. For example:

Category A – Fatty:

Your individual breast density classification on your recent mammogram is almost entirely fatty tissue based on the Breast Imaging Reporting and Data System established by the American College of Radiology, which is NOT considered "dense".

[Add specific state breast density legislation wording, if required in nondense breasts – i.e., MO, TX]

[Add ACR website for information about dense breasts]

Category B - Scattered Fibroglandular

Your individual breast density classification based on your recent mammogram is scattered fibroglandular tissue based on the American College of Radiology Breast Imaging Reporting and Data System and is NOT considered "dense".

[Add specific state breast density legislation wording, if required in nondense breasts, i.e., – MO, TX]

[Add ACR website for information about dense breasts]

Category C – Heterogeneously Dense

Your individual breast density classification based on your recent mammogram is heterogeneously dense tissue based on the American College of Radiology Breast Imaging Reporting and Data System and is considered "dense".

[Add specific state breast density legislation wording for dense breasts]

[Add ACR website for information about dense breasts]

Category D – Extremely Dense

Your individual breast density classification on your recent mammogram is extremely dense tissue based on the American College of Radiology Breast Imaging Reporting and Data System and is considered dense.

[Add specific state breast density legislation wording for dense breasts]

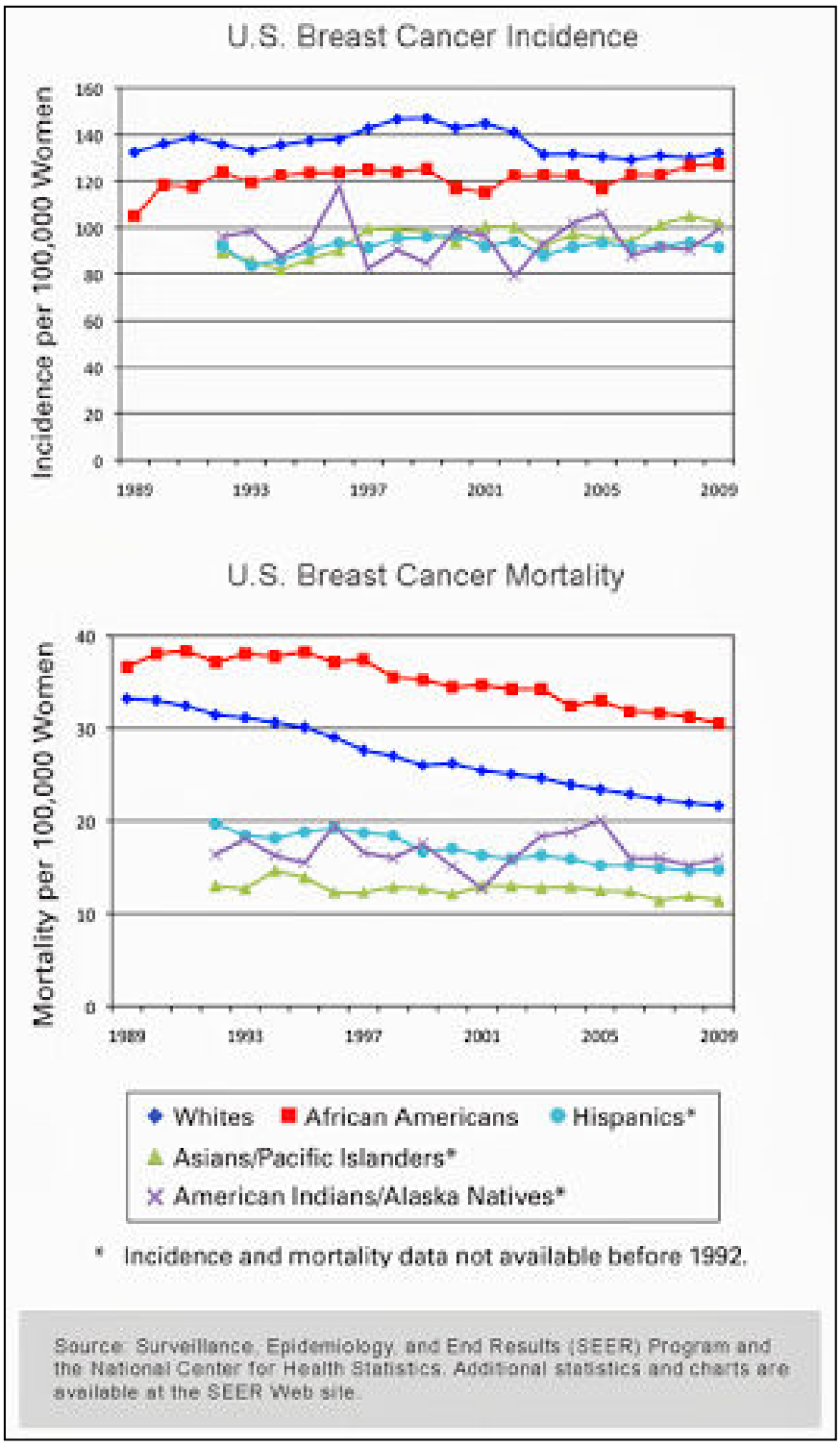
[Add ACR website for information about dense breasts]

Recommendations for Screening Mammography in Dense Breast

The recommendations for routine screening mammography are the same in women with dense breasts as in the remainder of the population, and none of the various state breast density laws that have been enacted change the current mammography screening guidelines. Mammograms are recommended, as they are effective in reducing breast cancer mortality in patients with all breast densities. There has been a 30% overall reduction in breast cancer deaths since 1990, largely attributed to earlier detection of breast cancer through mammographic screening (see Figure 4).

