DEPARTMENT OF RADIOLOGY

The Journey of Breast Density Legislation

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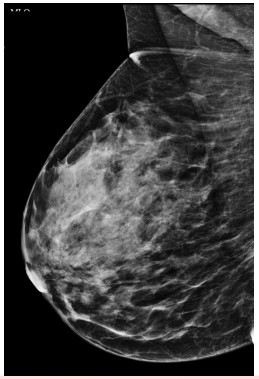
Why All the Hype?

Began in Connecticut in 2004

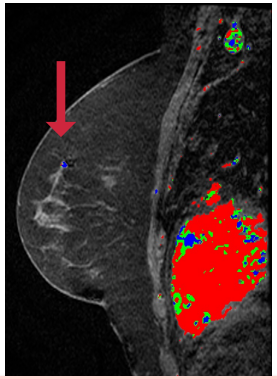
Nancy Cappello PhD was diagnosed with regionally metastatic stage 3 breast cancer

Her cancer was found on a clinical breast exam despite having a normal mammogram about a month prior



She had dense breasts on her mammogram

Her primary doctor and radiologist knew she had dense breasts; however, she was not informed



She concluded that had she known about her dense breasts she could have had supplemental screening

Connecticut Breast Density Legislation

2005

- Cappello lobbied to have **insurance coverage** for supplemental screening ultrasound in patients with dense breasts
- Bill passed in Connecticut

2008

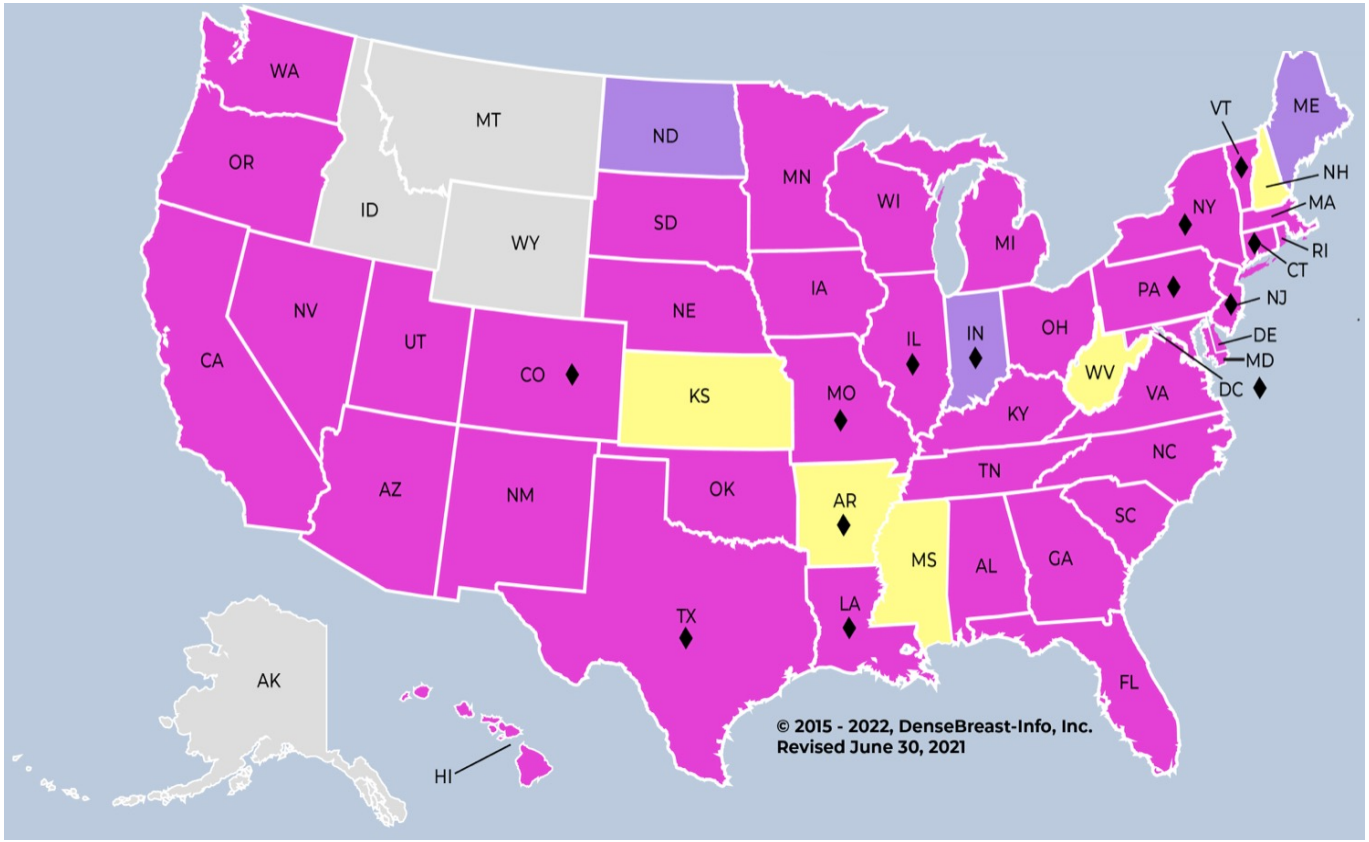
- Cappello founded “Are You Dense?” advocacy
- Advanced breast density legislation in other states

2009

- First breast **density notification** law passed in Connecticut
- Requires direct notification of breast density to the patient so she can seek supplemental screening, which is covered

U.S. Breast Density Legislation

- **38** states have inform laws
- **12** states cover supplemental screening
- **5** states have inactive bills
- **3** states inform/educate



Ohio Breast Density Legislation

As Reported by the House Health and Aging Committee

130th General Assembly
Regular Session
2013-2014

Sub. S. B. No. 54

Senators Kearney, Eklund

Cosponsors: Senators Cafaro, Gentile, Smith, Sawyer, Tavares, Schiavoni, Turner, Lehner, Jones, Bacon, Balderson, Beagle, Burke, Coley, Faber, Gardner, Hite, Hughes, LaRose, Manning, Obhof, Oelslager, Patton, Peterson, Schaffer, Seitz, Skindell, Uecker, Widener

Representatives Wachtmann, Brown

Signed January 2014

Effective March 2015

Ohio Breast Density Legislation

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.

