Breast Imaging Update: Screening Guidelines and using the ACR Appropriateness Criteria in clinical practice.

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Disclosures

- **I am employed by UMC Health System.**
- **I have no financial interests or relationships to disclose.**

Current breast cancer screening guidelines

- American College of Radiology
  - Early detection decreases breast cancer mortality.
  - The ACR recommends annual mammographic screening beginning at age 40 for women of average risk.
  - Higher-risk women should start mammographic screening earlier and may benefit from supplemental screening modalities such as ultrasound and MRI.
- American Cancer Society
  - Women between 40 and 44 have the option to start screening with a mammogram every year.
  - Women 45 to 54 should get mammograms every year.
  - Women 55 and older can switch to a mammogram every other year, or they can choose to continue yearly mammograms. Screening should continue as long as a woman is in good health and is expected to live at least 10 more years.

How is risk calculated?

- Each patient at UMC Breast Imaging Center enters their information into a questionnaire on a tablet when they arrive at their mammogram appointment and we calculate Tyrer-Cuzick risk
- Genetic testing available at UMC Cancer Center and UMC Breast Center
- Multiple different models and calculators available
  - **Tyrer-Cuzick Risk Model**: https://ibis.ikonopedia.com/
  - Age Height Weight
  - Age at menarche
  - Age at first delivery
  - Age at menopause
  - Breast density
  - Ashkenazi Jewish heritage
  - History of hormone use
  - Genetic testing results for BRCA 1 and BRCA 2
  - Number of daughters Number of sisters & half sisters Number of maternal aunts Number of paternal aunts
  - Atypical breast biopsies, ie: ADH, ALH, LCIS
  - History of breast biopsy/surgery
  - Personal or family history of Breast cancer Age cancer was diagnosed
  - Cancer in one breast or both breasts

Increasing incidence of premenopausal breast cancer

- In the past few years, there is an increasing incidence of breast cancer in young premenopausal women
- Associated with poorer prognosis, more aggressive histologic features, and more frequent recurrence rates
- Increased incidence of premenopausal breast cancer in non white women with revision of previous recommendations from the USPSTF to not begin screening until age 50.

Mammography Quality Standards Act

The Mammography Quality Standards Act (MQSA) became law on October 27, 1992 (P.L. 102-539).

MQSA required the Department of Health and Human Services (HHS) to develop standards that would be enforced through strict accreditation, certification and inspection of equipment and personnel at mammography facilities. The Food and Drug Administration (FDA) was tasked with implementing the federal regulations, which it published in October 1997, used to establish and enforce such procedures.

In newly issued final rule updates to the Mammography Quality Standards Act (MQSA) in March 2023, the Food and Drug Administration (FDA) will require standard breast density notification in mammography reports, beginning on September 10, 2024, for all women in the United States.

