# The Journey of Breast Density Legislation

## THE NEED FOR SUPPLEMENTAL SCREENING INSURANCE COVERAGE

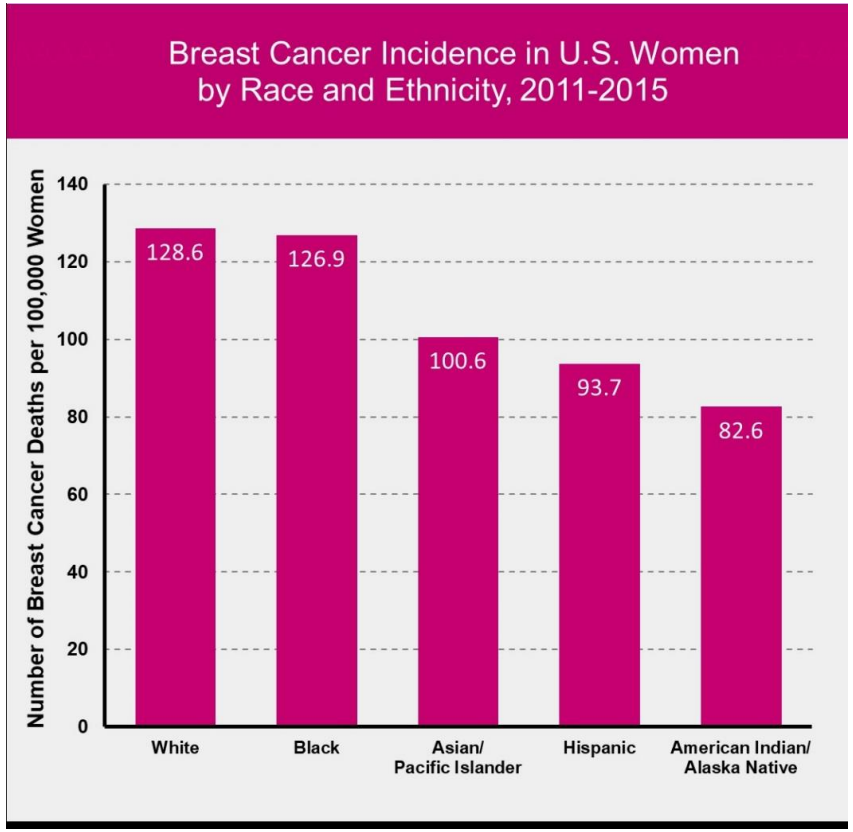
# Breast Cancer Statistics

It is estimated that in 2020, there were approximately 276,480 new cases of invasive breast cancer in women

75% of new breast cancers are diagnosed in patients with no family history

1 in 8 U.S. women will develop breast cancer in their lifetime (~12%)