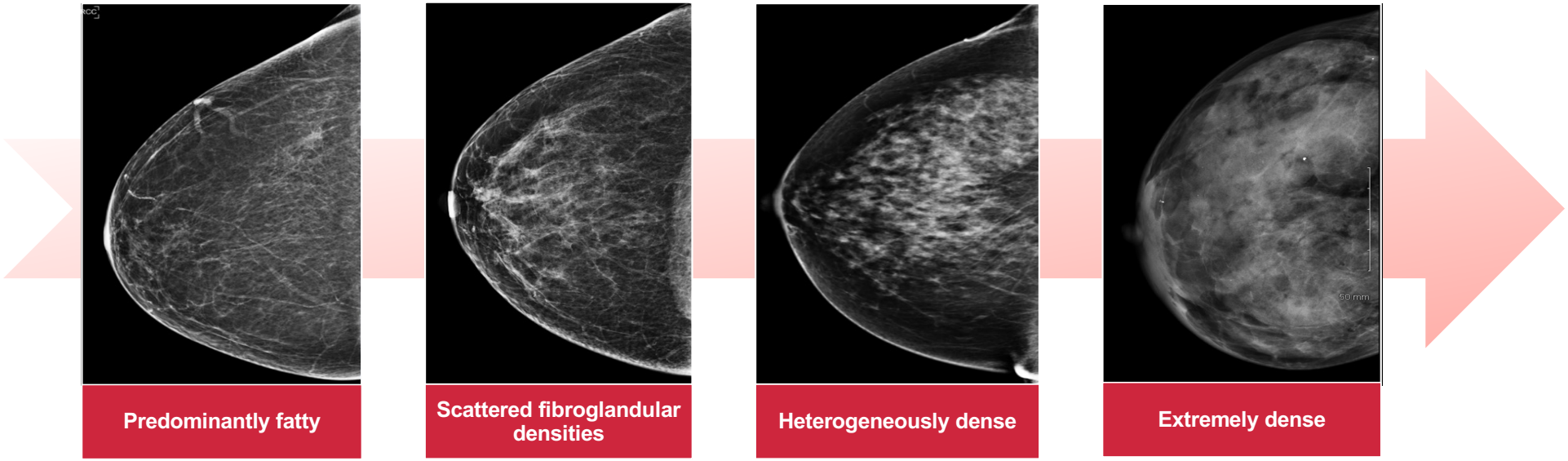
Ohio Breast Density Legislation: The Gap

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

- Ohio breast cancer screening coverage
  - Does not include women under age 50 or over age 65
  - Does not include tomosynthesis or supplemental screening

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

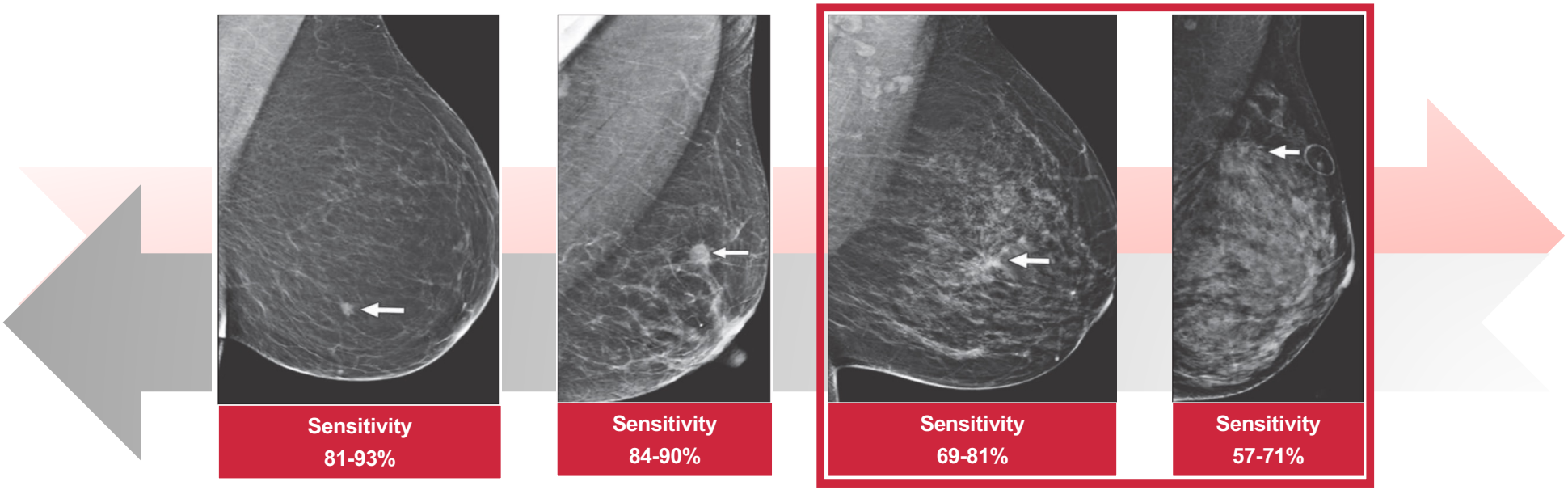
What is Breast Density?



The amount of fibroglandular tissue (white) compared with the amount of fat (black), as seen on a mammogram.

Sickles et al. *ACR BI-RADS® Atlas*, 2013

Why Does Breast Density Matter?



Dense breast tissue can mask cancers, which also show up white on the mammogram.

