Breast Cancer Screening & Breast Density

Jay Goldberg, MD, MSCP
Professor of OB/GYN
Einstein Medical Center Philadelphia
Disclosure

• Dr. Goldberg has no Conflict of Interest to disclose

• Dr. Goldberg has no Financial or Scientific disclosures

• Dr. Goldberg has no Off-Label disclosures.
OBJECTIVES

• Describe current recommendations for breast screening.
• Describe increased mammographic breast density.
• Describe strategies to medico-legally comply with mammographic breast density laws.
Screening Mammogram Guidelines

WARNING
MASS
CONFUSION AHEAD
US Preventive Services Task Force (USPSTF) Recommendations

• Women before the age of 50; decision to start regular, biennial screening mammography should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms

• **Women age 50-74;** USPSTF recommends biennial screening mammography

• Women age >75; current evidence is insufficient to assess the benefits and harms of screening

• **USPSTF recommends against teaching breast self examination**
THEN

EARLY DETECTION SAVES LIVES.

NOW

WAITING TEN YEARS SAVES MONEY.
Mammograms

This way for women under 50

New U.S. Task Force Guidelines
American Cancer Society
2016 Guidelines

• Women with average risk of breast cancer;
  – Regular screening mammography starting at age 45 years (strong recommendation), however women should have the opportunity to begin annual screening between the ages of 40 and 44 years
  – Age 45 to 54 years should be screened annually
  – Age 55 years and older should transition to biennial screening or have the opportunity to continue screening annually
  – Women should continue screening mammography as long as their overall health is good and they have a life expectancy of 10 years or longer
  – Do not recommend clinical breast examination for breast cancer screening among average-risk women at any age
American College of Radiology (ACR) Recommendations

• Recommend yearly mammograms starting at age 40
• Screening to continue until life expectancy is less than five to seven years, on the basis of age and co-morbidities
• Clinical breast exam
  —“May be offered* every 1-3 years for women aged 25-39 years and annually for women 40 years and older.”
• Mammography initiation age
  – Offer starting at age 40 years.
  – Initiate at age 40-49 years after counseling, if patient desires.
  – Recommend by no later than age 50 years if patient has not already initiated.
NEW MAMMOGRAM GUIDELINES
ACOG recommends initiation between 40 and 50 years old
Mammography screening interval
  – Annual or biennial
Mammography stop age
  – Continue until age 75. Beyond age 75, the decision to discontinue should be based on a shared decision-making process that includes a discussion of the woman’s health status and longevity.
Radiologists classify breast density using a 4-level density scale:

- Almost entirely fatty
- Scattered areas of fibroglandular density
- Heterogeneously dense
- Extremely dense
Breast density in the U.S. (See pie chart)

- 10% of women have almost entirely fatty breasts
- 10% have extremely dense breasts
- 80% are classified into one of two middle categories
Increased Mammographic Breast Density  
Why does it matter?

• Dense breast tissue absorbs more radiation during mammography compared with fatty breast tissue.

• This in theory reduces the accuracy of mammography to detect breast cancer.

• Compared to average breast density, the RR of breast cancer in women with heterogeneously dense and extremely dense breasts are increased by factors of 1.2 and 2.1, respectively. (Sickles. *Radiol Clin North Am* 2010)
<table>
<thead>
<tr>
<th>Relative risk &lt;2</th>
<th>Relative risk 2-4</th>
<th>Relative risk &gt;4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 25 to 34 at first live birth</td>
<td>Age &gt;35 at first live birth</td>
<td>Gene mutations (BRCA 1 or 2)</td>
</tr>
<tr>
<td>Early menarche</td>
<td>First-degree relative with breast cancer</td>
<td>Lobular carcinoma in situ</td>
</tr>
<tr>
<td>Late menopause</td>
<td>Nulliparity</td>
<td>Ductal carcinoma in situ</td>
</tr>
<tr>
<td>Proliferative benign disease</td>
<td>Radiation exposure</td>
<td>Atypical hyperplasia</td>
</tr>
<tr>
<td>Postmenopausal obesity</td>
<td>Prior breast cancer</td>
<td></td>
</tr>
<tr>
<td>Alcohol use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estrogen/progestogen hormone therapy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BREAST DENSITY NOTIFICATION ACTs