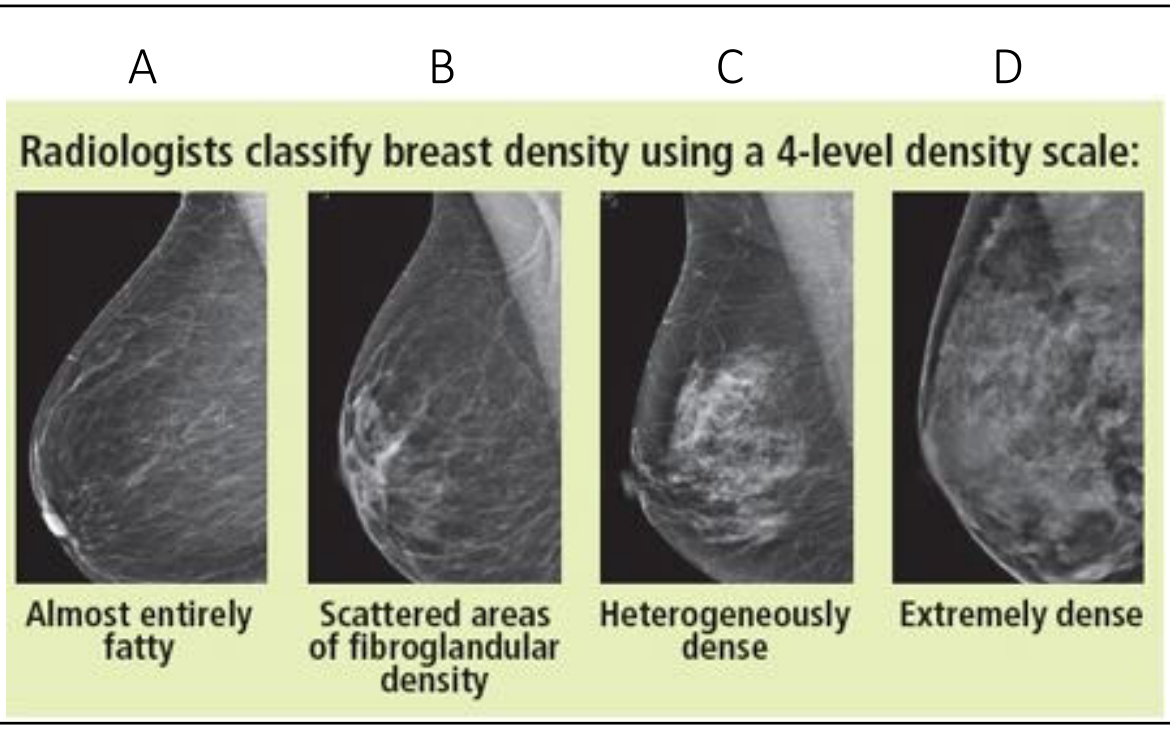
Henda's Law – State of Texas

- The legislation Texas HB 2102 requires that a certified mammography facility approved by the FDA or a certification agency approved by the FDA, shall upon completion of the mammogram provide to the patient educational materials about how dense breast tissue is prevalent and normal, and how it can reduce the efficacy of traditional screening tools such as mammograms.

Breast Density

ACR Bi-Rads Lexicon for Breast Density

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

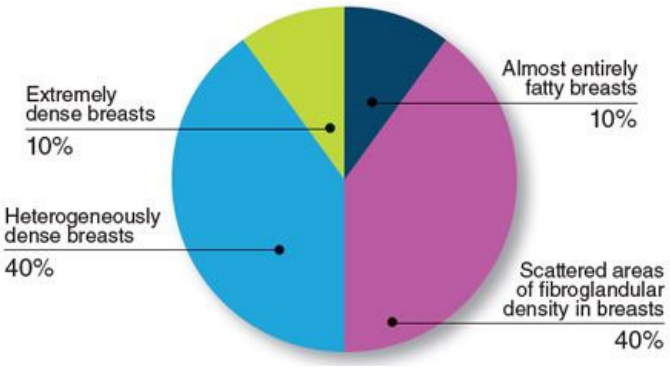


Why does Breast Density Matter?

Dense breast tissue makes breast cancer lowers the sensitivity of mammography and makes masses and cancer harder to detect

High breast density has been shown to be a strong, independent risk factor for breast cancer. This risk is separate from the effect of dense breasts on the ability to read a mammogram.

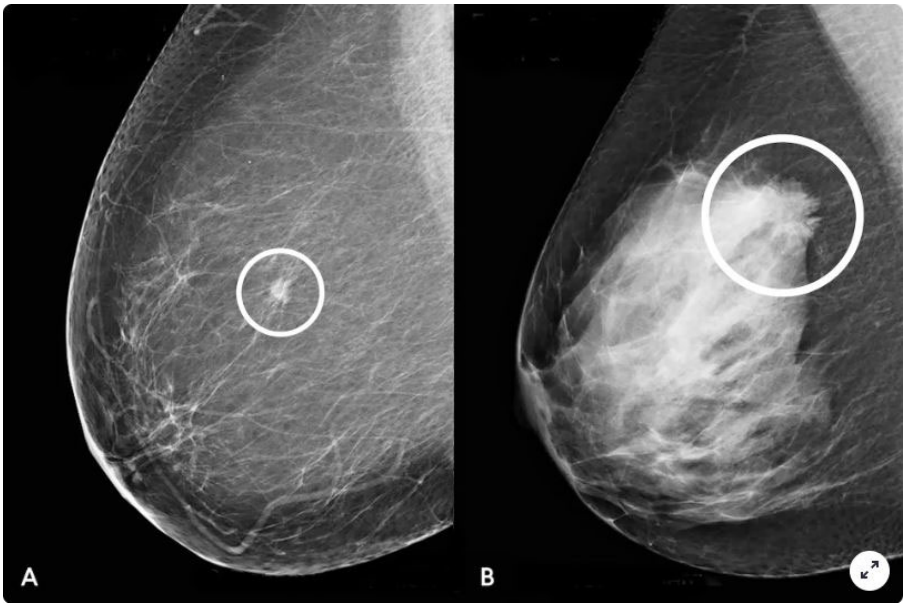
Dense breast tissue = more ducts and lobules