Yearly screening mammography is recommended, beginning at age 40 in average risk women, regardless of the breast density. Many cancers are detected on mammography in women with dense breasts, and certain indicators of breast cancer, such as calcifications, are seen best on mammography. This recommendation is supported by the American Cancer Society, American College of Obstetricians and Gynecologists, American College of Radiology and the Society of Breast Imaging. Screening mammography should continue for as long as a woman is in good health, has a life expectancy of at least 5 to 7 years, and is willing and able to receive treatment for any cancer found. This includes additional testing and a biopsy (See Table 3). [5]

Figure 4: Breast Cancer Incidence and Mortality in the US



From SEER website[13]

Table 3: Screening Mammography guidelines

Yearly screening mammography from age 40, in average risk women
- Same in dense breasts as remainder of population!
- None of enacted state breast density laws change guidelines
- Cancer detection rate of ~ 2-7/1000
- In certain high-risk women, may begin screening mammography earlier, from age 30

Screening should continue for as long as a woman is in good health
- Life expectancy of at least 5 to 7 years
- Patient willing and able to receive treatment for any potential cancer found, including additional testing and biopsies

Note: These guidelines apply only to screening mammography in asymptomatic women. If patient is symptomatic, diagnostic exam with appropriate workup is performed.

Adapted from reference 5

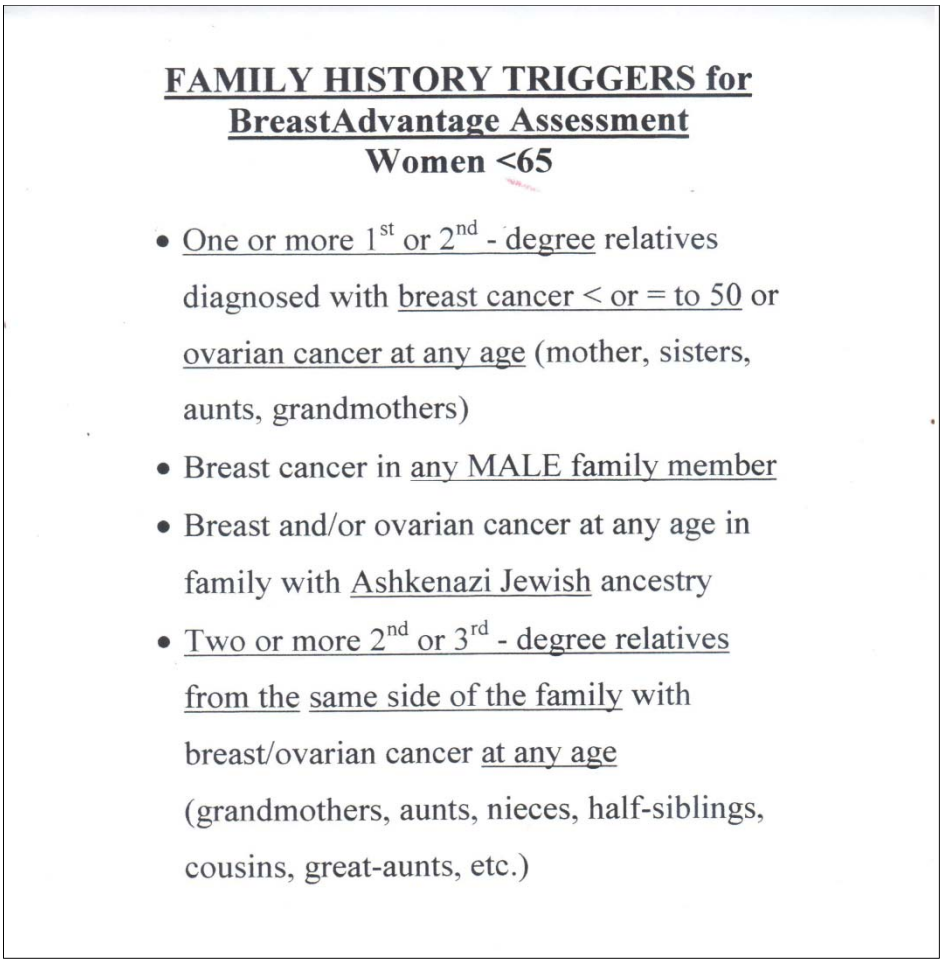
Calculating the Lifetime Risk of Developing Breast Cancer

It is very helpful to know a women's "risk" of developing breast cancer, especially if she has dense breast tissue, to help guide the referring physician and patient as to the appropriateness of additional breast imaging. If the patient with dense breasts has any other risk factors, such as a family history of breast or ovarian cancer, a formal breast cancer risk assessment is recommended. The family history triggers that we use at our center to prompt a more in-depth interview with the patient and a potential risk assessment are listed in Figure 5.

Risk assessments can be performed by the referring physician's office or the breast imaging center. If performed at the mammography center, they may be performed by a risk assessment coordinator, nurse, technologist, or the radiologist. If you decide to perform them at your center, it is helpful to designate a person or persons to perform the risk assessments. A centralized person could also perform the assessments by telephone. The radiologist should review all assessments that are performed at their breast center. The patients and referring physicians should be notified of results and recommendations in writing.

During the risk assessment process, the patient is interviewed to gather a more in depth family and personal history. This information is entered into a valid risk assessment model. There are many risk assessment models currently available to perform breast cancer risk assessment, and one popular model is the Tyrer-Cusiek model, (*http://www.ems-trials.org/riskevaluator*). These models are largely based upon family history, as well as any personal history of atypia on breast biopsies.

Figure 5 – Family History Triggers for Risk Assessment



From Rebecca Tackett, RN, MSN - adapted NCCN guidelines – Ref 19

A report is generated with the 10 year and lifetime risk calculations. A normal risk is considered < 15% lifetime risk. The average woman has 12.5% chance of developing invasive breast cancer over her lifetime, based upon a life expectancy of ~ 80 years. Women with a lifetime risk between 15 and 20% are considered at "moderate risk" of developing breast cancer. If a woman has a 20% or greater lifetime risk of developing breast cancer, she is considered "high-risk". See table 4. For obvious reasons, one may prefer to use the word "elevated risk" instead of "high-risk" with patients. Many models will also give the patient a probability of having a BRCA gene mutation. Obviously, the presence or absence of this gene mutation will markedly increase the lifetime risk of breast cancer.