Sensitivity decreases as breast density increases

Berg et al. *Am J Roentgenol*, 2021
Kerlikowske et al. *Ann Intern Med*, 2011

Breast Cancer Risk

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.

17.8 times more likely to have an interval cancer (missed by a mammogram and detected because of symptoms)

Boyd et al. *NEJM*, 2007

Breast Cancer Risk

- **Most risk factors cannot be altered** because they are part of our human characteristic.

75% of all new breast cancers are diagnosed in patients who have **no family history**

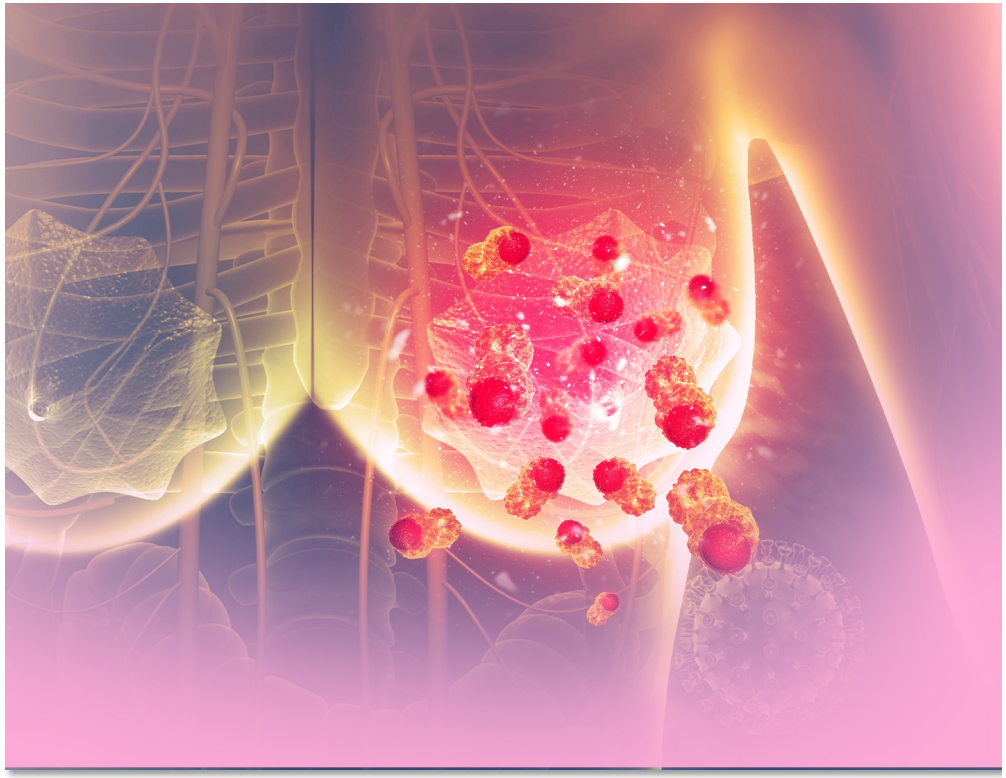
Table 4. Factors That Increase the Relative Risk for Invasive Breast Cancer in Women ACS Facts and Figures 2019-2020

Relative risk	Factor
>4.0	Age (65+ versus < 65 years, although risk increases across all ages until 80)
	Atypical hyperplasia
	Lobular carcinoma in situ
	Pathogenic genetic variations (e.g. BRCA1, BRCA2, PALB2, TP53)
2.1-4.0	Ductal carcinoma in situ
	High endogenous hormone levels
	High-dose radiation to chest (e.g. Hodgkin lymphoma treatment)
	Mammographically dense breasts
	Two or more first-degree relatives with breast cancer
1.1-2.0	Alcohol consumption
	Early menarche (<11 years)
	Excess body weight
	High endogenous estrogen or testosterone levels
	Late age at first full-term pregnancy (>30 years)
	Late menopause (> 55 years)
	Never breastfed a child
	No full-term pregnancies
	One first-degree relative with breast cancer
	Obesity
	Personal history of ovarian or endometrial cancer
	Physical inactivity
	Proliferative breast disease without atypia
	Recent and long-term use of menopausal hormone therapy
	Recent hormonal contraceptive use
	Weight gain in adulthood
	Tall height

Breast Cancer Risk

Women with **dense breasts** have breast cancers that are

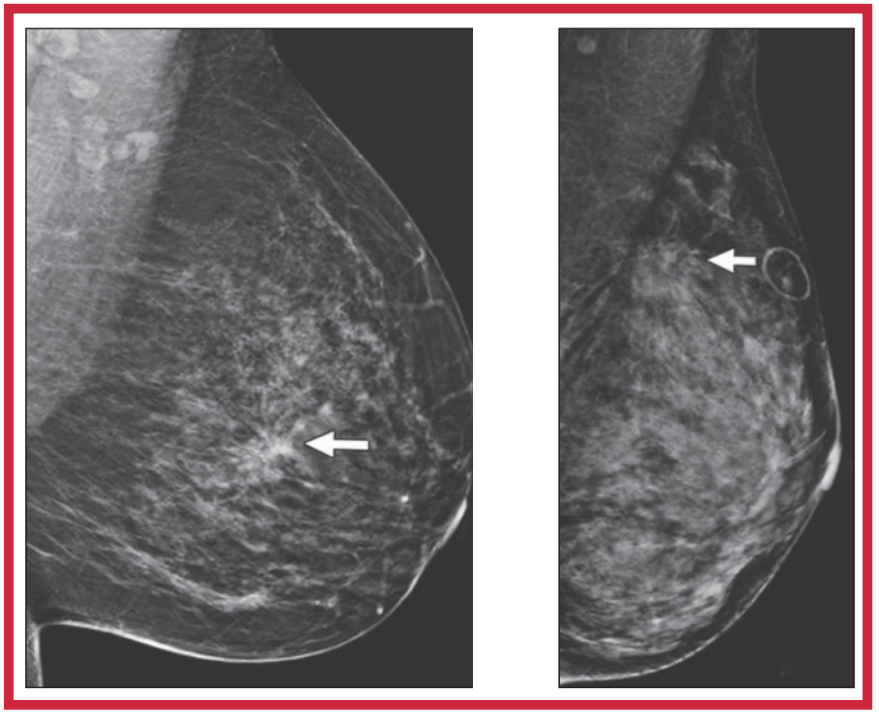
- Larger
- More likely to have metastatic lymph nodes
- Higher stage
- More often require mastectomy
- **Two-fold more likely to cause death**