Study of Breast Density and Incidence of Breast Cancer

- The 5-year cumulative incidence of invasive breast cancer increased in association with increasing breast density among women aged 65 to 74 years
  - (almost entirely fatty breasts: 11.3 per 1000 women
  - scattered fibroglandular densities: 17.2 per 1000
  - extremely or heterogeneously dense breasts: 23.7 per 1000 women

Breast Cancer in a fatty vs. dense breast



ACR Appropriateness Criteria

- https://acsearch.acr.org/
- Evidence-based guidelines from the American College of Radiology to assist referring physicians and other providers in making the most appropriate imaging or treatment decision for a specific clinical condition.
- Search by topic online at the link above
- Multiple different clinical scenarios / vignettes with narrative and ratings table, evidence table, and relevant literature searches.

American College of Radiology
ACR Appropriateness Criteria®
Breast Cancer Screening

Variant 1: **Breast cancer screening. Average-risk women: women with <15% lifetime risk of breast cancer.**

Procedure	Appropriateness Category	Relative Radiation Level
Mammography screening	Usually Appropriate	☢☢
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
US breast	May Be Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
FDG-PET breast dedicated	Usually Not Appropriate	☢☢☢☢
Sestamibi MBI	Usually Not Appropriate	☢☢☢

Variant 3: **Breast cancer screening. High-risk women: women with a BRCA gene mutation and their untested first-degree relatives, women with a history of chest irradiation between 10 to 30 years of age, women with 20% or greater lifetime risk of breast cancer.**

Procedure	Appropriateness Category	Relative Radiation Level
Mammography screening	Usually Appropriate	☢☢
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
MRI breast without and with IV contrast	Usually Appropriate	O
US breast	May Be Appropriate	O
FDG-PET breast dedicated	Usually Not Appropriate	☢☢☢☢
Sestamibi MBI	Usually Not Appropriate	☢☢☢
MRI breast without IV contrast	Usually Not Appropriate	O

Variant 5: Supplemental breast cancer screening. Intermediate-risk females with dense breasts.

Women at intermediate risk for breast cancer are defined as having a 15% to 20% lifetime risk [15]. Although there are clear screening guidelines for women with >20% lifetime risk, the screening guidelines have not been clearly defined for women who are at intermediate risk. Women in this category may include patients who have been diagnosed with lobular neoplasia, atypical ductal hyperplasia, previous history of breast cancer, or have a family history of breast cancer without known genetic mutations such as BRCA1/2.

Digital Breast Tomosynthesis Screening

DBT allows quasi 3-D images to be reconstructed from the acquired data set, allowing for viewing of the reconstructed planar images, thus decreasing the superimposition of normal parenchyma and "unmasking" clinically significant obscured lesions. The addition of DBT to 2-D mammography increases the CDR compared with use of 2-D mammography alone, resulting in an increase in the CDR, ranging from 1.2/1,000 to 3.0/1,000 [16-20]. Although most studies have reported a statistically significant increase in the CDR with the addition of DBT, some studies have failed to reach statistical significance [21-23]. In the UK National Health Service TOMMY trial, the odds ratio of DBT plus 2-D mammography, compared with 2-D mammography alone, in detecting breast cancer was 1.34; however, this did not reach statistical significance [21,22]. The increase in the CDR has also been demonstrated to be maintained with subsequent screening rounds [17].

The greatest improvement in the CDR with DBT is seen in women with dense breast tissue [21,22,57,58]. Although the TOMMY trial did not reach statistical significance across all breast densities, in women with >50% breast density, statistical significance was achieved with the sensitivity of 2-D mammography plus DBT reaching 93% versus 86% for 2-D mammography alone [21,22]. In a meta-analysis of 16 studies evaluating women with dense breasts, DBT improved the CDR compared with 2-D mammography alone, in both the diagnostic (RR: 1.16) and the screening (RR: 1.33) settings [58].

In addition to the increase in the CDR, another benefit of adding DBT to 2-D mammography is the reduction in the recall rate [16-19]. In a single-center screening program, Sharpe et al [18] reported a reduction in the recall rate by 18.8%. In the prospective Oslo Tomosynthesis Screening Trial, the recall rate was reduced from 6.7/1,000 to 3.6/1,000 [19]. There is also evidence that the reduction in the recall rate is maintained over consecutive screening episodes [18].