The risk assessment models are not used in women with a known breast cancer diagnosis. Also, the author is unaware of any current models that factor in breast density as a risk factor. If women have had radiation to the chest between the ages of 10 and 30, usually for Hodgkin's lymphoma, have a BRCA gene mutation or have first-degree relatives with a BRCA gene

Table 4: Breast Cancer Risk

Breast Cancer Risk	Lifetime Risk
Normal	< 15%
Moderate	15-19%
High	≥20%

Source: American Cancer Society (ACS) [17]

mutation, they will be candidates for screening breast MRI, as they will have a greater than 20% lifetime risk of developing breast cancer and do not need to undergo a formal risk assessment.

Table 5 below lists the recommendations from the Society of Breast Imaging and American College of Radiology for imaging screening for breast cancer by modality. [5] Depending on the results of the patient's risk assessment, other imaging tests, such as breast ultrasound or breast MRI may be recommended. It may be helpful to have a genetic counselor review the assessments in patients with moderate or high risk. If one doesn't have access to a genetic counselor, you can establish a relationship with a "High Risk" clinic for consultation and referral, as necessary.

Table 5 -SBI AND ACR RECOMMENDATIONS FOR IMAGING SCREENING FOR BREAST CANCER [5]

A. Mammography

1. Women at average risk for breast cancer
    - Annual screening from age 40
2. Women at increased risk of breast cancer
    A. Women with BRCA 1 or BRCA 2 gene mutations or who are untested, but have first degree relatives (mothers, sisters, daughters) who are proved to have BRCA gene mutations
        - Yearly starting by age 30 (but not before age 25)
    B. Women with ≥ 20% lifetime risk for breast cancer (both maternal and paternal)
        - Yearly starting by age 30 (but not before age 25), or 10 years earlier than the age of diagnosis of the youngest affected relative, whichever is later
    C. Women with mothers or sisters with pre-menopausal breast cancer
        - Yearly starting by age 30 (but not before ages 25), or 10 years earlier than the age of diagnosis of the youngest affected relative, whichever is later
    D. Women with histories of mantle radiation (usually for Hodgkin's disease) received between the ages of 10 and 30
        - Yearly starting 8 years after the radiation therapy, but not before age 25
3. Age at which annual screening mammography should stop:
    A. When life expectancy is ≤ 5 to 7 years on the basis of age or comorbid conditions
    B. When abnormal results of screening would not be acted on because of age or comorbid conditions

B. Ultrasound (in addition to mammography)

1. Can be considered in high-risk women for whom MRI screening may be appropriate but who cannot have MRI for any reason

2. Can be considered in women with dense breast tissue as an adjunct to mammography

C. MRI

1. Proven carriers of BRCA gene mutations and untested first degree relatives of BRCA gene mutations

    - Annually starting at age 30

2. Women with ≥ 20% lifetime risk for breast cancer on the basis of family history
    - Annually starting at age 30
3. Women with histories of chest irradiation (usually as treatment for Hodgkin's disease)
    - Annually starting 8 years after the radiation therapy
4. May be considered in women with between 15 and 20% lifetime risk for breast cancer on the basis of personal history of breast of ovarian cancer or biopsy-proven lobular neoplasia or ADH (atypical ductal hyperplasia or other atypia)

Supplemental Screening in Women with Dense Breasts

Given the ACR and SBI guidelines noted above, recommendations for patients with dense breasts can be made as follows:

A. Women with no other risk factors – No family history of breast and / or ovarian cancer and no prior personal breast biopsy with atypia

If there are no breast cancer risk factors other than dense breasts, the risk of breast cancer remains relatively low and you do not need to perform a risk assessment. The patient should be educated about the risks and benefits of additional screening, such as breast ultrasound and tomosynthesis, and should discuss these options with her physician or designated personnel at the mammography center. Breast US can be performed with hand held technique or automated whole breast US. Tomosynthesis is also very helpful in these patients, as it increases the cancer detection rates and decreases the callback rates.

B. Women with other risk factors for cancer - including a family history of breast and / or ovarian cancer and / or personal history of prior breast biopsy with atypia (atypical ductal hyperplasia, atypical lobular hyperplasia, or lobular carcinoma in-situ) or prior chest radiation

If the patient has any other risk factors in addition to dense breast tissue, including a family history of breast and / or ovarian cancer, breast cancer risk assessment is helpful, regardless of their breast density to help determine which supplemental tests will be beneficial.

Suggested Guidelines for Supplemental Screening Based on Lifetime Risk of Developing Breast Cancer

If lifetime risk is < 15% risk and patient has dense breast tissue (with or without any family history of breast cancer).

Patient should consult with her doctor or healthcare provider to determine if supplemental screening may be beneficial for her. If women are interested in additional breast screening examination, such as an ultrasound, they may have an out of pocket expense if there is no family history of breast cancer. If there is a family history of breast cancer, whole breast ultrasound will usually be covered by insurance with a physician's order. Breast US can be performed with hand held technique or automated whole breast US. Tomosynthesis is of great benefit in these patients, as the cancer detection rate will increase with a decrease in the callback rate.

If lifetime risk is between 15 and 19% and patient has dense breast tissue.

Breast ultrasound is recommended, preferably alternated at 6 month intervals with mammography, and is ordered by the referring physician. This is typically covered by insurance. Plans will vary and the patient's insurance coverage should be checked prior to performing the ultrasound. Although not typically recommended in this patient population, some insurance carriers will cover breast MRI for these women. The American Cancer Guidelines are equivocal for breast MRI in this patient population. If the patient has a breast MRI, she does not need a breast ultrasound examination also.