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

Dense Breasts

- Dense breasts are common
  - 40-50% of women
- Dense breasts significantly limit performance of mammography
- Dense breasts increase risk of breast cancer
- State level notification laws inform patients about breast density
- What to do?
  - **Supplemental screening**

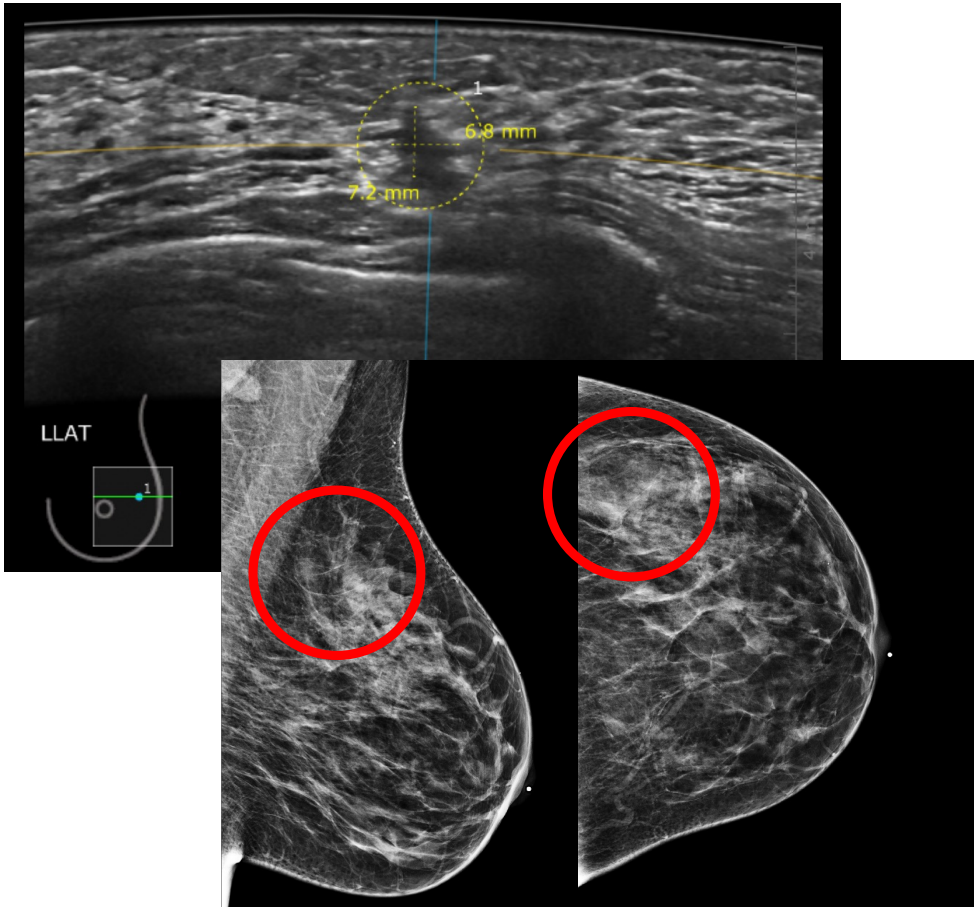


Berg et al. *Am J Roentgenol*, 2021

Supplemental Screening

- Adjunct to mammography
  - **Ultrasound**
  - Magnetic resonance imaging (MRI)
  - Contrast-enhanced mammography
  - Molecular breast imaging
  - Positron emission mammography

ALL can increase cancer detection



Case courtesy of Dr. Clayton Tyler at Ohio State University

Supplemental Screening

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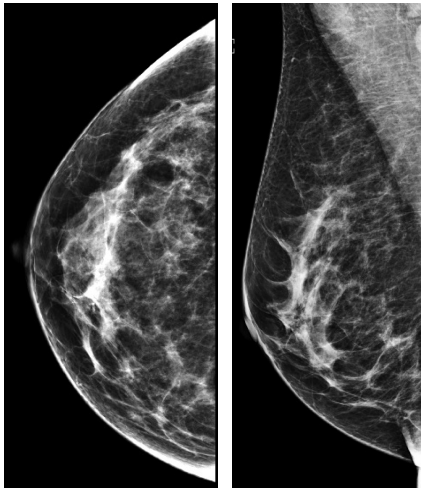

