BREAST DENSITY

WHAT IS IT?

WHY IS IT IMPORTANT?

&

What IOWA SF250 Means to Patients and Providers

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BREAST DENSITY LEGISLATION

• Nancy Capello’s story
  • November 2003 – Normal Mammogram
  • Did self exams
  • January 2004 – palpable ridge on clinical exam
  • January 2004 – no change in mammogram
    • January 2004 – 2.5 cm suspicious mass
    • Biopsy and workup = Stage 3 Breast Cancer ILCA/ 13 positive LN
  • Informed she had dense breast tissue
BREAST DENSITY LEGISLATION

Map Legend
- Some density notification required (30 states)
- Effort for inform/education; notification not required
- Active bill
- Inactive bill/no notification enacted
- State with insurance coverage

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Revised 18 August 2017
BREAST DENSITY LEGISLATION

• Federal Level
  • Reporting Act of 2015
  • H.R. 716 & S. 370

Through the MQSA :
  • Requires report to convey
    1. effect of breast density in masking breast cancer on mammography

    2. pts with dense breasts should confer with their providers regarding any questions or concerns regarding breast density and whether additional testing is necessary
This bill establishes a notification requirement for mammogram reports to patients. The bill directs the department of public health to adopt rules that require a facility performing mammography services to include information on breast density in reports sent to patients pursuant to federal law and rules. If a patient is categorized by an interpreting physician at the facility as having heterogeneously dense breasts or extremely dense breasts based on national standards the report to the patient must include notice that the patient has dense breast tissue, that this may make it more difficult to detect cancer on a mammogram, and that it may increase the patient’s risk of breast cancer. The bill provides language that such notice may contain.
IA BREAST DENSITY NOTIFICATION LEGISLATION

• Starting January 1, 2018, IA SF250, requires that all patients be notified of their breast density. This requires notification of all breast density types
  • Fatty
  • Scattered Breast Density
  • Heterogeneously Dense Breast tissue
  • Extremely Dense Breast Tissue

• Notification
  • Of breast density type
  • Provide evidence based:
    • Importance of breast density
    • Discussions to have with providers – additional testing and risk

“DENSE BREAST TISSUE”
~ 50% of patients
BREAST DENSITY- WHAT IS IT

• Relative amount of fibrous and glandular tissue Versus fatty tissue
• Greater the degree of “fibroglandular tissue” the denser the breast tissue
• Usually assessed subjectively
BREAST DENSITY- WHAT IT IS NOT

• Fibrocystic Breast tissue

• “Lumpy & Bumpy Breasts”
  • Fatty breast tissue can feel lump with fat lobules in areas supported by ligamentous structures
BREAST DENSITY

• Increased breast density bilateral:
  • Genetics and Age
    • >1/2 under age 50
    • ~40% women in their 50’s
    • ~25% women over 60
  • Hormones – increased density in HRT
  • Weight loss
  • Lactation
  • Edema

• Unilateral increase:
  • Radiation
  • Lymphatic obstruction
  • Malignancy
BREAST DENSITY SCORE

Density score is based on the proportion of fatty and fibroglandular tissue seen on mammogram

- “A” - The Breasts are almost entirely fatty (prevalence 10%)
- “B” - There are scattered fibroglandular densities (prevalence 50%)
- “C” - The Breasts are Heterogeneously Dense (prevalence 30%)* This may obscure small masses
- “D” - The Breasts are Extremely Dense (prevalence 10%): * This decreases the sensitivity of mammography
IOWA BREAST DENSITY LEGISLATION

- SF 250
- Requirements- lay letters
  - Inform patients of all breast densities
  - Heterogeneous or Extremely Dense Tissue
    - the importance of the effect on interpretation
    - the increased risk associated
- Does not require a statement about other methods of screening
- BUT
- We will provide additional information to patients and clinicians about alternative screening methods and their efficacy & risks
BREAST DENSITY

• Two issues associated with Dense Breast Tissue
  • #1 Most important is obscuring lesions – “Masking Effect”
  • #2 Increased Breast Cancer risk
    • Women with heterogeneously dense breasts & extremely dense breast tissue may have higher risk of breast cancer compared to women with lower density breasts.
    • Extremely Dense vs Fatty – 4-6x
    • Risk of breast cancer in dense vs scattered density is about 1.4-2.1x
DENSE BREAST TISSUE
Masking Effect