If lifetime risk is ≥ 20%, regardless if there is dense breast tissue or not (typically 3-5 % of your patient population)

Screening breast MRI is recommended in conjunction to mammography in women with a ≥20% lifetime risk of developing breast cancer based on the American Cancer Society Guidelines, as discussed below. The breast MRI is usually alternated at 6 month intervals with mammography and ordered by the referring physician. If the patient is not a candidate for breast MRI (pacemaker, body habitus, severe claustrophobia, MRI contrast allergy, renal insufficiency, limited insurance coverage plan, etc.), then a breast ultrasound examination is offered as the second-best supplementary screening test for high risk women and is typically covered by insurance. This can be alternated at 6 month intervals with the mammogram.

Breast MRI as Supplemental Screening in High Risk Women

In 2007, the American Cancer Society developed guidelines for screening breast MRI as an adjunct to screening mammography as follows for the following high-risk populations (See Table 6). [10]

In the ACRIN 6666 study, breast MRI was found to detect an additional 14.7 cancers per 1000 exams after negative screening mammography and negative breast ultrasound. Ultrasound detected an additional 24% of cancers over mammography alone and breast MRI detected an additional 56% of cancers over mammography alone.[14] Cancers detected by MRI were more likely invasive, most were stage T1, and 87% were node negative.

Typically, a successful screening breast MRI program will generally detect ~ 10-20 cancers/1000 exams over mammography alone, depending upon the patient population.

Table 6: ACS Guidelines for Breast MRI as an Adjunct to Screening Mammography – Ref 10

Recommend Annual MRI Screening - "High Risk"

> 20%-25% lifetime risk of developing breast cancer

BRCA gene mutation – have a 60-80% lifetime risk of developing breast cancer

First –degree relative of BRCA carrier, but untested

History of radiation to the chest between ages 10 and 30 (usually due to Hodgkin's Lymphoma)

Li-Fraumeni syndrome, Cowden syndrome, and Bannayan-Riley-Ruvalcaba syndrome and 1st degree relatives

Insufficient Evidence to Recommend for or against MRI Screening - "Moderate Risk"

Lifetime risk of 15-20%

Personal history of lobular carcinoma in-situ (LCIS), atypical lobular hyperplasia (ALH), atypical ductal hyperplasia (ADH) or breast cancer, including DCIS

Heterogeneously dense or extremely dense breast tissue on mammography

Recommend against MRI screening- Average Risk

Women with <15% lifetime risk of developing breast cancer

Breast US as a Supplemental Screening Exam in Women with Dense Breasts

Breast ultrasound has been shown to increase the cancer detection rate in women with dense breasts over mammography alone. The sensitivity of breast ultrasound is not affected by breast density. It does not use ionizing radiation and does not require the use of intravenous contrast. Ultrasound is easily tolerated by the patients, is readily available, and is relatively inexpensive.

Data from studies of over 40,000 women with dense breasts, found that adding hand held screening breast ultrasound to screening mammography detects an additional 3-4 cancers per 1000 exams over mammography alone, essentially doubling the cancer detection rate. 94% of the additional cancers detected on ultrasound were invasive cancers with a mean size of 1 cm, and 96% of these were node negative. These additional cancers were comprised largely of small early-stage treatable cancers. [6]

A recent study by Hooley, et al [7] from Yale examined the use of screening ultrasound in women with dense breasts and a previous negative mammogram, and found that the cancer yield varied with the patient's lifetime risk of developing breast cancer (see table 7).

Table 7: **Cancer Detection on Hand Held Screening Breast Ultrasound Based on Cancer Risk**

Life time Breast Cancer Risk	Additional Cancer Yield / 1000 Patients Screened
Low risk	1.6/1000
Intermediate risk	6.7/1000
High risk	11.5/1000

Average: Additional 3.2 cancers/1000

From reference 7

By comparison, mammography screening alone detects on average ~ 2-7 cancers / 1000 exams, depending upon the patient population.

The main drawback of breast ultrasound is an increase in the number of false positive findings. Studies have shown an increased rate of BIRADS 3 (probably benign) lesions and a relative decrease in the positive predictive value of ultrasound-based biopsy recommendations.

In studies performed in Connecticut (first state to enact a breast density law), the BIRADs 3 rates of screening breast ultrasound have ranged from 9 to 20%, compared with ~ 3% for mammography. This is significant, because these probably benign exams typically need short term follow up, and a significant number of these patients opt for biopsies and/or cyst aspirations.

Screening breast ultrasound has a lower PPV when compared to screening mammography. In some studies, the PPV of a biopsy recommendation on screening ultrasound is in the 5-6.5% range, which is significantly lower than accepted rate for screening mammography, which is in the 20-40% range.[6] This means that only ~ 5% of ultrasound recommended biopsies are positive for cancer compared with ~ 20-40% for mammography.

The ACR Bi-RADS committee strongly recommends that radiologists carefully audit their individual practice with respect to screening breast ultrasound exams and look at their callback rates, biopsy recommendation rates, and outcomes, etc.

Whole breast screening ultrasound can be performed by trained technologists or radiologists with either hand held or automated technique. There are advantages and drawbacks to each technique.

The advantages of hand held whole breast ultrasound is that it is more readily available and can be performed with existing equipment. The main disadvantage of hand held ultrasound is that it is operator dependent. Hand held breast ultrasound exams are typically performed by a technologist and reviewed by the radiologist at the time of the appointment. Studies have shown no statistically significant difference in the cancer detection rate between an ultrasound performed by a trained technologist or a radiologist. [12]

The advantages of automated whole breast ultrasound are that it is less operator dependent, can be batch read, and does not require physician time to acquire images. The potential disadvantages include an increased recall rate. In order to limit the number of recalls, some centers read the automated ultrasounds "live" with the patient in the department, so that any questionable lesion can be assessed at the time of the study. This approach, however, requires direct radiologist supervision.