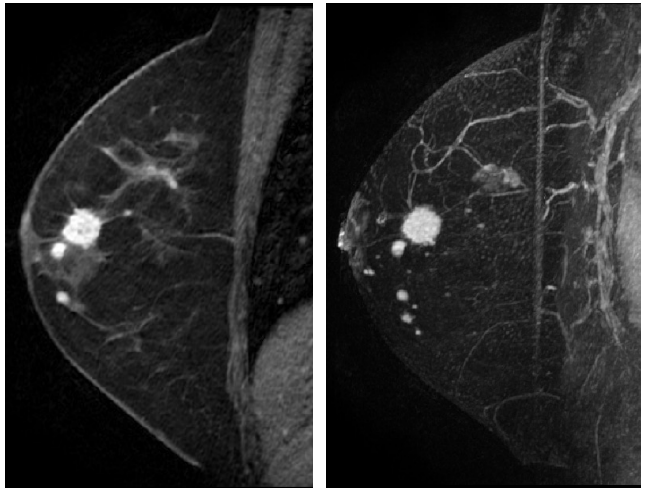

Supplemental Screening

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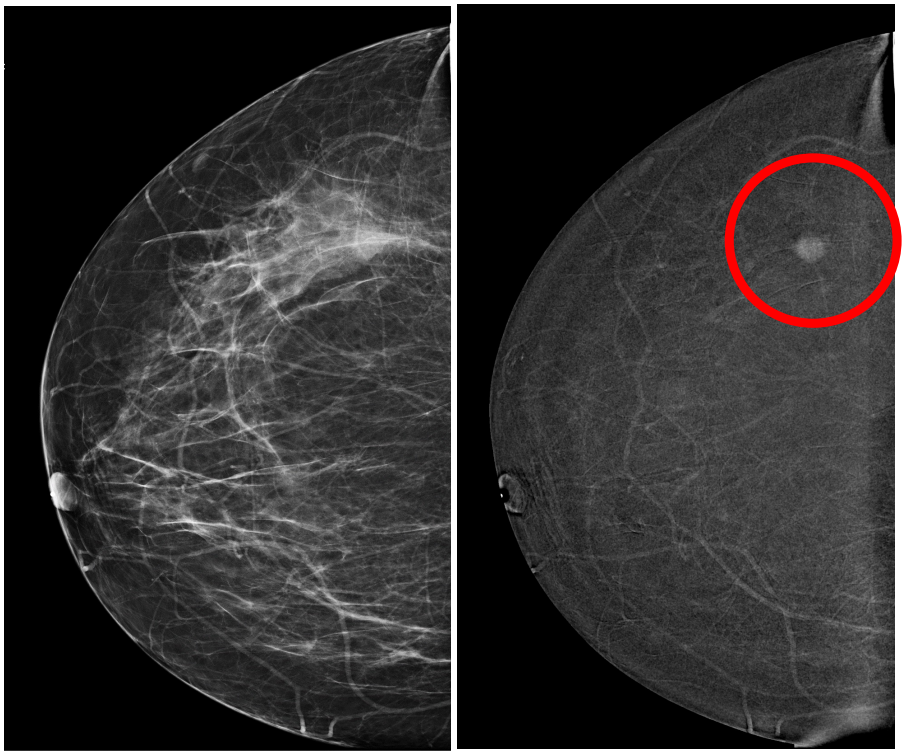


Case courtesy of Dr. Mitva Patel at Ohio State University

Supplemental Screening

Method	# of Additional Cancers	Estimated # of False Positives	Evidence Interval Cancers Reduced	Availability
Ultrasound (1st round)	2-3 per 1,000	75-117 per 1,000	Yes*	Moderate
Ultrasound (subsequent rounds)	3-4 per 1,000	70-98 per 1,000	Yes*	Moderate
MBI	7-9 per 1,000	54-77 per 1,000	Unknown	Limited
Contrast-enhanced mammography (CEM)	8-13 per 1,000	34-144 per 1,000	Unknown	Limited
MRI (1st round)	16 per 1,000	80 per 1,000	Yes^	Moderate
MRI (subsequent rounds)	6 per 1,000	26 per 1,000	Yes^	Moderate
Abbreviated (FAST) MRI	10 per 1,000	107 per 1,000	Expected†	Limited

* = ACRIN 6666; ASTOUND; ASTOUND-2 trials
^ = DENSE trial
† = EA 1141 (Comstock et al. *JAMA*, 2020); Kuhl et al. 2014 & 2017

Same or lower than the recall rate for mammography

Adapted from www.densebreast-info.org

Tomosynthesis ≠ Supplemental Screening

- This is the new gold standard mammogram!

Method	# of Additional Cancers	Estimated # of False Positives	Evidence Interval Cancers Reduced	Availability
Tomosynthesis (3-D mammography)	1-2 per 1,000	-15 to -44 per 1,000	Probably	Widespread

Helps us detect **~40% more** invasive cancers at earlier stages

Helps us recall **~20% fewer** false positive findings

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

Why Screen for Breast Cancer?

- Most **common** malignancy in women
  - 1 in 8 U.S. women (~12%) will have breast cancer in their lifetime
  - 1 in 6 breast cancers will be diagnosed in women 40-49 years of age
- Leading cause of cancer **death** in women
- It is a **progressive** disease
  - Early detection offers the opportunity to halt natural progression, increase treatment options, and ultimately, save lives

www.cdc.gov

Breast Cancer Statistics

- **Most common cancer in women** in the U.S. and in Ohio

276,480 invasive cancers/year in U.S.

9,832 invasive cancers/year in OH → **27** new cases/day in OH

48,530 *in situ* cancers/year in U.S.