1 in 6 breast cancers are diagnosed in women in their fourth decade of life



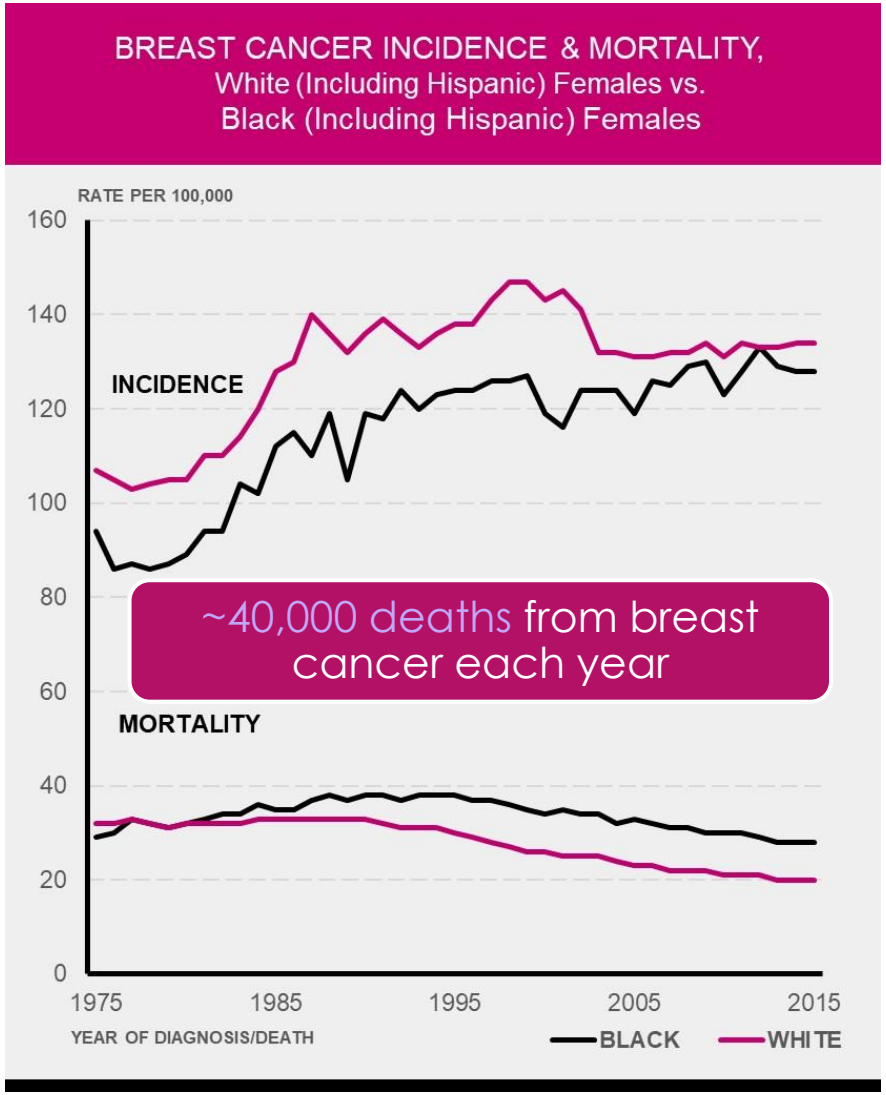

Source: SEER Cancer Statistics Review, 1975-2015, 2018

# Breast Cancer Mortality

Breast cancer death rates in the U.S. slowly rose from 1975 to 1990

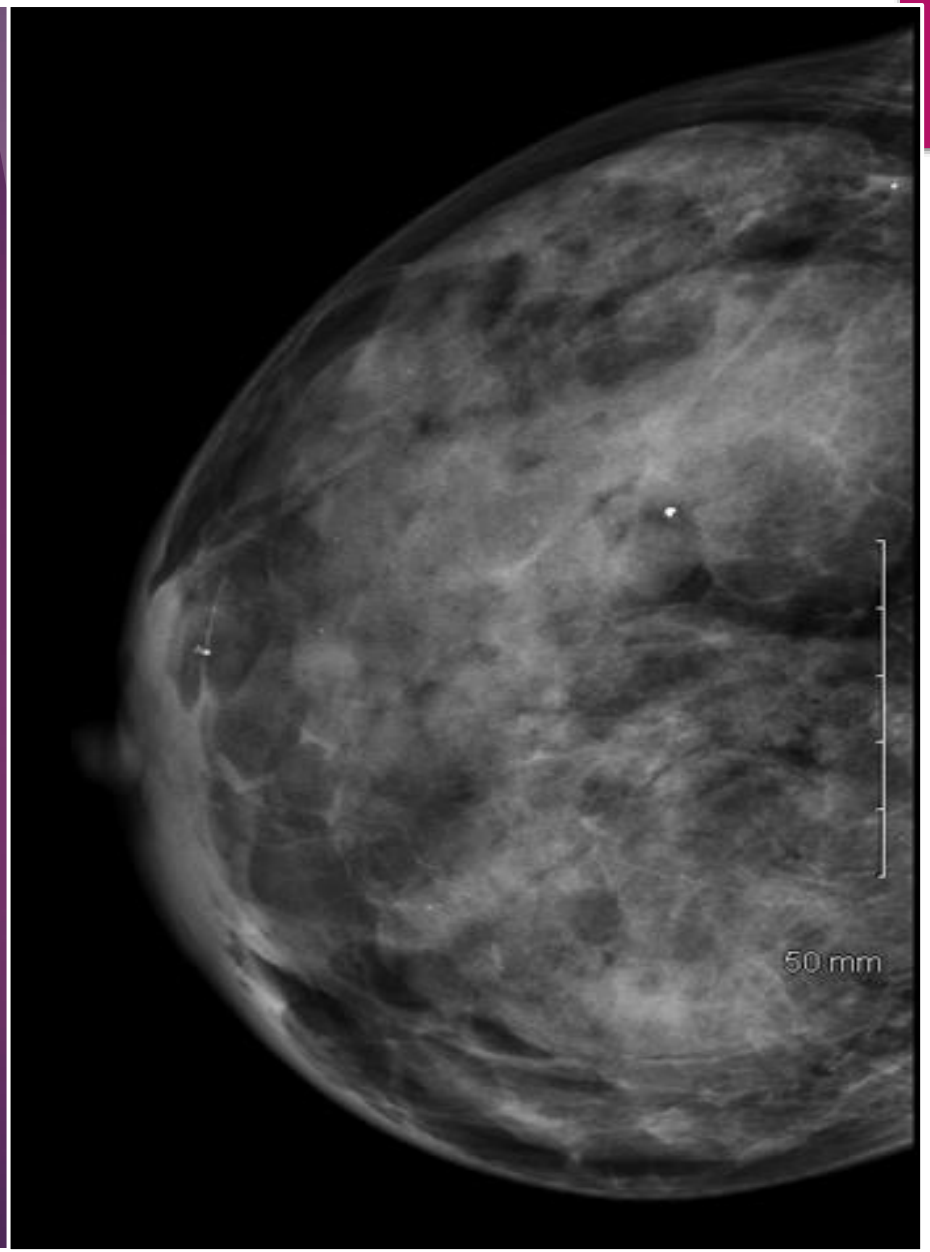
There has been a 39% decrease in breast cancer death rates between 1990 and 2015

The decline is attributed to improved detection and treatment

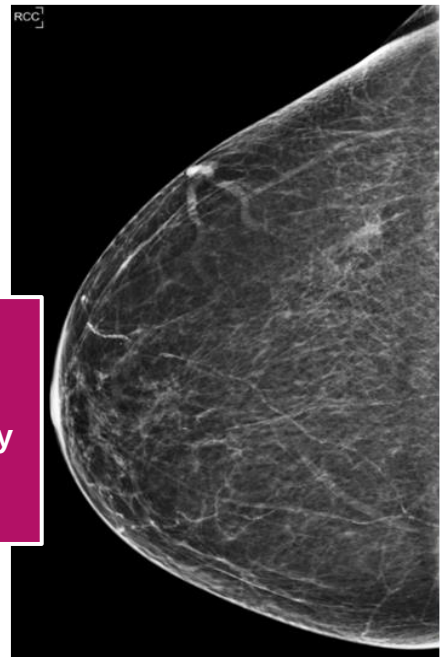



Source: SEER Cancer Statistics Review, 1975-2015, 2018

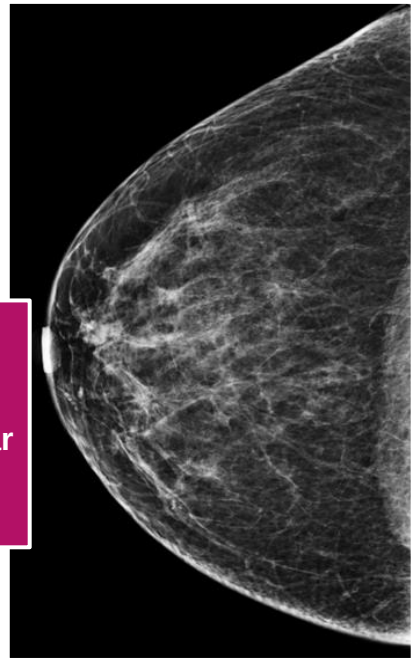
# Breast Density



Almost entirely fatty



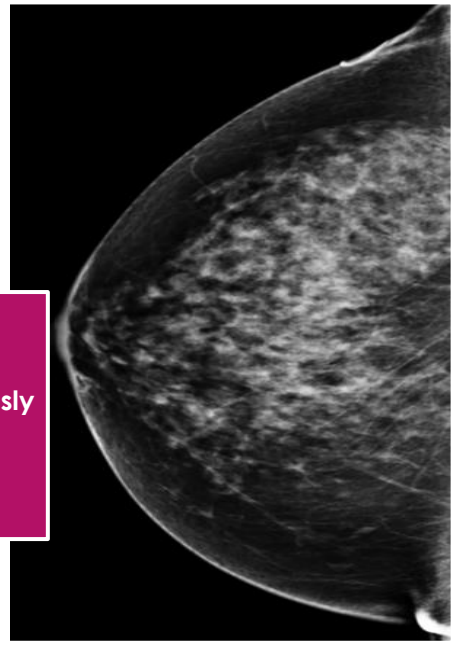

Scattered areas of fibroglandular density



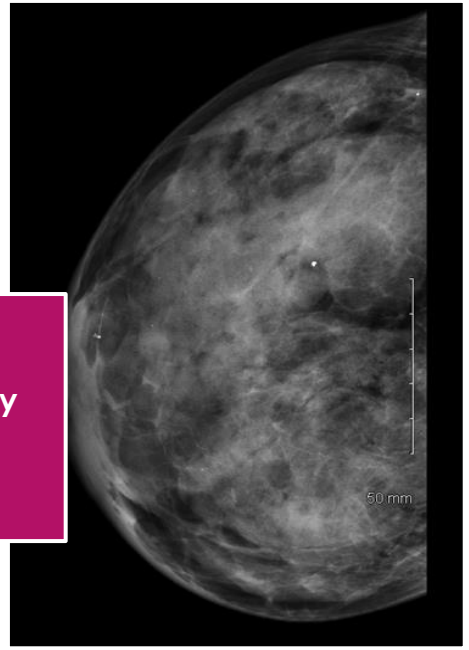
# 4 Categories of Breast Density

| Breast Composition Categories |
|---|
| a. The breasts are almost entirely fatty |
| b. There are scattered areas of fibroglandular density |
| c. The breasts are heterogeneously dense, which may obscure small masses |
| d. The breasts are extremely dense, which lowers the sensitivity of mammography |