Only 4 states (Connecticut, New Jersey, Indiana, and Illinois) have mandatory insurance coverage for supplementary breast ultrasound in women with dense breast tissue. In other states, there is no mandatory coverage at this time and patients with no other risk factors other than dense breast tissue will likely have to pay out of pocket. Data has shown that in states without mandatory breast ultrasound coverage, the acceptance rate of ultrasound in women with dense breast has been only 2-5%. [5] Patients can request help with determining if their insurance covers breast ultrasound through the CDI/Insight patient advocates.

Tomosynthesis (3D Mammography)

Tomosynthesis is a powerful technology, as it increases the cancer detection rate and decreases the recall rate (false positives). It does this removing the superimposition of overlapping tissues, so breast cancers become more conspicuous, while reducing the likelihood of pseudolesions due to overlapping tissue

See Figures 7-9 below.

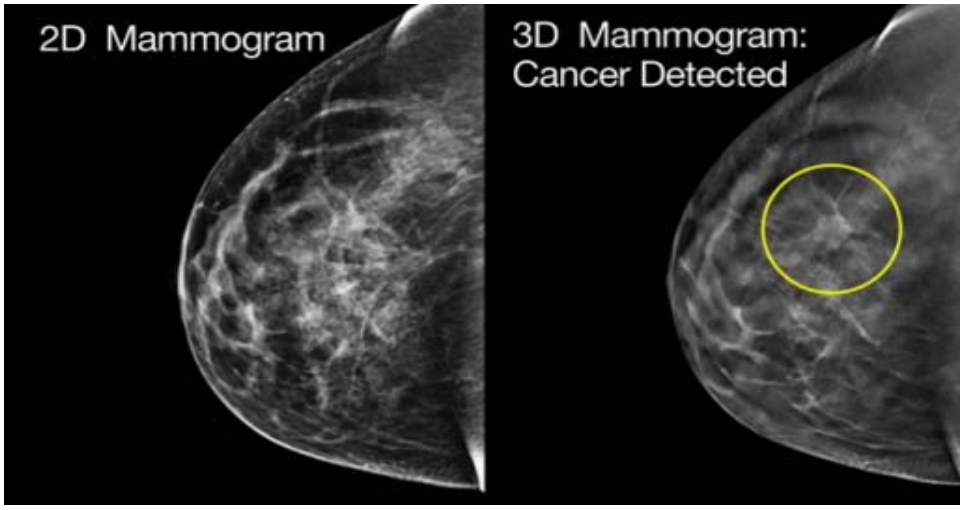
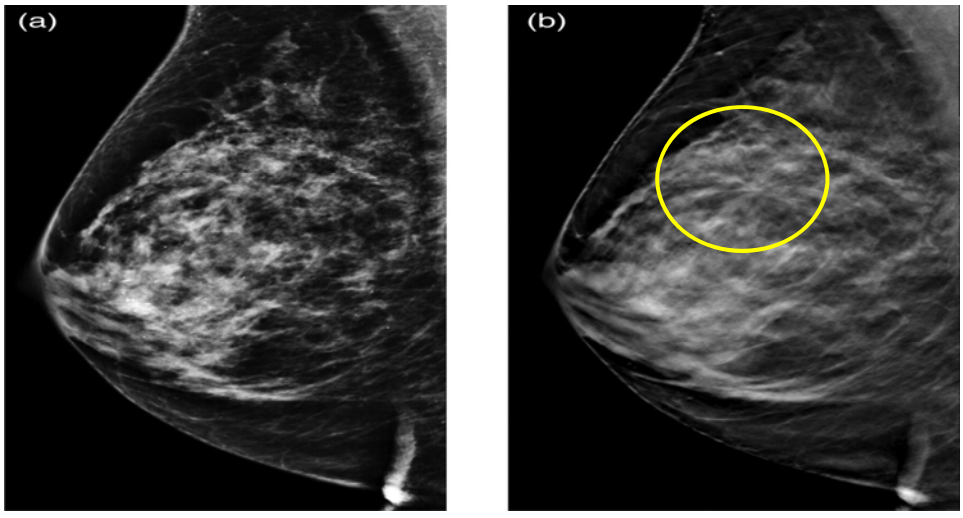
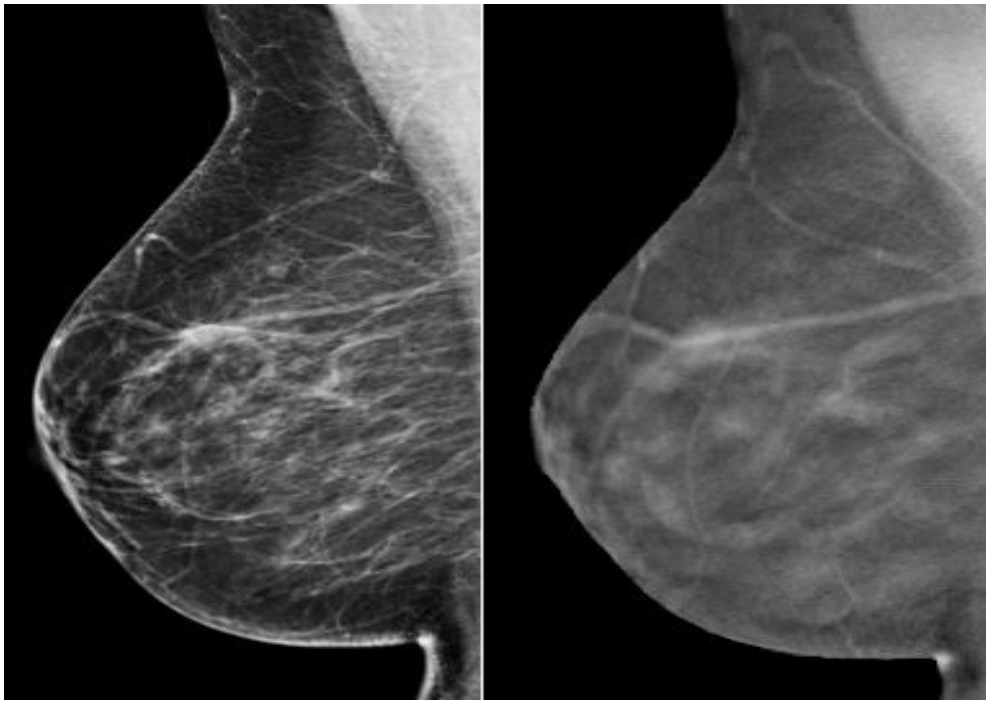


Figure 7: 3D (tomosynthesis) image on the right shows a cancer not detected on the 2D mammogram (left). Source Hologic.