www.areyoudenseadvocacy.org
Pennsylvania’s Breast Density Notification Act

• Enacted 2013
• “This notice contains the results of your recent mammogram, including information about breast density. If your mammogram shows that your breast tissue is dense, you should know that dense breast tissue is a common finding and is not abnormal. Statistics show many women could have dense or highly dense breasts. Dense breast tissue can make it harder to find cancer on a mammogram and may be associated with an increased risk of cancer. This information about the result of your mammogram is given to you to raise your awareness and to inform your conversations with your physician. Together, you can decide which screening options are right for you based on your mammogram results, individual risk factors or physical examination. A report of your results was sent to your physician.”
ACOG 2015 Committee Opinion 625
Management of Women With Dense Breasts Diagnosed by Mammography

• No studies have demonstrated earlier detection or improved prognosis when additional breast imaging is obtained.

• ACOG advocates against recommending additional breast imaging in otherwise asymptomatic women with increased breast density.

• Physicians should comply with state laws requiring disclosure of increased mammographic breast density, many mandating offering additional breast imaging.
“… to inform your conversations with your physician. Together, you can decide which screening options are right for you …”

• Which screening options are being referred to?
  – Breast Ultrasound ?
  – Breast MRI ?
  – Breast Tomosynthesis ?
  – Molecular Breast Imaging ?
Digital Breast Tomosynthesis

Also called 3-dimensional (3D) Mammography

Low dose radiation and computer reconstruction forms a 3D model of the breasts

Higher cancer detection rates with fewer recalls
Digital Breast Tomosynthesis
Your mammographic breast density on today's study is considered dense. Please understand that assessment of breast density is subjective and that variations in breast density from year to year may be of no clinical significance. Dense breast tissue can make it harder to find cancer on a mammogram and may be associated with an increased risk of cancer. Dense Breast tissue in and of itself is a relatively common condition and is normal. 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 presense of dense breast tissue in addition to other risk factors.

Because of your breast density, secondary screening with MBI(Molecular Breast Imaging) is now being offered. To schedule please call (215) 456-3282.

For more information about secondary screening options, please visit www.becertain.info

Sincerely,

Einstein Healthcare Network
Department of Radiology
Division of Breast Imaging
Supplemental Breast Cancer Screening With Molecular Breast Imaging for Women With Dense Breast Tissue
Shermis. AJR 2016

• Retrospective study of clinical performance of molecular breast imaging as a supplementary screening tool for women with dense breasts.
• Women with dense breasts and negative mammography subsequently underwent screening with 300 MBq (8 mCi) 99mTc-sestamibi molecular breast imaging
Tomosynthesis scan of woman with dense breast tissue.

Molecular Breast Imaging (MBI) scan of same woman.
Supplemental Breast Cancer Screening With Molecular Breast Imaging for Women With Dense Breast Tissue
Shermis. AJR 2016

- Molecular breast imaging screening of 1,696 women
- Detection of 13 mammographically occult malignancies (11 invasive, 1 node positive).
- Incremental cancer detection rate was 8%.
- Recall rate was 8%.
- Biopsy rate was 4%.
- PPV for recall was 9%.
- PPV for biopsy was 19%.
Breast density laws.
Are you in compliance?
Contemporary OB/GYN 2016

Jay Goldberg, MD, MSCP, Sara Mirghani, MD, Sarah Woodman, MD

Einstein Medical Center Philadelphia
Conemporary OB/GYN
DECEMBER 2016
VOL. 91 NO. 12
Expert Advice for Today's Ob/Gyn For Doctors by Doctors ContemporaryOBGYN.net

BREAST DENSITY LAWS
ARE YOU IN COMPLIANCE?
Jay Goldberg, MD, MSCP, Sara Mirkhani, MD, & Sarah Woodman, MD

Care after sexual assault

Pessaries for preterm birth prevention?