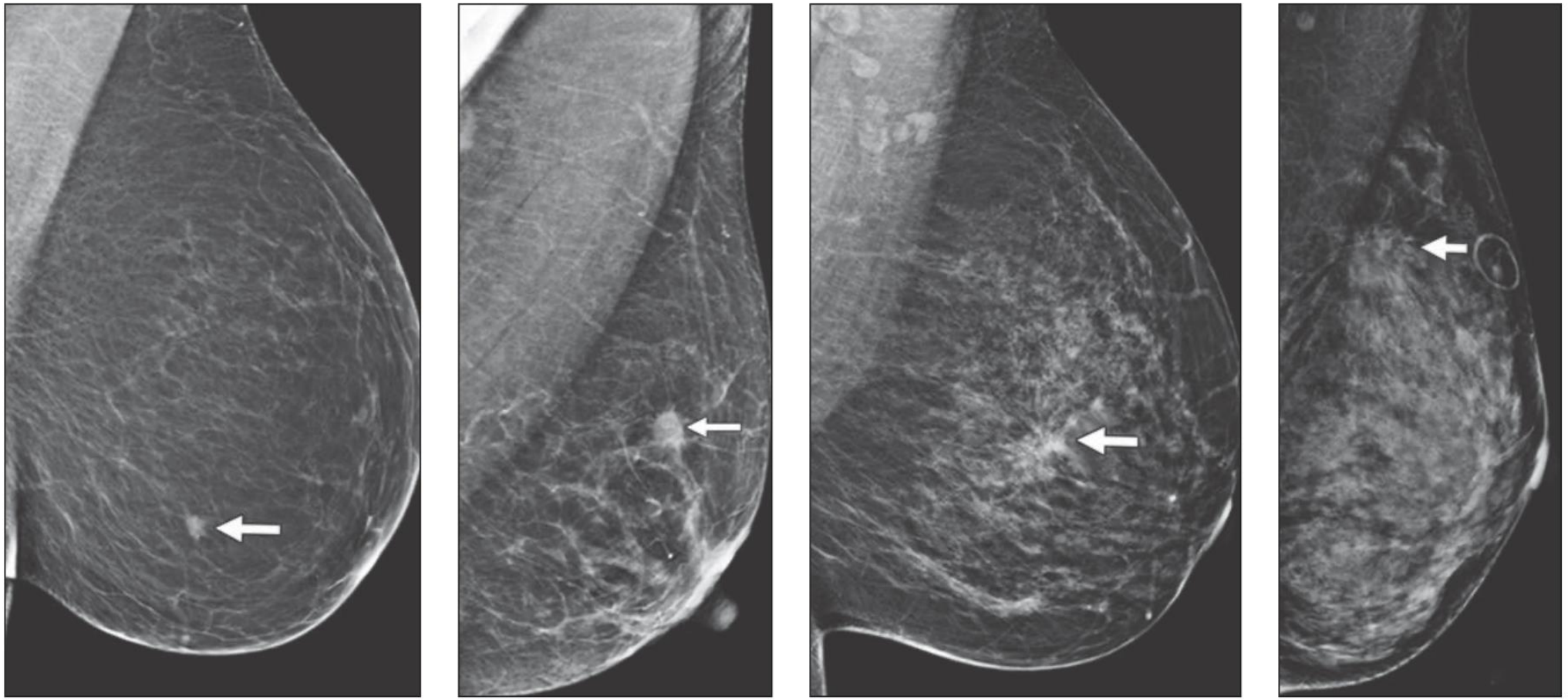
Heterogeneously dense



Extremely dense




- **~40%** of women have dense breasts (**Categories c & d**)

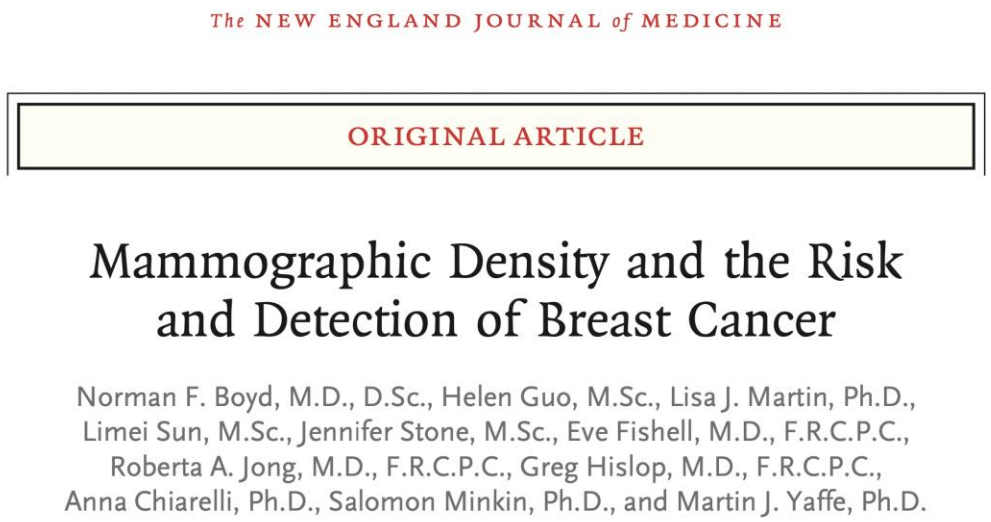


**Masking** is caused by the **lack of contrast** between the fibroglandular tissue and breast cancer, both of which appear **white** on mammography, while fat appears black

Berg et al. *Am J Roentgenol*, 2021

# Breast Cancer Risk

- Density is a three-pronged risk factor
  - **4-6 times more likely** to have cancer
  - **17.8 times more likely** to have an interval cancer (missed on a mammogram)
  - Kerlikowske et al. showed **decreased specificity** with higher density