2D mammo **Tomo**

Figure 8: 3D (tomosynthesis) image on the right shows a subtle cancer not detected on the 2D mammogram (left). Source Hologic.



2D Mammo Tomo

Figure 9: 3D (tomosynthesis) image on the right shows that an asymmetry in the superior right breast is due to summation artifact and not a true mass and thus saved the patient from a callback exam. Note that the tissue is not dense in this patient. Source Hologic.

Below is a summary of recent studies demonstrating the use of tomosynthesis:

In a study by Skaane et al. of over 12,000 2D digital screening mammogram examinations with tomosynthesis, they found a 25% increase in their the cancer detection rate (from 6.1/1000 to 8.1/1000), while achieving a 15% decrease in their false positive rate. [8]

In a study by Rose, et al. with over 45,000 exams, they found a 61% increase in their cancer detection rate (from 3.6/1000 to 5.8/1000) with the addition of tomosynthesis to 2D mammography, and a 39.5 % decrease in recall rate (from 8.7% to 5.3%).[9]

In a study by Philpotts, et al[11] with over 7500 screening mammograms, they found a 40% decrease in their callback rate (from 11.6 % to 6.6%) and this was best for asymmetries on mammography.

A recent paper published in June 2014 by Friedewald, et al. in JAMA, looked at the addition of tomosynthesis to digital mammography in over 170,000 examinations compared to digital mammography alone in ~ 281,000 examinations performed at 13 different academic and nonacademic breast centers. [18] With the addition of tomosynthesis, they found a 15% decrease in the callback rate, a 29 % increase in the overall cancer detection rate, and a 41% increase in the invasive cancer detection rate over 2D digital mammography alone. The positive predictive value for a recall increased 49%, from 4.3% to 6.4% and the positive predictive value for a

biopsy increased 21%, from 24.2% to 29.2%. [18]

Typically, both the standard 2D mammogram and the tomosynthesis are performed in the CC and MLO projections and this is referred to as a combined technique. The addition of tomosynthesis adds less than 1 minute (~ 30 seconds) to the exam acquisition time.

The radiation dose for the combined technique is similar to an analog mammogram and is still well below the federal requirements for screening mammography. For a 2D 4 view screening mammography, the average dose is 0.5 mSv (See Table 8).

Table 8: Comparison of Radiation Doses - Standard 4-view Screening Exam

Exam	Effective Dose (mSv)
2D digital	0.5
2D + 3D	1.0
Avg annual background U.S.	3.0
(Analog mammogram dose ~ 1 mSv)	

From reference 11.

2D images can now be reconstructed from the 3D images (similar to a MIP or Maximum Intensity Projection) and are referred to as synthesized 2D images or C-views (See Figure 10). The C-view is been shown to perform as well as the 2D mammogram for masses. In some studies, it has been shown slightly better for calcifications, but most radiologists are still acquiring the 2D images at this point. The main reason centers have not dropped the standard 2D images at this time is that they are awaiting widespread use of CAD for the tomosynthesis. When this is available, we can likely drop the 2D images and the radiation dose for tomosynthesis will be nearly the same as a standard 2D digital mammogram. The total patient radiation exposure will also be decreased by the reduction in callbacks.

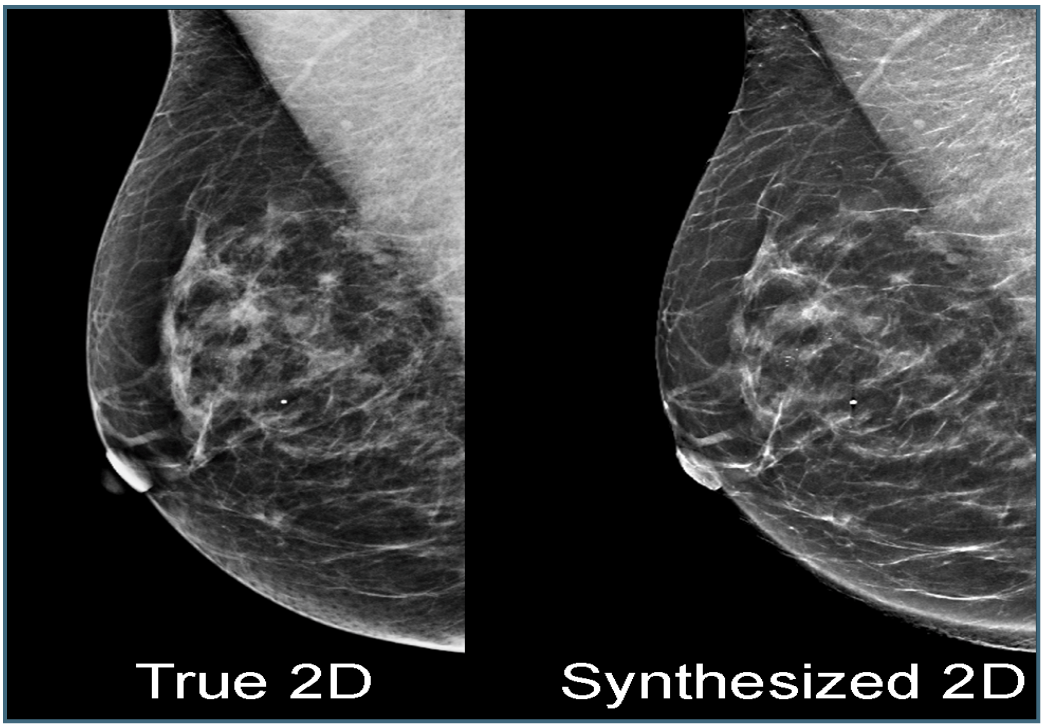


Figure 10: Comparison of a 2D mammogram with a C-view (synthesized) mammogram. Source Hologic.