TAKING SIDES
Delivery for intrahepatic cholestasis

LEGALLY SPEAKING
Asherman's after a cesarean

DR LOCKWOOD
President Trump and healthcare
Contemporary OB/GYN

DECEMBER 2016

VOL. 61 NO. 12

BREAST DENSITY LAWS
ARE YOU IN COMPLIANCE?

Jay Goldberg, MD, MSCP; Sara Mirhashi, MD, & Sarah Woodman, MD

Care after sexual assault

Pessaries for preterm birth prevention?

TAKING SIDES
Delivery for intrahepatic cholestasis

LEGALLY SPEAKING
Asherman’s after a cesarean

DR LOCKWOOD
President Trump and healthcare

DR LOCKWOOD
President Trump and healthcare
Provider Density Survey

• 79% unaware of the 4 density categories
• 68% unaware of Breast Density Notification Act
• 64% focus on “Impression/Recommendation” section of mammogram report
• 85% rely on radiology to determine if additional imaging is needed
Provider Density Survey

• When aware of increased density on a screening mammogram:
  – 60% take no action
  – 19% personally notify the woman
  – 21% personally notify the woman and discuss the option of additional breast imaging
- No action
- Personally notify the patient
- Personally notify the patient and offer additional imaging
Patient Density Survey

• 72% unaware of Breast Density Notification Act
• 40% would be anxious if notified of increased density
• 84% would request additional imaging if 100% covered by insurance
• 44% would pay out of pocket if not covered
• 88% believed PA law economically discriminates
Risk Management Interventions

• Providers education regarding the significance of increased breast density on mammography and the corresponding state law.

• Mammogram reports sent to ordering providers have been reformatted so that the breast density category is now more obvious, being listed in the “Impression/Recommendations” section.
Radiology result letters sent to patients now contain the following:

• “The American College of Obstetricians and Gynecologists has addressed increased breast density, noting that no research studies have demonstrated earlier cancer detection or improved prognosis when additional breast imaging is obtained. ACOG advocates against routinely recommending additional breast imaging in otherwise asymptomatic women with increased breast density on mammogram. Some patients, however, wish to discuss increased breast density further or are interested in obtaining additional breast imaging. If you also do, given the complexity of the issue, you should schedule a breast density consult with your provider.”
Further Areas of Confusion

• Is written notification from the radiologist or health care provider legally acceptable or must a discussion regarding breast density occur?

• If a woman’s breast density is not reported as significantly changed from year to year, are providers legally required to repeat a discussion regarding increased mammographic density and possibly offer additional imaging every time that a screening mammogram is performed?
Further Areas of Confusion

• What is the economic cost to insurers and women?

• Do the breast density notification laws actually lead to the earlier detection and treatment of more breast cancers, as well as improved survival?

• Do these laws lead to more unnecessary benign breast biopsies and at what emotional toll for the 50% of women being notified of their increased breast density?
Case 1

• A 49-year-old asymptomatic woman with a recent normal check-up, including a breast exam, obtained a referral for a screening bilateral mammogram from her PCP/GYN/NP/CNM/PA.

• The bilateral screening mammogram was performed.
• The patient later received a letter from the radiology center stating in bold at the top of the page “We wish to inform you that the results of your recent mammography examination are normal.”

• “Your mammographic breast density is considered dense. Dense breast tissue is a common finding and is not abnormal. A report of your results was sent to your physician.”
• The ordering provider received a mammography report:
  “BIRADS 1: Negative evaluation. Impression:
  1) No mammographic evidence of malignancy in either breast.
  2) A bilateral mammogram is recommended in one year.”