The NEW ENGLAND JOURNAL of MEDICINE

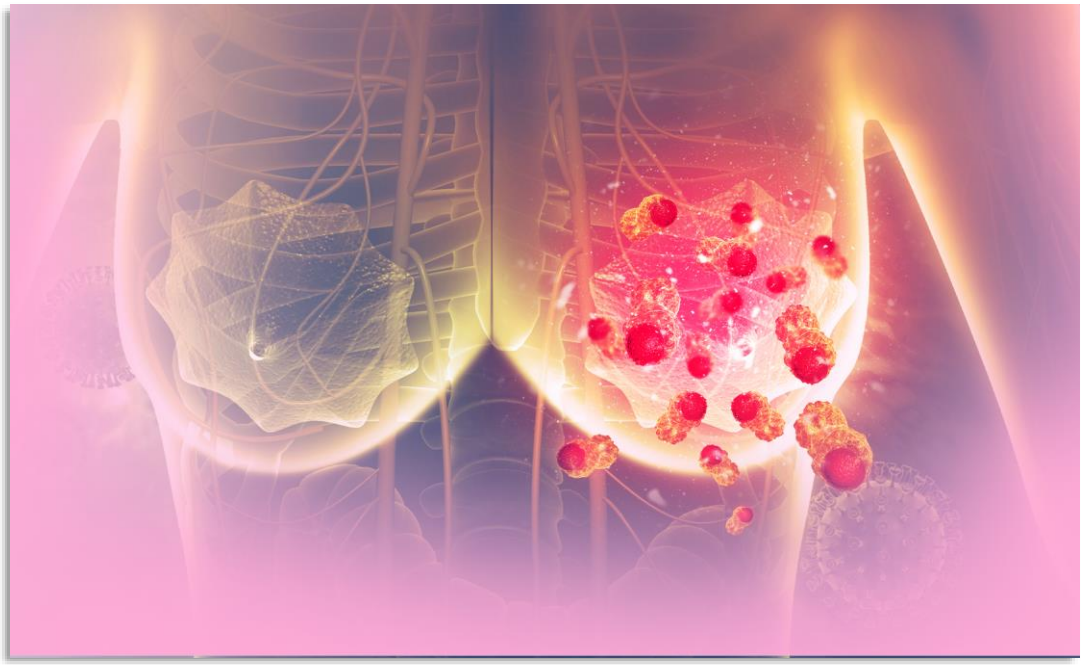
ORIGINAL ARTICLE

## Mammographic Density and the Risk and Detection of Breast Cancer

Norman F. Boyd, M.D., D.Sc., Helen Guo, M.Sc., Lisa J. Martin, Ph.D., Limei Sun, M.Sc., Jennifer Stone, M.Sc., Eve Fishell, M.D., F.R.C.P.C., Roberta A. Jong, M.D., F.R.C.P.C., Greg Hislop, M.D., F.R.C.P.C., Anna Chiarelli, Ph.D., Salomon Minkin, Ph.D., and Martin J. Yaffe, Ph.D.

Boyd et al. *NEJM*, 2007
Kerlikowske et al. *Ann Intern Med*, 2011

# Breast Cancer Risk

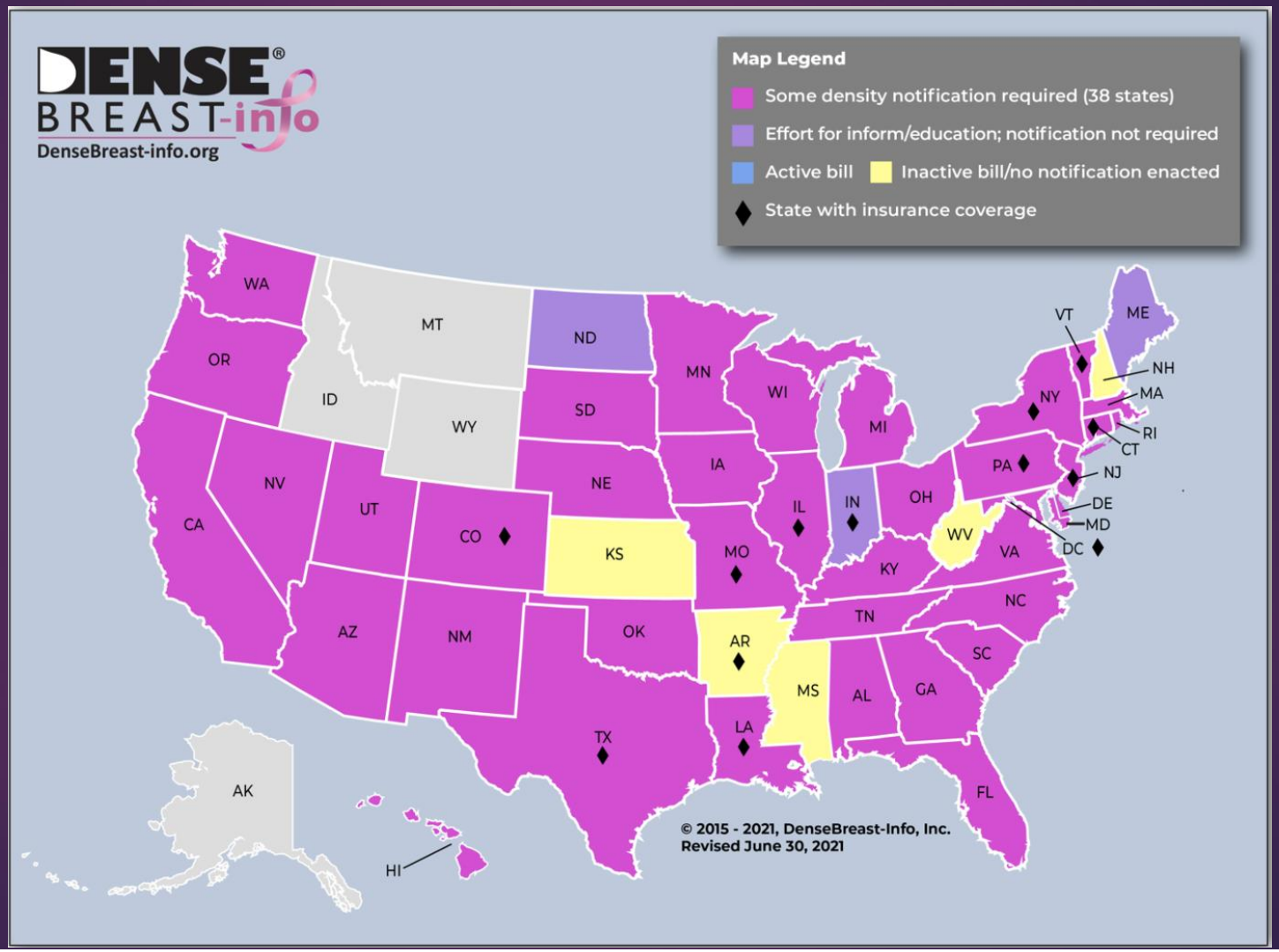


- Women with dense tissue have breast cancers that are
  - Larger
  - More likely lymph node positive
  - Higher stage
  - More often require mastectomy
  - **Two-fold more likely to result in death**

Bertrand et al. *Breast Cancer Res*, 2013
Chiu et al. *Cancer Epidemiology Biomarkers & Prevention*, 2010
Arora et al. *Ann Surg Oncol*, 2010

# Breast Density Legislation

# Currently, only **12 states** mandate insurance coverage of supplemental breast cancer screening



# Ohio Breast Density Law in 2014

**Sec. 3702.40.** (A) As used in this section, "mammogram" and "facility" have the same meanings as in section 263b(a) of the "Mammography Quality Standards Act of 1992," 106 Stat. 3547 (1992), 42 U.S.C. 263b(a), as amended.