Some of the drawbacks of tomosynthesis are the cost, learning curve to read, longer reading times, slightly higher radiation dose, and significantly larger data sets for storage.

Currently, there is no universal insurance coverage for tomosynthesis. Many breast centers now offer this for a nominal out of pocket fee (~ $20 to $70). Medicare patients should not be charged until at least 2015. Some centers in Pennsylvania and New Mexico have obtained insurance coverage for tomosynthesis by sharing their individual data with the insurance companies documenting a decrease in their screening callback rates.

Many sites are not using tomosynthesis in patients with very large breasts or in patients with encapsulated breast implants.

Below is a summary of the different breast screening examinations with respect to their callback rates and cancer detection rates from Wendie Berg, M.D. Ph.D. (Table 9). [16]

Table 9

TABLE 1. SUMMARY OF RECALL AND CANCER DETECTION RATES FOR COMMONLY AVAILABLE BREAST SCREENING TESTS

Screen 1,000 women with:	Number of Women Recommended for Additional Testing	Number of Women Found to Have Cancer
Regular 2-D mammogram alone	100	2-7*
2-D mammogram plus or including 3-D mammogram (tomosynthesis)	70	Mammogram 2-7 + tomosynthesis 2-3** = 4-10 total
Regular 2-D mammogram plus ultrasound (US)	170-230	Mammogram 2-7 + US 3-4 = 5-11 total
Regular 2-D mammogram plus MRI	160-220	Mammogram 2-7 + MRI 10 = 12-17 total

TABLE COURTESY OF WENDIE BERG, M.D., PH.D.

*Mammography performance in dense breasts is slightly improved when digital, rather than film, technique is used, though the ranges stated apply to either.
**Cancer detection rate for regular 2-D mammogram plus tomosynthesis. Studies on cancer detection rate for synthetic 2-D mammogram with tomosynthesis are not fully known, but are estimated to be comparable.

From reference 16.

Information Regarding Supplementary Breast Screening Exams in Women with Dense Breasts

There are several very informative websites for guidance with supplemental screening in women with dense breast tissue. These include:

1. American College of Radiology Breast Density: Breast Cancer Screening - http://www.acr.org/~/media/ACR/Documents/PDF/QualitySafety/Resources/Breast%20Imaging/Breast%20Density%20bro_ACR_SBI_lores.pdf

This is very informative for patients. It can also be printed, folded into a pamphlet, with an individual breast center logo added, and placed in the mammography center for easy patient access. A copy of the brochure is included on the following 2 pages (Figure 6a-b).

2. Breast Density: Are You Informed. A primer for questions your patients may ask by Dr. W. Berg - http://www.itnonline.com/article/breast-density-are-you-informed

3. The California Breast Density Information Group (CBDIG)[3] also has a very informative website for both physicians and patients regarding breast density with case scenarios– BreastDensity.Info

