



Dear Medical Society Member,

The State of California Legislature has recently passed but not funded a law mandating that radiologists must report to the patient her breast density in the patient lay letter and that increased density could increase the patients risk for breast Cancer.

The Santa Barbara Breast Alliance is concerned that this report addition could cause anxiety among providers and patients and in turn precipitate calls for extra and, perhaps unnecessary, imaging procedures including mammograms, ultrasound and MRI of the breast.

The Alliance's breast imagers have prepared a white paper (see below) with an in depth explanations as well as multiple web sites that you and your patients can access to determine the patient's Life Time Risk (LTR) of breast cancer. The Alliance encourages you to use this information to determine your patients LTR which will assist you and your patient in shared decision making in regards to the appropriateness of additional screening.

Breast cancer screening is multidisciplinary. The Santa Barbara Breast Care Alliance encourages a continued multidisciplinary approach to breast health. Please feel free to contact us or encourage your patients to contact us via our breast care navigators at 805-897-0660 or by email to [navigator@ccsb.org](mailto:navigator@ccsb.org).

A handwritten signature in black ink, appearing to read "Ron Latimer".

Ronald G. Latimer, MD FACS,  
Chairman, Santa Barbara Breast Alliance



## Breast Density Notification

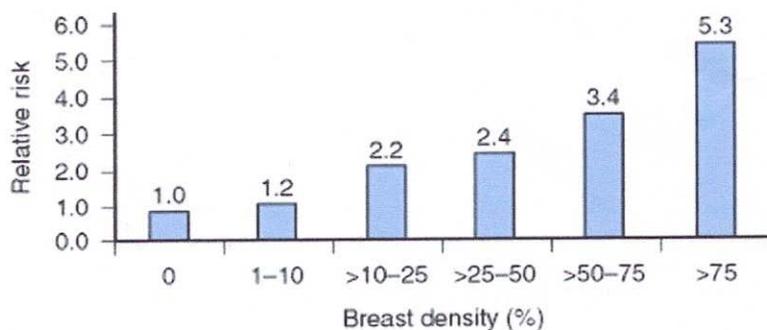
### The law

Connecticut was the first state in 2009 to enact breast density legislation. The first component mandates that the radiologist include breast density risk language in the lay report sent to women following a screening mammogram. The second component mandates that insurance companies provide coverage for screening breast ultrasounds in those women whose mammograms demonstrate dense breast tissue. Subsequent states to enact such legislation, including Texas, Virginia, New York and California, have not required insurers to cover supplemental screening. We recognize that this will create an additional barrier of access to the underinsured.

The language to be used in the lay summary will notify the woman of dense breast tissue, advise that she may benefit from supplementary screening such as ultrasound and MRI and recommend that she speak with her physician regarding her risk factors to determine if she is a suitable candidate for supplemental screening. The statute is not intended to create a cause for action or new standard of care in the context of litigation.

### The medicine behind it

It is intuitive that dense breast tissue can mask an underlying breast cancer, thereby increasing the inherent false negative rate of mammography. Literature also supports breast density as an independent risk factor for breast cancer.<sup>i ii</sup> The mechanism for density as an aspect for risk and how density fits into risk assessment remains unclear. Please also note in the figure below, that this is relative and not absolute risk.



**Figure 15-12** Risks of breast cancer with increasing breast density.  
(Adapted from Santen RJ and Mansel R: *Benign breast disorders*. *N Engl J Med* 355:279, 2005.)

Decades of epidemiologic data and several large population randomized control trials have validated mammography as the only screening modality to reduce breast cancer mortality.<sup>iii iv</sup> Other modalities of breast imaging, including MRI and ultrasound, have not had validation of screening benefit. However, it is becoming increasingly clear that mammography may be insufficient for screening in women at higher than average risk. In



2007, the American Cancer Society issued recommendations for supplemental screening with annual breast MRI for the highest risk population.<sup>v</sup> This population is defined by women who have a greater than 20% lifetime risk of developing breast cancer based largely on family history ascertained by BRCAPRO or other models that are based largely on family history.