(B) As required by 21 C.F.R. 900.12(c)(2), a facility shall send to each patient who has a mammogram at the facility a summary of the written report containing the results of the patient's mammogram. If, based on the breast imaging reporting and data system established by the American college of radiology, the patient's mammogram demonstrates that the patient has dense breast tissue, the summary shall include the following statement:

"Your mammogram demonstrates that you have dense breast tissue, which could hide abnormalities. Dense breast tissue, in and of itself, is a relatively common condition. Therefore, this information is not provided to cause undue concern; rather, it is to raise your awareness and promote discussion with your health care provider regarding the presence of dense breast tissue in addition to other risk factors."

As required by 21 C.F.R. 900.12(c)(3), the facility shall send to the patient's health care provider, if known, a copy of the written report containing the results of the patient's mammogram not later than thirty days after the mammogram was performed.

(C) This section does not do either of the following:

(1) Create a new cause of action or substantive legal right against a person, facility, or other entity;

(2) Create a standard of care, obligation, or duty for a person, facility, or other entity that would provide the basis for a cause of action or substantive legal right, other than the duty to send the summary and written report described in division (B) of this section.

The State of Ohio — The Buckeye State

State Capitol *Columbus


Breast Density Notification Law Section 3702.40 (Effective March 19, 2015)

No information about increased breast cancer risk or supplemental screening

# Breast Density Legislation: The Gap

- State mandated density notification
  - Does not include information about **supplemental screening** tests
  - Does not include information about **increased risk** of breast cancer
  - Uses language that **exceeds recommended readability levels**

- State mandated breast cancer screening coverage does not include **tomosynthesis/3D mammography** or **supplemental screening**

Results in income-based health care disparities particularly in rural and urban communities

# Bridging the Gap: Advanced Screening

# Cancer Detection with Advanced Mammography

## Digital Breast Tomosynthesis (DBT)/ 3-D Mammography

- ✓ Improves sensitivity and specificity of screening mammography
  - ✓ ~40% more invasive cancers
  - ✓ Earlier stage at diagnosis
  - ❑ **No benefit in extremely dense breasts**
- ✓ Decreases recall rate
  - ✓ ~20% fewer callbacks for false positive findings

Greenberg et al. *Am J Roentgenol*, 2014
Rafferty et al. *JAMA*, 2016

# Cancer Detection with Supplemental Screening

Supplemental screening tests, such as **ultrasound and MRI**, in addition to the mammogram can substantially **increase detection of early-stage, node negative breast cancers** and **reduce interval cancers** in dense breasts

- **ACRIN 6666 (2012) –** Ultrasound
- **Kuhl et al. (2014) –** Abbreviated MRI
- **ASTOUND trial (2016) –** Ultrasound
- **Kuhl et al. (2017) –** Abbreviated MRI
- **ASTOUND-2 trial (2018) –** Ultrasound
- **DENSE trial – Round 1 (2019) –** MRI
- **EA 1141 (2020) –** Abbreviated MRI
- **DENSE trial – Round 2 (2021) –** MRI

Berg et al. *JAMA*, 2012
Bakker et al. *NEJM*, 2019
Comstock et al. *JAMA*, 2020
Veenhuizen et al. *Radiology*, 2021

# Cancer Detection with Supplemental Screening

Ultrasound detects up to **2 times more** breast cancers than the 2D mammogram

MRI detects **>2.4 times more** breast cancers than the 3D mammogram and **up to 5 times more** than the 2D mammogram in women with dense breasts who are average risk

| Method | Breast Density | Added Cancer Detection | Projected Impact on False Positive Rate | Types of Cancers Seen |
|---|---|---|---|---|
| Tomosynthesis (3D mammography)[a] | Scattered fibroglandular density or Heterogeneously dense | 1-2 per 1000 [1-3] | Overall decrease in false positive recalls to 80 to 90 per 1000; May drop to 60 to 70 per 1000 after multiple screening rounds (based on a single-center study) [5] | The cancers seen only on tomosynthesis are nearly all invasive; greatest detection benefit and shift to smaller, better prognosis cancers seen in women 40-49 years old [6] |
| Tomosynthesis (3D mammography)[a] | Extremely dense | Negligible [2, 7, 8] | No significant reduction in false positive recall rate | Not applicable |
| Ultrasound (US) (first round) | Heterogeneously dense or Extremely dense | 2-3 per 1000 [9] | Increase in false positive recalls to 170 to 200 per 1000 | More than 85% of cancers seen only on US are invasive; 82-90% are node negative [9] (still contained within the breast) |
| Ultrasound (US) (subsequent rounds) | Heterogeneously dense or Extremely dense | 2-3 per 1000 | Increase in false positive recalls to 150 to 170 per 1000 [10, 11] | More than 85% of cancers seen only on US are invasive; 82-90% are node negative [9] (still contained within the breast) |
| Ultrasound vs. tomosynthesis | Heterogeneously dense or Extremely dense | 2-3 per 1000 more with US [12, 13] | Increase in false positive recalls with US[b] | |
| MRI (first round) | Extremely dense | 16 per 1000 [14] | Increase in false positive recalls to 178 per 1000 | 13 per 1000 invasive cancer yield (3 per 1000 are non-invasive, i.e. DCIS) seen only on MRI |
| MRI (subsequent rounds) | Extremely dense | 6 per 1000 [15] | Increase in false positive recalls to 127 per 1000 | 4 per 1000 invasive cancer yield (2 per 1000 are non-invasive, i.e. DCIS) seen only on MRI |
| Abbreviated ("fast" or "mini") MRI after tomosynthesis[c] | Heterogeneously dense or Extremely dense | 10 per 1000 [16] | Increase in false positive recalls: 133 per 1000 for MRI vs. 26 per 1000 for tomosynthesis | 7 per 1000 invasive cancer yield (3 per 1000 are non-invasive) seen only on MRI in first round of screening<br><br>© DenseBreast-info.org and Dr. Wendie Berg |