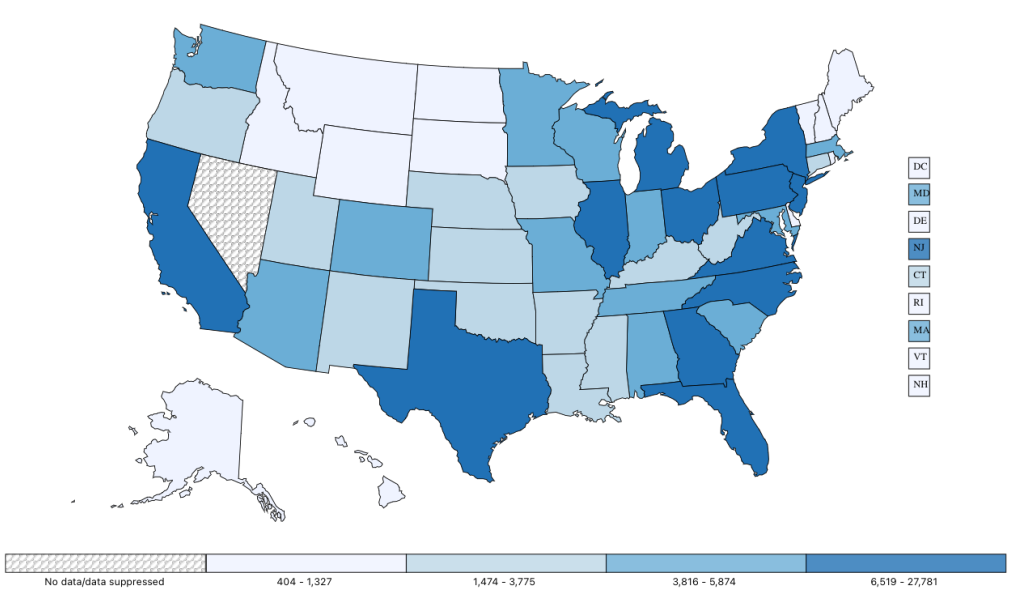
1,987 *in situ* cancers/year in OH → **5** new cases/day in OH

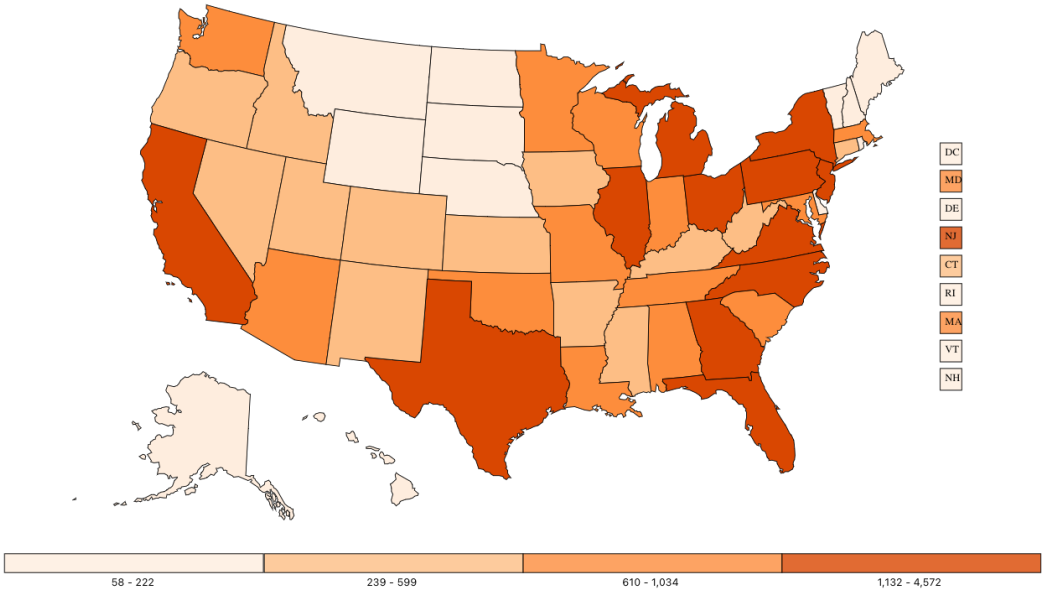
42,170 deaths due to breast cancer/year in U.S.

1,744 deaths/year in OH → **5** deaths/day in OH

SEER Cancer Statistics Review, 1975-2015, 2018
Ohio Department of Health, 2018-2019

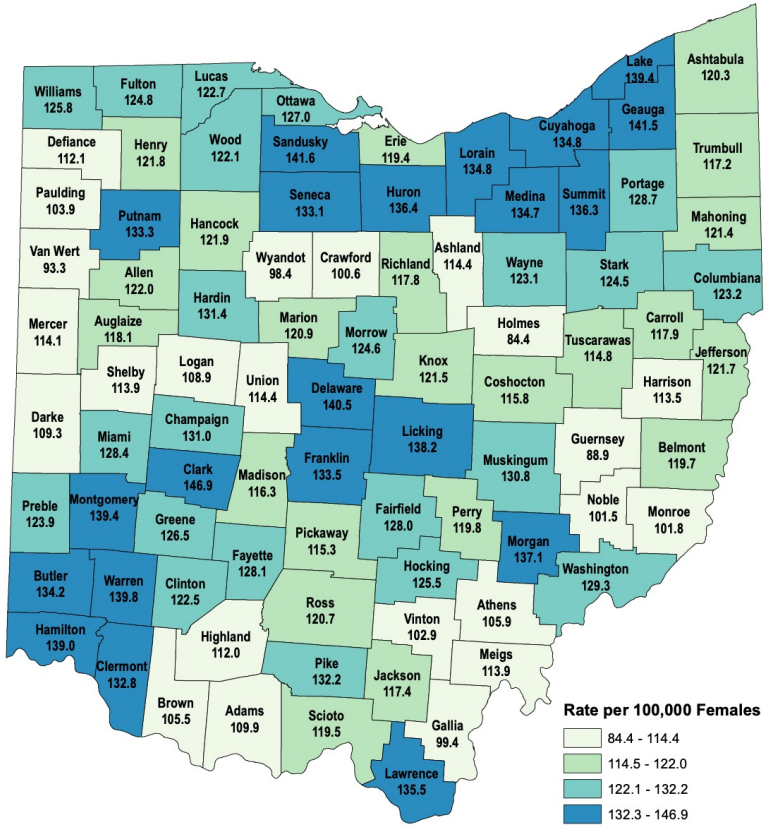
U.S. Breast Cancer Incidence vs. Mortality, 2018



