Pink States:
AL
AZ
CA
CT*
MD
HI
MA
MI
MN
MO
NC
NJ*
NV
NY
OH
OR
PA
RI
TN
TX
VA

PINK: Enacted Law
RED: Introduced Bill
BLUE: Working on Bill
WHITE: No Action
STAR *: Insurance Coverage Law

D.E.N.S.E.® © 2011 – 2015, Are You Dense Advocacy, Inc.. All rights reserved. Accessed 2-2-2015
What is Breast Density?

• Assessed on mammography
• Different X-ray absorption of fibrous & glandular (FG) tissue vs fat
• Density is the relative amount of white (FG) vs black/gray (fat)

FAT DENSITY

EXTREMELY DENSE
BI-RADS (Breast Imaging Reporting and Data System)

• Qualitative
  a. Almost entirely fatty
  b. Scattered areas of fibroglandular density
  c. Heterogeneously dense
  d. Extremely dense


**BI-RADS (Breast Imaging Reporting and Data System)**

- **Qualitative**
  
a. Almost entirely fatty
b. Scattered areas of fibroglandular density
c. Heterogeneously dense
d. Extremely dense

= DENSE BREASTS
Computerized methods

- **Semi automated** *(Cumulus®)*
  - Human input needed
  - Research

- **Fully Automated**
  - No human input/time
  - Reproducible
  - Include:
    - **Volpara® Volumetric** - VolparaSolutions
      - Sept 2014- Brand et al- similar performance in risk prediction
    - **Quantra® Volumetric** - Hologic


Density Changes

• Decreases breast density
  – Increasing age
  – Increasing BMI
  – Tamoxifen

• Increases breast density
  – Weight loss
  – Exogenous hormones
  – Lactation
## Distribution of Breast Density

<table>
<thead>
<tr>
<th>BIRADS Breast Density</th>
<th># of Women (~600,000)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fatty</strong></td>
<td>57,961</td>
<td>10</td>
</tr>
<tr>
<td><strong>Scattered</strong></td>
<td>259,018</td>
<td>44</td>
</tr>
<tr>
<td><strong>Heterogeneous</strong></td>
<td>216,395</td>
<td>37</td>
</tr>
<tr>
<td><strong>Extremely Dense</strong></td>
<td>53,995</td>
<td>9</td>
</tr>
</tbody>
</table>

Impact of Breast Density

1: MASKING-
Dense tissue hiding a cancer on a mammogram

Sensitivity:
Dense 63%
Fatty 87%

Carney PA et al Individual and combined effects of age, breast density, and hormone replacement therapy use on the accuracy of screening mammography Ann Intern Med. 2003 Feb 4;138(3):168-75
2: RISK

A meta analysis of 11 studies with >14,000 cases

Density risk*

- Heterogeneously dense- 1.2x
- Extremely dense- 2.1x

*compared to average density

Supplemental Screening

• In addition to mammography!

• Digital Mammo and Tomosynthesis
• US
• MRI
DMIST Trial-2005

- Digital Mammography vs film screen
  - Digital imaging MORE ACCURATE
    - Under age 50
    - Dense breasts (>50% dense)
    - Pre or peri-menopausal

Film 1993  Digital 2011  >95% of units in US are digital

http://www.fda.gov.RadiationEmittingProducts
Tomosynthesis

Decrease recall rates
Increase cancer detection

Screening US

• ACRIN 6666-2008
  – Screening mammogram
  – Screening US
  – 2637 Women
  • Increased risk AND >50% dense
  • Based on personal hx, previous high risk biopsy, Gail model
## Screening US

4.2 additional cancers/1000 women
3.7/1000 in years 2 and 3

<table>
<thead>
<tr>
<th></th>
<th>False +</th>
<th>PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammo alone</td>
<td>4.4</td>
<td>22.6 %</td>
</tr>
<tr>
<td>US alone</td>
<td>8.1</td>
<td>8.9 %</td>
</tr>
<tr>
<td>Mammo + US</td>
<td>10.4</td>
<td>11.2 %</td>
</tr>
</tbody>
</table>

*ACRIN 6666*

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*Berg WA, et al, Combined Screening With Ultrasound and Mammography vs. Mammography Alone in Women at Elevated Risk of Breast Cancer JAMA, 2008; 299, 2151-2163*
Automated US

• Limited outcome studies to date
• May become more widely used with further study
• Concerns
  – High recall rate
  – Cost benefit ratio - many images, low reimbursement
  – Learning curve
Berg 2012 JAMA
Expanded ACRIN trial:
Higher risk AND dense
Added MRI screening after 3 rounds of M/US
ACRIN +MRI

612 women in MRI-added group
16/612 had Cancer

Supplemental cancer
yield of MRI- **14.7/1000**

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>Recall Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammo alone</td>
<td>56%</td>
<td>89%</td>
<td>29%</td>
<td>11%</td>
</tr>
<tr>
<td>Mammo + US</td>
<td>94%</td>
<td>74%</td>
<td>11%</td>
<td>16%</td>
</tr>
<tr>
<td>MRI</td>
<td><strong>100%</strong></td>
<td>70%</td>
<td><strong>19%</strong></td>
<td><strong>31%</strong></td>
</tr>
</tbody>
</table>

## Cost of supplemental studies

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>2014 Medicare Allowable $</th>
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</thead>
<tbody>
<tr>
<td>77057</td>
<td>Screening Mammogram Bilateral - Digital</td>
<td>134.73</td>
</tr>
<tr>
<td>77059</td>
<td>MRI Breast w/contrast Bilateral</td>
<td>535.60</td>
</tr>
<tr>
<td>76641</td>
<td>Ultrasound Breast Bilateral</td>
<td>164.45</td>
</tr>
</tbody>
</table>

Reported Jan. 2015 UM
Recommendations for High Risk Women

- Lifetime risk >20%
- 5 year risk >1.7%
- BRCA +
- Thoracic radiation
- Rare genetic syndromes

- Annual mammogram
- Annual screening MRI
  - Regardless of breast density
- Screening US only if MRI cannot be performed
Recommendations for Intermediate Risk Women

• 15-20% lifetime risk based on models
• Personal h/o breast cancer
• LCIS or atypia on prior biopsy

• Less clear cut management

• ACR/SBI appropriateness criteria:
  – MRI ‘is usually appropriate’
  – US ‘may be appropriate’
  – If dense breasts raise a woman’s risk to this level with other risk factors, supplementary screening could be considered
Recommendations for Average Risk Women With Dense Breasts

- Screening mammography
- Supplemental screening is not supported
  - NCCN: insufficient evidence to support it in absence of other risk factors
  - ACR/SBI
  - ACOG
  - ACS
  - USPSTF
  - Cochrane Review
Recommendations For Dense Breasts

• Continue Screening Mammography
• Comprehensive discussion with patients
  – Acknowledge limitations
    • Subjective density assessment
    • Density can vary with patient and technical factors
  – All risk factors
  – Reassurance- density is a small risk factor
  – Supplementary screening options-strengths and weaknesses
  – Formal genetic counseling
Provider support

- Michigan Cancer Consortium/MDCH grant
- Breast Density notification law
- On-line modular CME activity
- Interactive / Educational
- Clinical practice based
- Goal for release: Summer 2015
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