• Hidden within the report “The breast tissue is heterogenously dense.”
• The patient, believing that her “normal” mammogram required no additional action, did not contact the ordering physician for further discussion.

• No further action was taken by the ordering provider.
• One year later, after newly appearing microcalcifications were noted on her next screening mammogram, a biopsy found invasive ductal breast carcinoma.

• Unilateral mastectomy, axillary node dissection, chemotherapy, and radiation treatment for a Stage II breast cancer.
• Lawsuit: Provider negligently failed to comply with the state’s breast density notification act.

• The woman stated that she would have elected to undergo a breast MRI if offered due to her increased breast density.

• The Complaint alleged that a breast MRI would have led to earlier diagnosis and treatment of her breast cancer, as well as a greater likelihood of survival.
Case 2

• 45-year-old woman with no complaints has a normal GYN check-up including a normal breast examination

• A screening mammogram is ordered
• The patient later received a letter from the radiology center “We wish to inform you that the results of your recent mammography examination are normal.”

• “Your mammographic breast density is considered dense. Dense breast tissue is a common finding and is not abnormal. A report of your results was sent to your physician.”
• The provider’s report: “BIRADS 1: Negative evaluation.”
• “Impression: 1) No mammographic evidence of malignancy in either breast. and 2) A bilateral mammogram is recommended in one year.”
• Hidden within the report “The breast tissue is extremely dense.”
• The patient, believing that her "normal" mammogram required no additional action, did not contact the ordering physician for further discussion.
• Her provider, aware of the Breast Density Notification Act, searches through the screening mammogram report, noting increased density.

• The provider calls her, notifies her of her increased density, and offers additional breast imaging.

• The patient, previously believing her screening MXR was completely normal, is very confused.
• After 3 phone calls with her provider, the patient requests additional breast imaging.
• Her insurer declines coverage.
• Out of pocket costs:
  – $2400 breast MRI
  – $250 breast ultrasound
• The patient cannot afford the additional testing
• Significant anxiety
“C’mon, c’mon — it’s either one or the other.”
Breast Cancer Screening in Denmark: A Cohort Study of Tumor Size and Over-Diagnosis
Jorgensen. *Annals of Internal Medicine* 2017

- Effective breast cancer screening should detect early-stage cancer and prevent advanced disease.
- Objective: To assess the association between screening and the size of detected tumors and to estimate over-diagnosis (detection of tumors that would not become clinically relevant).
Breast Cancer Screening in Denmark: A Cohort Study of Tumor Size and Overdiagnosis
Jorgensen. *Annals of Internal Medicine* 2017

- Screening programs offering biennial mammography for women aged 50 to 69. Compared screened vs. nonscreened.
- Incidence of advanced (>20 mm) and nonadvanced (≤20 mm) breast cancer tumors in screened and nonscreened women.
- Screening was not associated with lower incidence of advanced tumors.
- Incidence of nonadvanced tumors increased in the screening vs. prescreening periods (1.49 [95% CI, 1.43 to 1.54]). Overdiagnosis rate of 24% [including DCIS] and 15% [excluding DCIS]).
- In women younger than the screening age, over-diagnosis rate of 48% [including DCIS] and 30% [excluding DCIS]).
Breast Cancer Screening in Denmark: A Cohort Study of Tumor Size and Overdiagnosis

Jorgensen. Annals of Internal Medicine 2017

• Conclusion: Breast cancer screening was not associated with a reduction in the incidence of advanced cancer. 1 in every 3 invasive tumors and cases of DCIS diagnosed in women offered screening represent over-diagnosis (incidence increase of 48%).
If Women controlled medicine

The Manogram
SUMMARY

• New mammography screening recommendations
• 4 categories of mammographic breast density
• Mammographic breast density laws are not evidence based
• Providers not complying with mammographic breast density laws may face medico-legal consequences
New Breast Exam Standard
Start at 50

Yeah, we know we said 40, but now it's 50...

Look what's supposed to happen next.