US Breast

Mammography is the only screening modality proven to decrease breast cancer mortality; however, limited sensitivity of mammography in women with elevated breast density has been in the national spotlight. Currently, national breast density notification legislation is pending, although >75% of the states have currently passed the legislation at the state level. The sensitivity of mammography in fatty breast tissue has been reported to be as high as 98% [5]. In a group of 1,399 women diagnosed with invasive breast carcinoma, Häberle et al [24] assessed the probability of mammography failure based on the breast density. Only 107/1,399 cancers were visible on sonography, and the authors found a strong correlation between breast density and mammographic failure. For low-risk women with low breast density, the probability of mammographic failure was 1%, whereas the risk was as high as 40% for high-risk women with dense breast tissue.

In women with a personal history of breast cancer, the supplemental CDR of screening US has been reported to be 2.88/1,000 [34]. There was no difference in the CDR based on breast density or age. However, the authors reported an interval cancer rate of 1.5/1,000, which was higher in women who were <50 years of age and in those with dense breast tissue, indicating the failure of screening US in the 2 subgroups.

Appropriateness Criteria Evidence Table

Supplemental Breast Cancer Screening Based on Breast Density

Reference	Study Type	Patients/Events	Study Objective(Purpose of Study)	Study Results	Study Quality
1. Broeders M, Moss S, Nystrom L, et al. The impact of mammographic screening on breast cancer mortality in Europe: a review of observational studies. [Review]. J Med Screen. 19 Suppl 1:14-25, 2012.	Review/Other-Dx	20 studies	To assess the impact of population-based mammographic screening on breast cancer mortality in Europe, considering different methodologies and limitations of the data.	Twelve of the 17 trend studies quantified the impact of population-based screening on breast cancer mortality. The estimated breast cancer mortality reductions ranged from 1% to 9% per year in studies reporting an annual percentage change, and from 28% to 36% in those comparing post- and prescreening periods. In the IBM studies, the pooled mortality reduction was 25% (relative risk [RR] 0.75, 95% confidence interval [CI] 0.69-0.81) among invited women and 38% (RR 0.62, 95% CI 0.56-0.69) among those actually screened. The corresponding pooled estimates from the CC studies were 31% (odds ratio [OR] 0.69, 95% CI 0.57-0.83), and 48% (OR 0.52, 95% CI 0.42-0.65) adjusted for self-selection.	4
2. Nickson C, Mason KE, English DR, Kavanagh AM. Mammographic screening and breast cancer mortality: a case-control study and meta-analysis. Cancer Epidemiol Biomarkers Prev. 21(9):1479-88, 2012 Sep.	Meta-analysis	9 studies	To evaluate the effect of participation in the BreastScreen Australia program, we conducted a case–control study of deaths from breast cancer in Western Australia. To evaluate the potential effect of biases discussed in the literature on case–control studies of screening, we conducted several sensitivity analyses. We also conducted a meta-analysis of case–control studies evaluating mammographic screening.	The OR for participation in the Western Australian BreastScreen program in relation to death from breast cancer was 0.48 [95% confidence interval (CI), 0.38-0.59; P < 0.001]. We were unable to identify biases that could negate this finding: sensitivity analyses generated ORs from 0.45 to 0.52. Our meta-analysis yielded an OR of 0.51 (95% CI, 0.46-0.55).	Good
3. Tabar L, Vitak B, Chen TH, et al. Swedish two-county trial: impact of mammographic screening on breast cancer mortality during 3 decades. Radiology 2011;260:658-63.	Observational-Dx	133,065 women	To estimate the long-term (29-year) effect of mammographic screening on breast cancer mortality in terms of both relative and absolute effects.	There was a highly significant reduction in breast cancer mortality in women invited to screening according to both local end point committee data (relative risk [RR] = 0.69; 95% confidence interval: 0.56, 0.84; P < .0001) and consensus data (RR = 0.73; 95% confidence interval: 0.59, 0.89; P = .002). At 29 years of follow-up, the number of women needed to undergo screening for 7 years to prevent one breast cancer death was 414 according to local data and 519 according to consensus data. Most prevented breast cancer deaths would have occurred (in the absence of screening) after the first 10 years of follow-up.	1
4. D'Orsi CJ, Sickles EA, Mendelson EB, et al. ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA: American College of Radiology; 2013.	Review/Other-Dx	N/A	To provide standardized breast imaging findings terminology, report organization, assessment structure and a classification system for mammography, ultrasound and MRI of the breast.	No abstract available.	4

Should my patient have bilateral complete breast screening ultrasound or MRI?

- Does the patient have dense breasts or not?
- What is their lifetime risk of breast cancer?