*DenseBreast-Info.org*

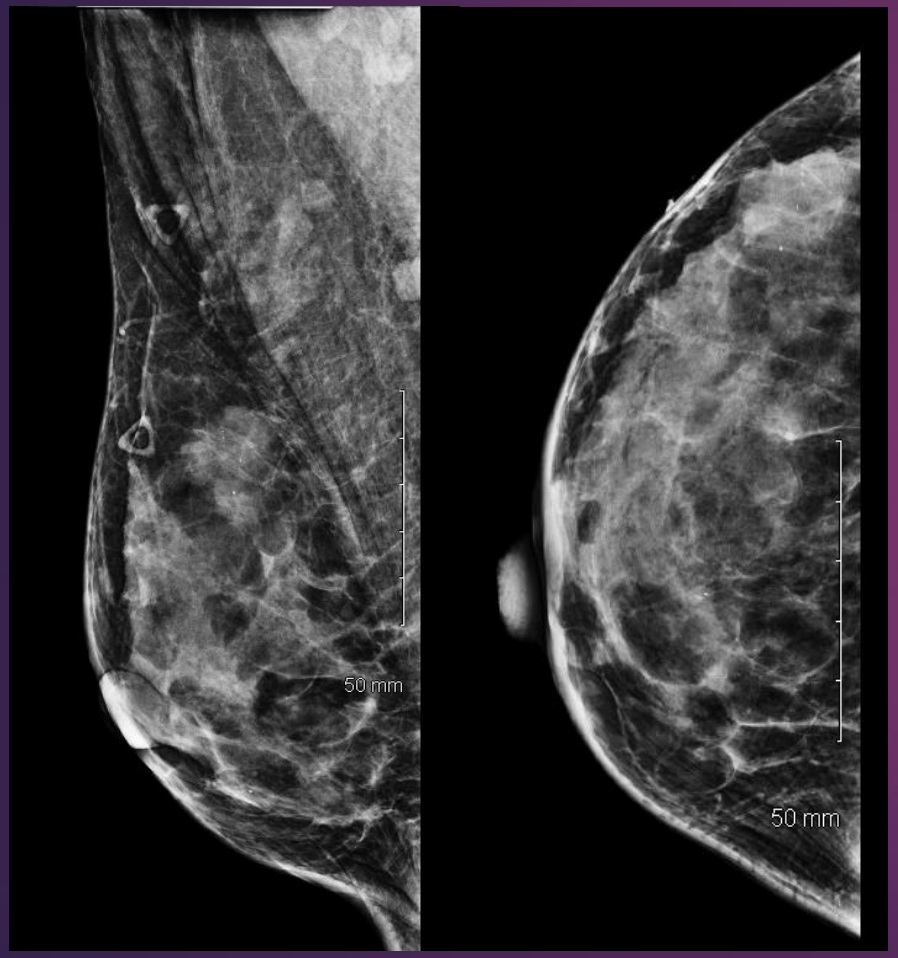
DCIS = ductal carcinoma in situ

[a] In many centers, a "standard" 2D mammogram can be created from the same projection images used to generate the tomosynthesis ("synthetic" 2D mammogram) so that there is no added radiation or second exposure for the 2D mammogram.

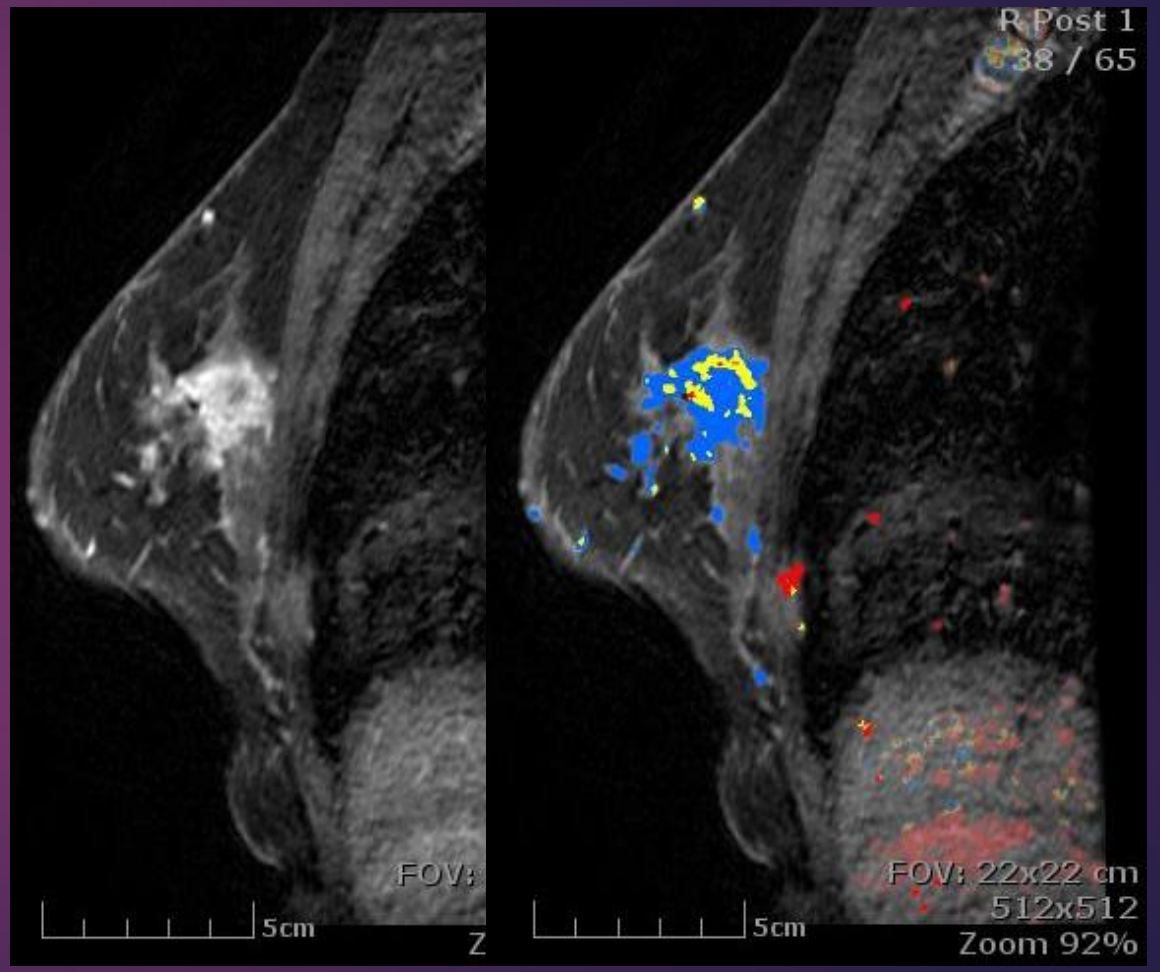
[b] In the Italian multicenter ASTOUND-2 trial, ultrasound increased recalls more than tomosynthesis (1.0% vs. 0.3%) after a negative 2D mammogram, but recall rates are not comparable to those in the United States.

[c] In this prospective trial across 48 centers in the United States and Germany, abbreviated MRI was compared to tomosynthesis (3D mammography).