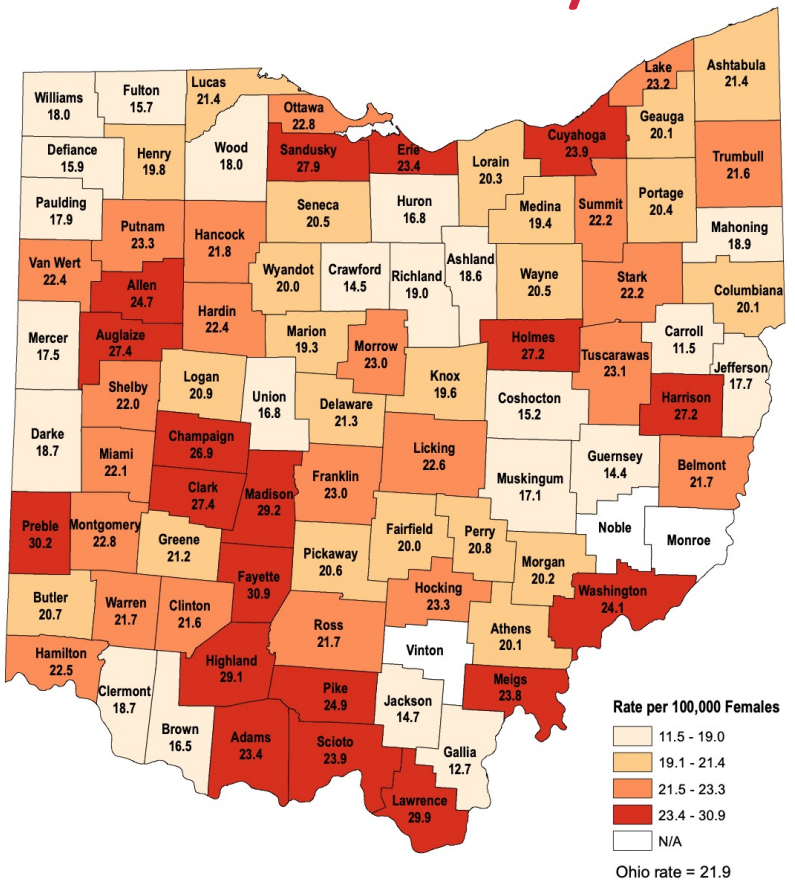


Source: Centers for Disease Control, All Ages, All Races and Ethnicities, 2018

Ohio Breast Cancer Incidence vs. Mortality



Source: Ohio Department of Health, 2014-2018

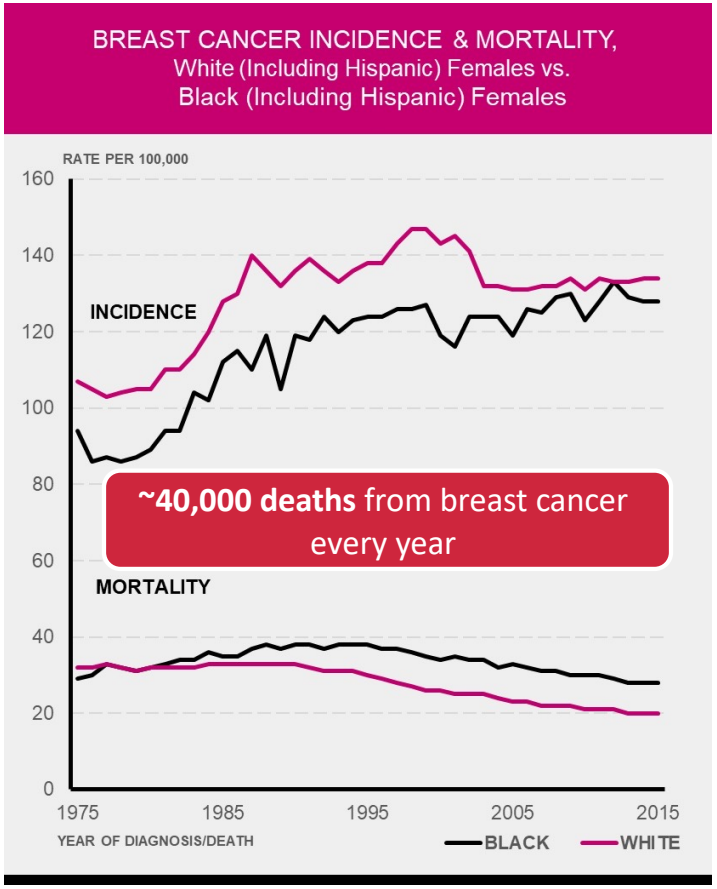


U.S. Breast Cancer Mortality

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

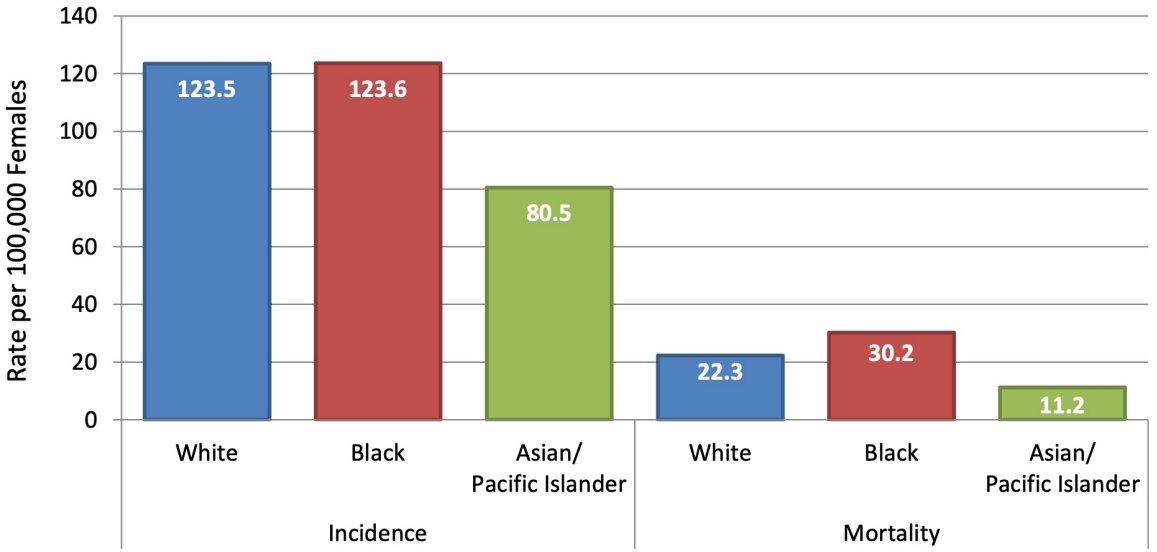
The decline is attributed to **improved detection and treatment**