Beyond the majority of average risk women and the minority of women at highest risk, there is a significant population at intermediate risk.

Mirroring the conclusions of the ACRIN 6666 trial in which nearly 3,000 women deemed intermediate risk on the basis of breast density and other risk factors were screened with supplemental ultrasound and MRI<sup>vi</sup>, the American Society of Breast Disease has provided an algorithm for supplemental screening (appendix A). The algorithm utilizes two elements for risk stratification. The first is based on lifetime risk, calculated by several software programs including Tyrer-Cuzik and Gail Model, which assess risk based on factors including family history, prolongation to estrogen therapy and prior breast biopsies. These software programs are available for download <http://www.ems-trials.org/riskevaluator/> or online <http://www.cancer.gov/bcrisktool/Default.asp>. The second element to risk stratification is based on mammographic breast density.

The radiologists in the Santa Barbara community will be utilizing the Gail Model as the risk assessment tool, at the time the woman presents to radiology for her mammogram. Please note that the Gail model does have limitations when applied to an individual patient and there are more predictive models available (e.g., IBIS Risk Tool). Unfortunately, those more predictive models are much more detailed and currently not compatible with the radiologists' PACS (picture archiving and communication system). It is anticipated that a more precise model will eventually be employed with PACS. In the meantime, patients who are flagged as high risk based on the Gail model should consider seeking genetic counseling to see if they are appropriate candidates for high risk screening MRI.

A proposed algorithm (see also diagram attached)

Women at average risk, less than 10% lifetime risk of breast cancer, regardless of breast density, remain with current recommendations of annual screening mammography starting at age 40.

Women with intermediate risk, 11-19% lifetime risk of breast cancer, are stratified according to mammographic breast density.

- fatty or average density (i.e., not dense) remain with current recommendations of annual screening mammography starting at age 40.
- heterogeneously dense or extremely dense (i.e., dense breast groups) offered supplemental screening with whole breast ultrasound in addition to annual mammography



Women at high risk, greater than 20% lifetime risk of breast cancer, should be considered for annual high risk screening breast MRI as well as genetic counseling for more in-depth risk calculation.

- fatty or average density (i.e., not dense) remain with current recommendations of annual screening mammography starting at age 40. Additionally, the patient may benefit from evaluation with one of the Breast Care Navigators or genetics counselor to determine if MRI should be performed based upon more in-depth predictive models.
- heterogeneously dense or extremely dense (i.e., dense) should be referred for supplemental screening with breast MRI, in addition to annual mammography.

#### Sources

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<sup>i</sup> Harvey, et al. Quantitative Assessment of Mammographic Breast Density: Relationship with Breast Cancer Risk. *Radiology*. 2004; 230: 29-41

<sup>ii</sup> Yaghjian, et al. Mammographic Breast Density and Subsequent Risk of Breast Cancer in Postmenopausal Women According to Tumor Characteristics. *JNCI J Natl Cancer Inst*. 2011;103 (15): 1179-1189.

<sup>iii</sup> Tabar, et al. Swedish Two-County Trial: Impact of Mammographic Screening on Breast Cancer Mortality during 3 Decades. *Radiology*. 2011; 260(3):658-63)

<sup>iv</sup> National Cancer Institute. Surveillance Epidemiology and End Results. Cancer statistics Breast. Available at: <http://seer.cancer.gov/statfacts/html/breast.html>. Accessed January 29, 2013

<sup>v</sup> Saslow, et al. American Cancer Society Guidelines for Breast Screening with MRI as an adjunct to Mammography. *CA Cancer J Clin*. 2007; 57:75-89

<sup>vi</sup> Berg, et al. Detection of breast cancer with addition of annual screening ultrasound or a single screening MRI to mammography in women with elevated breast cancer risk. *JAMA*. 2012; 307(13):1394-404