“Polar Bear in the Snow”
DENSE BREAST TISSUE
Masking Effect

“Polar Bear in the Snow”
BREAST DENSITY-Distribution


Sensitivity: 87%  
Specificity: 97%
BREAST DENSITY

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  - #1 Most important is obscuring lesions – “Masking Effect”
  
  - #2 Increased Breast Cancer risk
    - Women with heterogeneously dense breasts & extremely dense breast tissue may have higher risk of breast cancer compared to women with lower density breasts.
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Mammographic Density and the Risk and Detection of Breast Cancer

BACKGROUND
Extensive mammographic density is associated with an increased risk of breast cancer and makes the detection of cancer by mammography difficult, but the influence of density on risk according to method of cancer detection is unknown.

CONCLUSIONS
Extensive mammographic density is strongly associated with the risk of breast cancer detected by screening or between screening tests. A substantial fraction of breast cancers can be attributed to this risk factor.

As compared with women with density in less than 10% of the mammogram, women with density in 75% or more had an increased risk of breast cancer (odds ratio, 4.7; 95% confidence interval [CI]
DENSE BREAST TISSUE- WHY THE INCREASED RISK

• Glands tend to be made up of relatively actively dividing cells that
  • Can mutate and become cancerous: the more glandular the tissue, the greater the risk.

• Local environment around the glands may produce certain growth hormones that stimulate cells to divide
  • Seems to be more true for fibrous than fatty tissue.
BREAST DENSITY

BR CA RISK vs DENSITY

• Relative Risk (RR)
  • Density D vs A: 4-6x
  • 80% of screened women are density B & C = Average
  • RR density D vs average = 2x
  • RR density C vs density B = 1.5x
# BREAST CANCER RISK FACTORS

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nulliparity/late parity</td>
<td>1.3</td>
</tr>
<tr>
<td>Early menarche/late menopause</td>
<td>1.3</td>
</tr>
<tr>
<td>Alcohol Use</td>
<td>1.3</td>
</tr>
<tr>
<td>Menopause Hormone Tx</td>
<td>1.4</td>
</tr>
<tr>
<td>Obesity</td>
<td>1.5</td>
</tr>
<tr>
<td>Female age &gt;65 y.o.</td>
<td>1.7</td>
</tr>
<tr>
<td>Family History</td>
<td>1.7</td>
</tr>
<tr>
<td>Dense Breast Tissue</td>
<td>OR 4.3</td>
</tr>
<tr>
<td>Bx with ADH/LCIS</td>
<td>5.0</td>
</tr>
<tr>
<td>Prior Breast Ca Hx</td>
<td>7.0</td>
</tr>
</tbody>
</table>
Dense Breast Tissue and Supplemental Screening

• Controversial
  • Is this for average risk patients
  • Recent studies suggest the benefit for all risk patients with dense breast tissue
    • Detecting breast cancers at a smaller size and earlier stage
    • Occult to mammography
  • Limiting “Masking” effect is most important

• As breast density increases, there is a moderate increased risk of breast cancer as an independent factor
BREAST DENSITY

• Assessing benefits of screening
  • Most important prognostic factors
    • Stage at diagnosis
    • Nodal status

• Dense Breast Patients
  • masked breast cancers more likely to be Stage 2 or 3
  • cancers in extremely dense breast tissue patients
    • 18x more likely detected as palpable abnormality
    • ~85% of cancers detected only by Screening US are node negative
BREAST DENSITY

• Imaging options for women with dense breasts
  • Screening Mammography
    • Continue at routine intervals
    • Digital mammography is preferred over film due to improved breast cancer detection

• Additional Modalities
  • Digital Breast Tomosynthesis (3-D Mammography)
  • Whole Breast Ultrasound (U/S)
  • MBI (Molecular Breast Imaging)
  • Breast MRI
Screening Alternatives – 3D Mammogram

<table>
<thead>
<tr>
<th>Examination</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
</table>
| 3-D mammogram     | • Estimated to detect an additional 1-2 cancers per 1,000 women, over standard 2D mammography  
                        • Done at the same time as a standard mammogram  
                        • Reduces the need for additional testing for areas of concern that aren't cancer  
                        • Same breast radiation dose as standard mammogram | • Not available everywhere, though becoming more common (Available at all Cedar Rapids facilities) |
## Screening Alternatives – Whole Breast Screening Ultrasound