- ACR Appropriateness Criteria for Non Dense breasts with risk stratification
  - Average risk (<15% lifetime risk) – no
  - Intermediate risk (15-20%) – MRI may be appropriate, US usually not appropriate
  - High risk (>20%) – usually appropriate

- ACR Appropriateness Criteria for dense breasts with risk stratification
  - Average risk (<15% lifetime risk) – US consensus panel split (no agreement), MRI may be appropriate
  - Intermediate risk (15-20%) – US and MRI may be appropriate
  - High risk (>20%) – US and MRI usually appropriate

Supplemental Screening for Dense Breasts

Variant 4: Supplemental breast cancer screening. Average-risk females with dense breasts.

Procedure	Appropriateness Category	Relative Radiation Level
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
Mammography with IV contrast	May Be Appropriate	☢☢
US breast	May Be Appropriate (Disagreement)	O
MRI breast without and with IV contrast	May Be Appropriate	O
MRI breast without and with IV contrast abbreviated	May Be Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast abbreviated	Usually Not Appropriate	O
Sestamibi MBI	Usually Not Appropriate	☢☢☢
FDG-PET breast dedicated	Usually Not Appropriate	☢☢☢☢

Variant 5: Supplemental breast cancer screening. Intermediate-risk females with dense breasts.

Procedure	Appropriateness Category	Relative Radiation Level
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
Mammography with IV contrast	May Be Appropriate	☢☢
US breast	May Be Appropriate	O
MRI breast without and with IV contrast	May Be Appropriate	O
MRI breast without and with IV contrast abbreviated	May Be Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast abbreviated	Usually Not Appropriate	O
Sestamibi MBI	Usually Not Appropriate	☢☢☢
FDG-PET breast dedicated	Usually Not Appropriate	☢☢☢☢

High Risk patients with dense breasts

Variant 6: Supplemental breast cancer screening. High-risk females with dense breasts.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Appropriate	O
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
MRI breast without and with IV contrast	Usually Appropriate	O
MRI breast without and with IV contrast abbreviated	Usually Appropriate	O
Mammography with IV contrast	May Be Appropriate	☢☢
MRI breast without IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast abbreviated	Usually Not Appropriate	O
Sestamibi MBI	Usually Not Appropriate	☢☢☢
FDG-PET breast dedicated	Usually Not Appropriate	☢☢☢☢

High Risk patients with non dense breasts

Variant 3: **Supplemental breast cancer screening. High-risk females with nondense breasts.**

Procedure	Appropriateness Category	Relative Radiation Level
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
MRI breast without and with IV contrast	Usually Appropriate	O
Mammography with IV contrast	May Be Appropriate	☢☢
US breast	May Be Appropriate	O
MRI breast without and with IV contrast abbreviated	May Be Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast abbreviated	Usually Not Appropriate	O
Sestamibi MBI	Usually Not Appropriate	☢☢☢
FDG-PET breast dedicated	Usually Not Appropriate	☢☢☢☢

How are patient's and their physicians or other provider's notified of breast density?

- Patient's are mailed their mammogram results using lay terminology and they are informed that if they have dense breast tissue to discuss supplemental screening with their ordering provider
- Provider's will be able to view the actual mammogram report in the patient's chart and it will state Type A/B/C/D

Can breast density change?

- Yes
- Qualitative appearance on mammogram and is up to the interpreting radiologist
- Can change year to year
- Can change with hormonal fluctuations including pregnancy, breast feeding, menopause, HRT (including pellets), weight loss, age

How should I order additional screening tests?

- Breast Ultrasound
- Please specify “Bilateral Complete” breast ultrasound in your order and state “supplemental breast cancer screening” in your provided history

- MRI of the breasts
- If your patient is high risk when calculated, consider referring to our High Risk breast cancer screening program at the UMC cancer center

References

- Http://www.acr.org
- https://acsearch.acr.org/
- https://ibis.ikonopedia.com/
- Okello J, Kisembo H, Bugeza S, Galukande M. Breast cancer detection using sonography in women with mammographically dense breasts. BMC Med Imaging. 2014 Dec 30;14:41. doi: 10.1186/s12880-014-0041-0. PMID: 25547239; PMCID: PMC4311471.
- https://www.acr.org/Practice-Management-Quality-Informatics/Practice-Toolkit/Patient-Resources/Mammography-Saves-Lives/Breast-Density-and-You
- https://www.cancer.gov/types/breast/breast-changes/dense-breasts
- https://www.breastcancer.org/risk/risk-factors/dense-breasts

References

- Advani SM, Zhu W, Demb J, et al. Association of Breast Density With Breast Cancer Risk Among Women Aged 65 Years or Older by Age Group and Body Mass Index. JAMA Netw Open. 2021;4(8):e2122810. doi:10.1001/jamanetworkopen.2021.22810