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

Ohio Breast Cancer Mortality

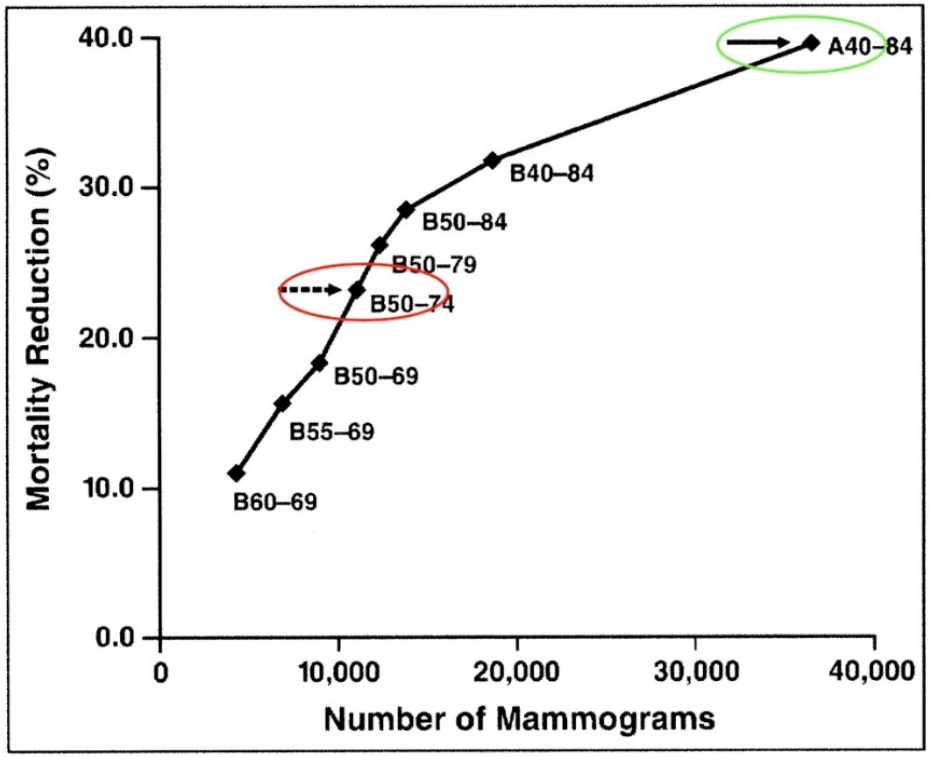
- Black women have a higher death rate than white women in Ohio, despite same incidence



Source: Ohio Department of Health, 2010-2014

Cost/Benefit Analysis

- Benefits of Screening
  - 40% fewer breast cancer deaths
  - Less extensive surgery
  - Less chemotherapy
  - Chemotherapy is more effective
  - Diagnosis of high risk lesions



Ray et al. *AJR* 2018
AmSurg 1999; *AJR* 2005; *BrJCa*, 2006; *Rad* 2012; *Rad* 2014; *Cancer* 2018

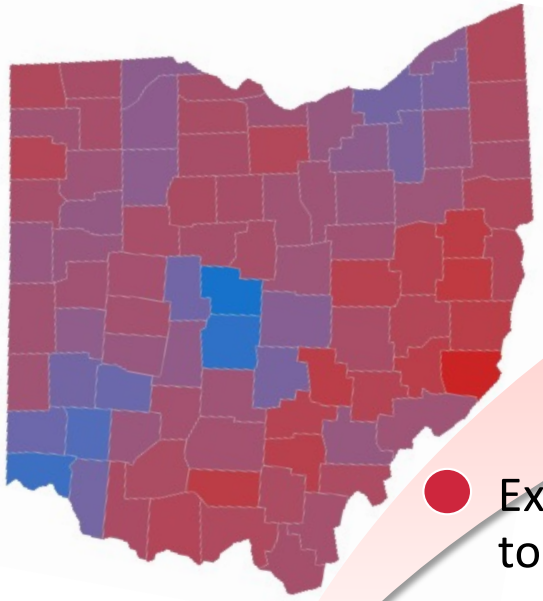
Cost/Benefit Analysis

- Computer model study of supplemental screening ultrasound
  - Ages 50-74
  - Dense breasts
  - Per 1,000 women
    - 0.36 additional deaths averted
    - 1.7 QALY (Quality Adjusted Life Years) gained
    - 354 biopsy recommendations
    - **Cost effectiveness ratio: $325,000 per QALY gained**

Excludes **women under 50 years of age** who have the most potential life-years to gain/lose

Sprague BL. *Ann Intern Med*, 2015

H.B. 371: Ohio Breast Cancer Screening Modernization Act



- Removes age limitations
- Extends coverage to include yearly mammograms
- Extends coverage to include tomosynthesis
- Improves breast density notification to women
- Provides additional coverage for supplemental screening

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DENSEBREAST-INFO WEBSITE. CANCER DETECTION BY SCREENING METHOD. DENSEBREAST-INFO. ORG/SCREENING-TECHNOLOGIES/CANCER-DETECTION-BY-SCREENING-METHOD. ACCESSED OCTOBER 12, 2021

Thank you! Questions?

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