<table>
<thead>
<tr>
<th>Examination</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast ultrasound</td>
<td>• Estimated to detect an additional 3-4 cancers per 1,000 women</td>
<td>• Likely to find areas of concern that aren't cancer, but that require additional imaging or a biopsy – False positives</td>
</tr>
<tr>
<td></td>
<td>• No additional radiation exposure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ultrasound is widely available, requires additional expertise and may be done automated (ABUS)</td>
<td>• Quality of exam dependent on experience of person doing the test in handheld exam, standardized with Automated Breast Ultrasound (ABUS)</td>
</tr>
</tbody>
</table>
Breast US Screening

Automated- “ABUS”

Handheld “HHUS”
Breast cancer screening
“Ultrasound Screening”

ACRIN 6666

- Results:
  - Mammo Ca detection 7.6/1,000
    - Increases Ca detection by 4.2/1,000
    - Majority of cancers found are invasive ca & node negative
  - Recall rate is higher than mammography
  - PPV is lower
  - With experience these statistics improve
Whole Breast US vs DBT

ASTOUND TRIAL

‘Adjunct Screening W/ Tomosynthesis or Ultrasound in Women With Mammography-Negative Dense’ Breast’

• In over 3,000 women, 2D mammogram negative with dense breasts
• DBT and HHUS
• The additional screening tests found a total of 24 breast cancers missed by 2D mammography

• Cancer Detection Rate (CDR)- Incremental
  • DBT 4.0/1,000
  • US Screening : 7.1/1,000
Whole Breast US vs DBT
ASTOUND TRIAL

• Cancer Detection Rate (CDR)- Incremental
  • DBT 4.0/1,000
  • US Screening : 7.1/1,000
• Recall leading to biopsy of ~1.0%
• Average size Cancer detected the same DBT vs US
  • 1.5cm, Invasive cancers
  • 32% node positive at screening, almost all grade 3 tumors
BREAST ULTRASOUND SCREENING

- Connecticut Experience-
  - Earliest experience, required offer Whole Breast US
  - Started in 2009

<table>
<thead>
<tr>
<th>Year</th>
<th>% Eligible Women</th>
<th>Cancers &amp; High Risk /1,000</th>
<th>PPV of all cancers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>28</td>
<td>4.0</td>
<td>7.3</td>
</tr>
<tr>
<td>2</td>
<td>26</td>
<td>3.3</td>
<td>6.1</td>
</tr>
<tr>
<td>3</td>
<td>32</td>
<td>3.1</td>
<td>8.8</td>
</tr>
<tr>
<td>4</td>
<td>28</td>
<td>3.3</td>
<td>20.1</td>
</tr>
</tbody>
</table>
BREAST ULTRASOUND SCREENING

• Connecticut Experience-
  
  • Increasing Positive Predictive Value
    • Decrease in biopsy rate, increase follow up
  
  • Decreased Recall rates:
    • 5 year experience with recall rate decrease from 25% to ~6%
    • Biopsy rate decreased from 5% to ~1%
  
  • Lesson learned:
    • With experience, the performance and outcome of supplemental screening ultrasound is greatly improved
Diagnostic RT, palpation 2017
Diagnostic Exam palpation RT 2017
Post Biopsy
Whole Breast Ultrasound Screening

• Insurance coverage varies and patients may have out-of-pocket costs.
• **When ordering additional screening examinations:
  • Bilateral Breast Ultrasound: 76641-50, (Bilateral)
  • Use ICD10 Code 92.2
### Screening Alternatives – Molecular Breast Imaging (MBI)

<table>
<thead>
<tr>
<th>Examination</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBI</td>
<td>• Estimated to detect an additional 7 - 8 cancers per 1,000 women</td>
<td>• Involves injection of a radioactive tracer, which exposes you to a very low level of radiation – about the equivalent of two mammograms</td>
</tr>
<tr>
<td></td>
<td>• Less likely to find areas of concern that aren't cancer</td>
<td>• A positive test would lead to additional imaging to locate any abnormality</td>
</tr>
<tr>
<td></td>
<td>• Negative predictive value of about 98%</td>
<td>• Fewer locations</td>
</tr>
<tr>
<td></td>
<td>• Normal exam can be repeated biennial</td>
<td>• Lesion localization</td>
</tr>
<tr>
<td></td>
<td>• Available at both hospitals in Cedar Rapids</td>
<td></td>
</tr>
</tbody>
</table>
MBI - Molecular Breast Imaging
Rapid Breast MRI