Figure 6a: ACR Website Density Info

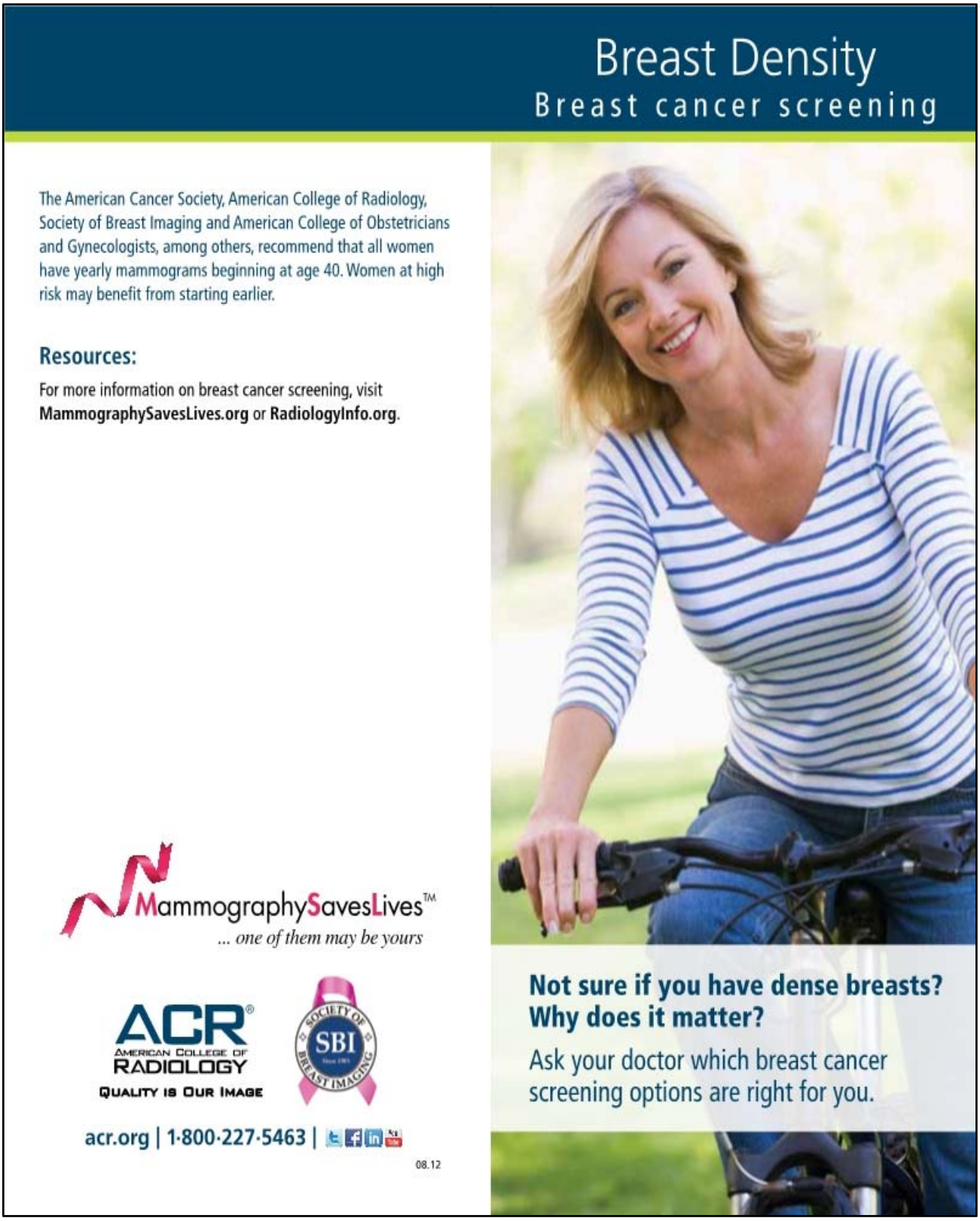


Figure 6b: ACR Website Density Info

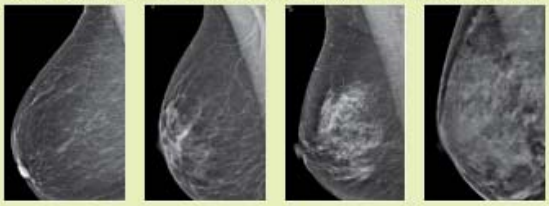
What is breast density?

Breasts are made up of a mixture of fibrous and glandular tissue and fatty tissue. Your breasts are considered dense if you have a lot of fibrous or glandular tissue but not much fat. Density may decrease with age, but there is little, if any, change in most women.

How do I know if I have dense breasts?

Breast density is determined by the radiologist who reads your mammogram. There are four categories of mammographic density. The radiologist assigns each mammogram to one of the categories. Your doctor should be able to tell you whether you have dense breasts based on where you fall on the density scale. (See scale below.)

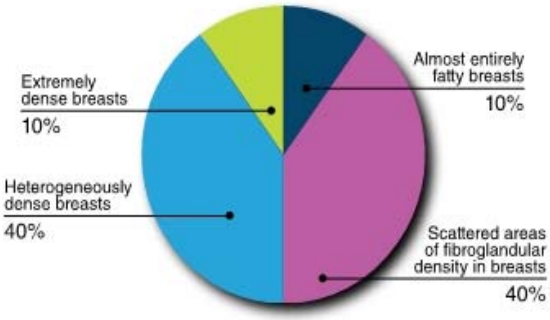
Radiologists classify breast density using a 4-level density scale:



Almost entirely fatty | Scattered areas of fibroglandular density | Heterogeneously dense | Extremely dense

Breast density in the U.S. (See pie chart)

- 10% of women have almost entirely fatty breasts
- 10% have extremely dense breasts
- 80% are classified into one of two middle categories



Why is breast density important?

Having dense breast tissue may increase your risk of getting breast cancer. Dense breasts also make it more difficult for doctors to spot cancer on mammograms. Dense tissue appears white on a mammogram. Lumps, both benign and cancerous, also appear white. So, mammograms can be less accurate in women with dense breasts.

If I have dense breasts, do I still need a mammogram?

Yes. A mammogram is the only medical imaging screening test proven to reduce breast cancer deaths. Many cancers are seen on mammograms even if you have dense breast tissue.

Are there any tests that are better than a mammogram for dense breasts?

In breasts that are dense, cancer can be hard to see on a mammogram. Studies have shown that **ultrasound** and **magnetic resonance imaging (MRI)** can help find breast cancers that can't be seen on a mammogram. However, both MRI and ultrasound, show more findings that are not cancer, which can result in added testing and unnecessary biopsies. Also, the cost of ultrasound and MRI may not be covered by insurance.

What should I do if I have dense breasts? What if I don't?

If you have dense breasts, please talk to your doctor. Together, you can decide which, if any, additional screening exams are right for you.

If your breasts are not dense, other factors may still place you at increased risk for breast cancer — including a family history of the disease, previous chest radiation treatment for cancer and previous breast biopsies that show you are high risk. Talk to your doctor and discuss your history.

Even if you are at low risk, and have entirely fatty breasts, you should still get an annual mammogram starting at age 40.

Summary:

Based on the guidelines from the American College of Radiology, the Society of Breast Imaging, the American Cancer Society, and author's personal experience, Table 10 is a "suggested" guideline for breast screening regimen.

Please note: These suggested guidelines are meant to help the radiologist with questions from referring physicians and / or patients and not as an addition to the mammography report. The breast density laws in most states only require the radiologist to notify patients of dense breast tissue and possible ramifications of such, not to tell them which supplemental screening tests should be performed. In some states, breast ultrasound and MRI are mentioned as potential supplemental tests in the lay letters.

Table 10: "Suggested" Guideline for Breast Imaging Screening in Patients with Dense Breasts

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- Normal Risk (<15% lifetime)
    - Mammography
    - If dense, and especially if FH of breast cancer, consider addition of US
- Intermediate risk (15-19% lifetime)
    - Mammography
    - If dense, recommend US
- High risk (>20% lifetime)
    - Mammography
    - MRI (regardless of density) - if not candidate for MRI, recommend US

When available, tomosynthesis is recommended, especially in dense breast tissue, as it will increase the cancer detection rate (25-61%) and decrease the callback rate (15-40%) for mammography in all risk and density levels.

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