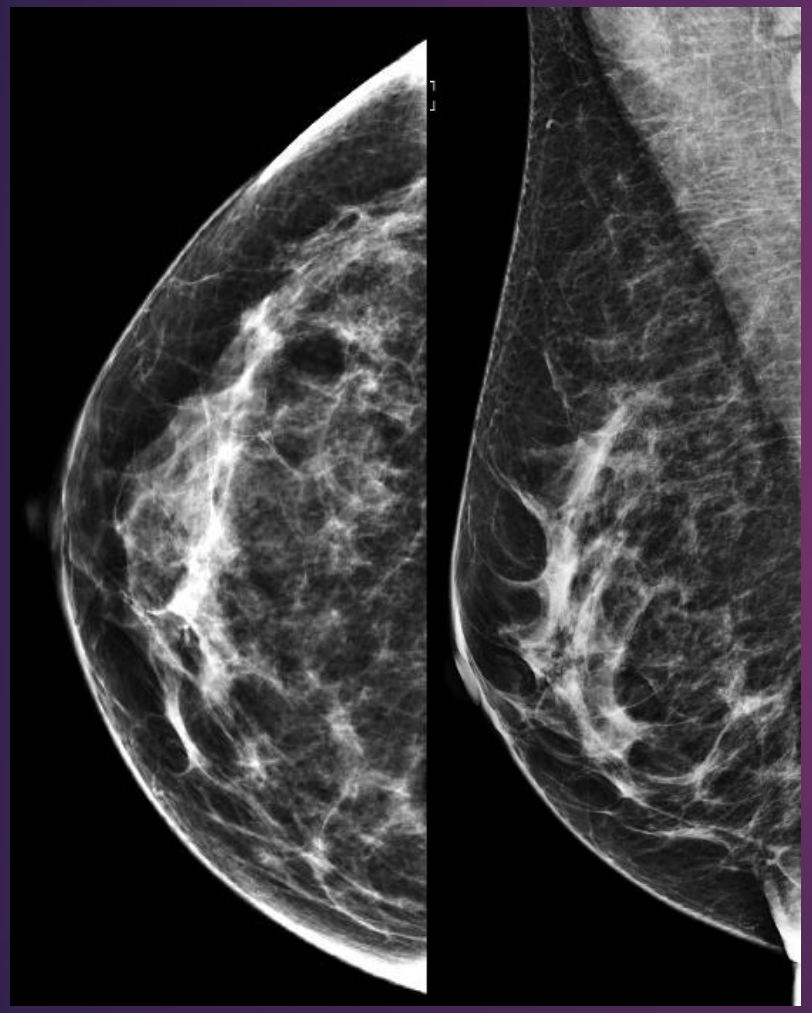
## Mammogram from June



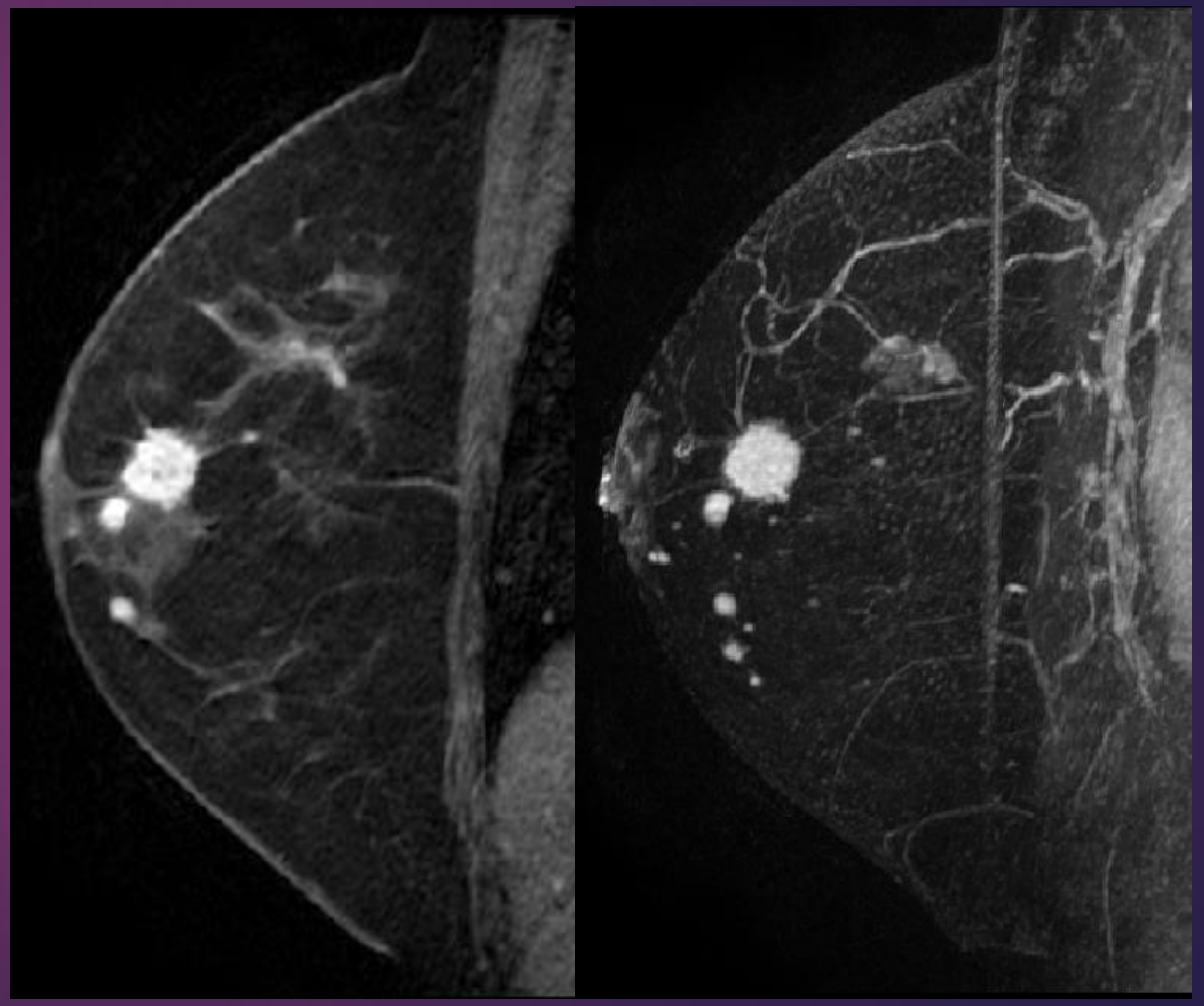

## Breast MRI from June



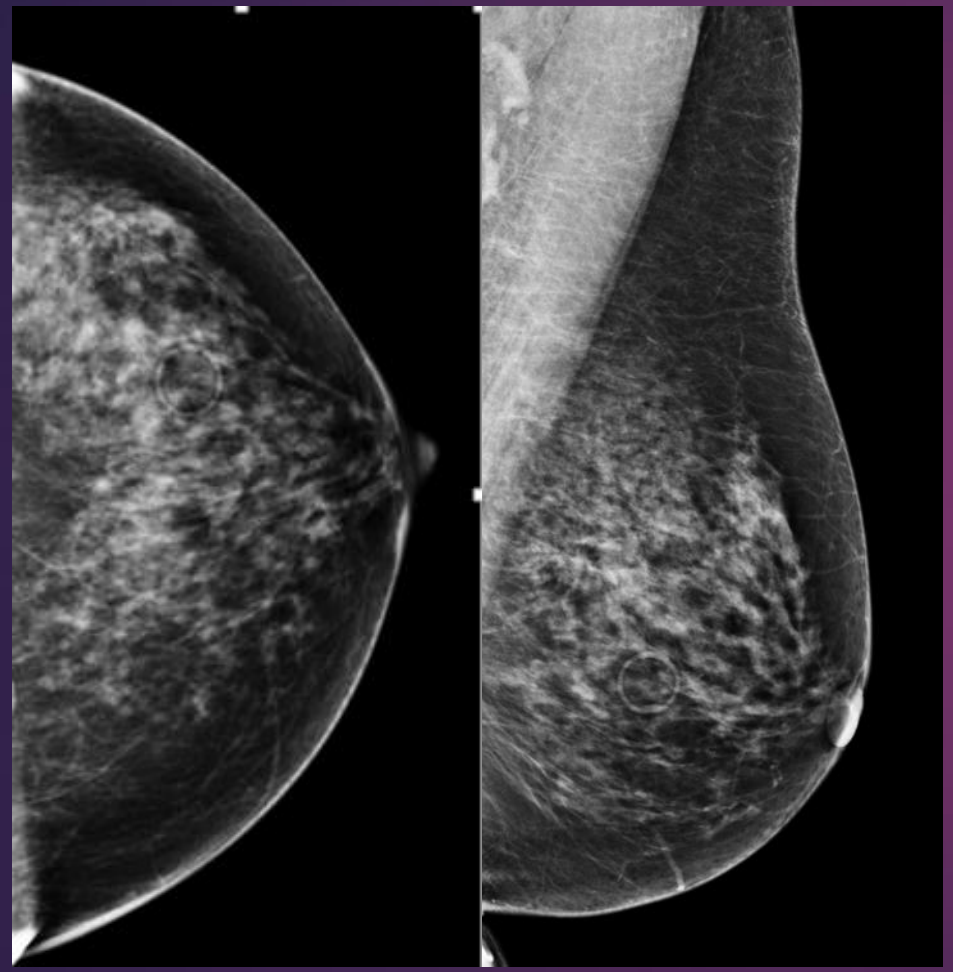
Screening Mammogram from March



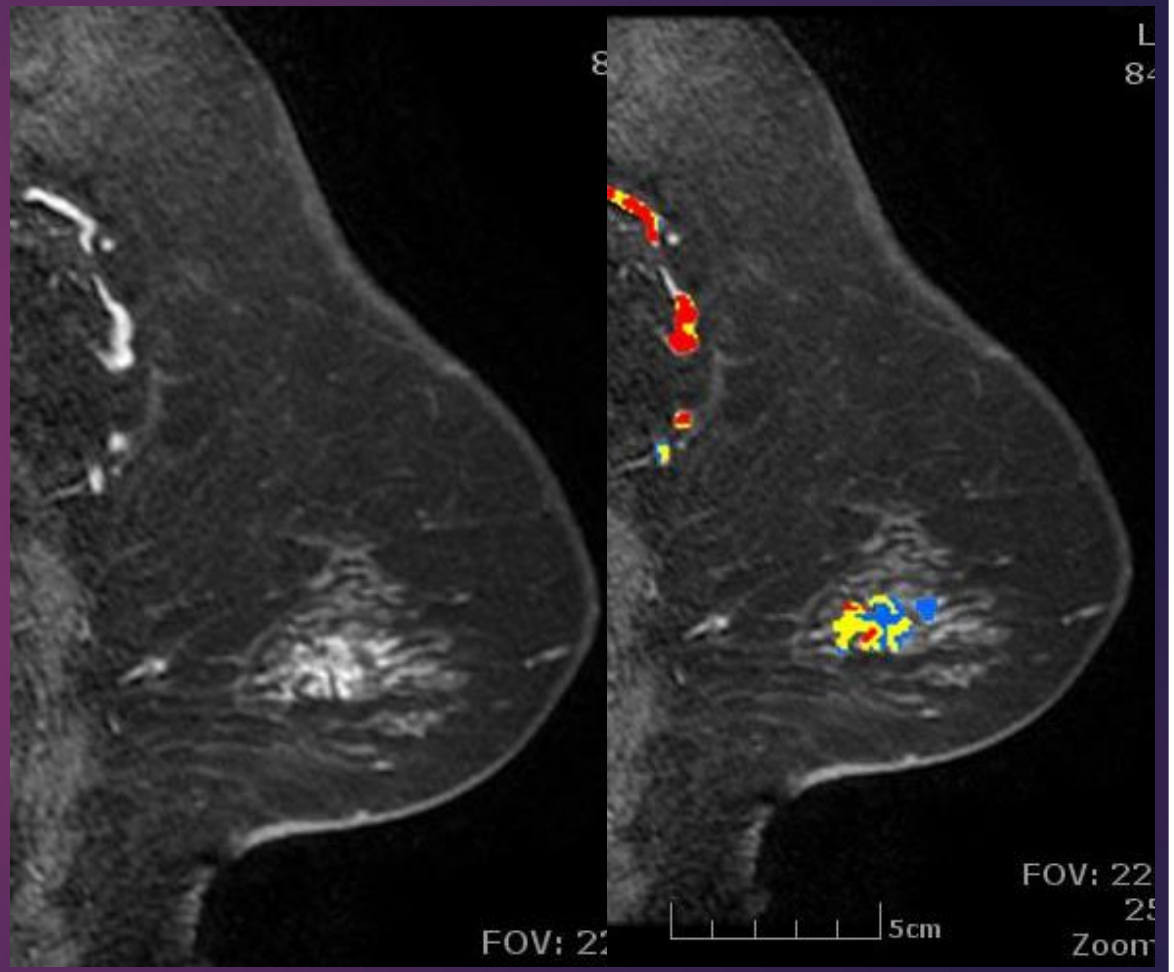
Breast MRI from April



## Screening Mammogram from May



## Breast MRI from May




University of CINCINNATI

# Ohio Breast Cancer Screening Modernization Act

# Ohio H.B. 371

- Extends coverage to include tomosynthesis
- Extends coverage to include a yearly mammogram
- Removes age limitations for screening mammography
- Provides additional coverage for supplemental screening
- Improves dense breast notification letter to patients

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