• Modified protocol to decrease time/cost of the study
  • 7-8 minutes of scan time versus up to 30 minutes for standard
  • Contrast enhanced exam
  • Screening for those patients with > 50% breast density
  • Interpretation times: the same or shorter than standard DBT exam

• Results:
  • Significant improved Ca Detection of 16-20/1,000
  • Ca detected much sooner than mammography
  • Cost in some centers equal to or slightly higher than mammography charges
<table>
<thead>
<tr>
<th>Examination</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI</td>
<td>• Estimated to detect an additional &gt;10/1,000 cancers detected with Mammography + MRI</td>
<td>• Involves injection of a contrast agent, Gadolinium</td>
</tr>
<tr>
<td></td>
<td>• No additional radiation</td>
<td>• Not covered by insurance</td>
</tr>
<tr>
<td></td>
<td>• Widely available</td>
<td>• Some patients may not tolerate due to claustrophobia or have MRI contraindications.</td>
</tr>
<tr>
<td></td>
<td>• Abbreviated exam</td>
<td>• Like all other ancillary screening tests may find areas requiring further evaluation that may turn out to be benign.</td>
</tr>
</tbody>
</table>
High risk, Screening MRI
High Risk, asymptomatic
US follow up MRI
Post Bx
<table>
<thead>
<tr>
<th>If 1,000 Women are Screened with</th>
<th># Women Found to have Cancer</th>
<th>Type of Technology</th>
<th># Women Recalled for more Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>2D-mammogram alone</td>
<td>2-7 total</td>
<td>Ionizing radiation</td>
<td>100</td>
</tr>
<tr>
<td>2D-mammogram plus 3D-mammogram (tomosynthesis)*</td>
<td>Mammogram 2-7 + Tomosynthesis 1-2 = 3-9 total</td>
<td>Ionizing radiation</td>
<td>70</td>
</tr>
<tr>
<td>Regular 2D-mammogram plus ultrasound (US)*</td>
<td>Mammogram 2-7 + Ultrasound 2-4 = 4-11 total</td>
<td>Sound waves</td>
<td>170-230</td>
</tr>
<tr>
<td>Regular 2D-mammogram plus contrast-enhanced MRI</td>
<td>Mammogram 2-7 + MRI 10 or more = 12-17 or more total</td>
<td>Magnetic field and intravenous contrast</td>
<td>160-220</td>
</tr>
</tbody>
</table>
Partnering with Patients
The Conversation

• **Acknowledge:**
  • There is some increased risk of breast cancer based on increased density
    • ~ 4-6x for extremely dense breast tissue versus fatty breasts
    • ~2x for all “dense” breast patients versus average density patients
  • “Masking” effect in mammography for patients with increased breast density
Partnering with Patients
The Conversation

• **Share:**
  • Additional screening may identify breast cancers, not identified by mammography
  • Additional cancers found have not been established to decrease mortality
  • Ancillary screening tests improve detection of breast cancer in dense breast patients and diagnosing breast cancer at earlier stages decreases the morbidity of treatment and overall mortality.

• **Inform:** All imaging studies involve the risk of false positive and false negative results
Partnering with Patients-The Conversation

- **Encourage**: Lifestyle options that reduce breast cancer risk:
  - maintain normal weight
  - exercise regularly
  - eat a lower fat diet
  - drink \( \leq 1 \) alcoholic beverage a day on average.
Partnering with Patients-The Conversation
The Next Steps

- **Obtain:** A careful family history. You or your patient may employ one of several risk assessment tools to predict breast cancer risk.

- **Consider:** Genetic counseling for women with known or suspected increased risk of breast cancer, e.g., prior chest radiation, strong family history of breast or ovarian cancer, family history of BRCA mutation, or risk calculation suggesting ≥ 20% lifetime risk of breast cancer.
Breast Cancer Risk Calculators Resources

• NCI:*
  http://www.cancer.gov/bcrisktool/

• Densebreast- Info Chart

• Tyrer Cuzick:
  http://www.ems-trials.org/riskevaluator/
Woman with heterogeneously dense or extremely dense breasts

Significant family history of breast or ovarian cancer OR personal history of LCIS or atypical hyperplasia?

Yes

Formal breast cancer risk assessment

Risk \( \geq 20\% \) using Tyrer-Cuzick, Claus, and/or other models based largely on family history?

Yes

Consider medications for breast cancer risk reductions

No

5-year gail model risk of breast cancer \( \geq 1.66\% \)

Yes

5-year gail model risk of breast cancer \( \leq 1.66\% \)

Reassure her that up to 50% of women have dense breasts and that currently having dense breasts alone does not necessitate medications or additional tests

No

Reassure her that up to 50% of women have dense breasts and that currently having dense breasts alone does not necessitate medications or additional tests

Digital mammograms based on screening guidelines for her age group

- Optimize lifestyle habits to promote breast health
- May consider additional testing, such as tomosynthesis, ABUS, and MBI, as appropriate after discussing risks and benefits, recognizing that these tests are done in addition to mammography and may not be covered by insurance

Annual screening MRI and digital mammogram

Consider referral for genetic counseling if appropriate

Abbreviations: ABUS = automated whole-breast ultrasound; LCIS = lobular carcinoma in situ; MBI = molecular based imaging; MRI = magnetic resonance imaging.

a Significant family history includes a first-degree relative with breast or ovarian cancer, multiple relatives with breast or ovarian cancer on one side of the family, especially premenopausal or in male relatives.

b Risk assessment should be done by clinicians with expertise in using breast cancer risk prediction models.

c Breast cancer risk reduction medications include tamoxifen, raloxifene, and exemestane.

d MBI is not available at many centers. Currently there is little consensus as to when or which additional screening test should be used.
"Your mammogram shows that your breast tissue is dense. Dense breast tissue is very common, occurring in more than 40% of women. Having dense breast tissue is normal, but dense breast tissue can make it harder to find cancer on a mammogram. Also, dense breast tissue may increase your breast cancer risk. This information about the result of your mammogram report is given to you and your clinician to raise your awareness. Together you can decide whether additional screening tests are right for you based on your mammogram results, individual risk factors, or physical examination."
BREAST DENSITY STATEMENTS
HETEROGENEOUS/EXTREME BREAST DENSITY

"Your mammogram indicates that you have predominantly fatty replaced breast tissue or scattered breast density. This is a normal finding and is not associated with an increased risk of breast cancer. You are encouraged to consult with your primary health care provider regarding the results of your mammogram and to determine the recommended timing for your screening mammogram."
Iowa Breast Density Law – your mammogram result letter will now inform you of your breast density category.

What is Breast Density?
Breasts are made up of a mixture of fibrous, glandular and fatty tissue. Your breasts are considered dense if you have a lot of fibrous or glandular tissue (dense) but not much fat (not dense). Breast density is not a measure of how breasts feel but rather how the breasts look on a mammogram.

Breast Density: Why it matters
Although normal, dense breast tissue makes interpretation of mammograms more difficult. Dense tissue can hide a breast cancer at an early stage. Depending on how dense your breast tissue is, it may moderately increase your risk of breast cancer.

How do I know if I have dense breast tissue?
Breast density is determined by the radiologist who reads your mammogram. There are four categories of mammographic density. The radiologist decides which category best describes your breast tissue density.

Radiologists classify breast density using a 4-level scale

<table>
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<th>Scattered areas of fibroglandular density</th>
<th>Heterogeneously Dense</th>
<th>Extremely Dense</th>
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This information is given to you to raise your awareness and to promote discussion with your physician regarding other risk factors, in addition to dense breast tissue. Together you can decide whether additional screening options are appropriate for you.

RESOURCES

Densebreast-info.org    iowabreastdensity.com
BREAST DENSITY

Additional resources

• Physician consolidated PowerPoint

• Webex lecture on our website – November 2017

• Patient Pamphlet explaining Dense Breast Tissue
Breast Density

• Helpful Sites
  
  www.densebreast-info.org

  &

  www.iowabreastdensity.com
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