Radiology



# The California Breast Density Information Group: A Collaborative Response to the Issues of Breast Density, Breast Cancer Risk, and Breast Density Notification Legislation[1]

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In anticipation of breast density notification legislation in the state of California, which would require notification of women with heterogeneously and extremely dense breast tissue, a working group of breast imagers and breast cancer risk specialists was formed to provide a common response framework. The California Breast Density Information Group identified key elements and implications of the law, researching scientific evidence needed to develop a robust response. In particular, issues of risk associated with dense breast tissue, masking of cancers by dense tissue on mammograms, and the efficacy, benefits, and harms of supplementary screening tests were studied and consensus reached. National guidelines and peer-reviewed published literature were used to recommend that women with dense breast tissue at screening mammography follow supplemental screening guidelines based on breast cancer risk assessment. The goal of developing educational materials for referring clinicians and patients was reached with the construction of an easily accessible Web site that contains information about breast density, breast cancer risk assessment, and supplementary imaging. This multi-institutional, multidisciplinary approach may be useful for organizations to frame responses as similar legislation is passed across the United States.



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In 2009, Connecticut enacted a law mandating patient and referring physician notification when the pattern of fibroglandular tissue on a patient's mammogram was considered dense by the interpreting radiologist. Similar bills have since been proposed in many other states, nine of which have already passed into law. In California, mandatory reporting requirements took effect on April 1, 2013.

Radiologists are now faced with responding to both patients and referring physicians in trying to reconcile the legislative intent of density notification with realistic and practical practice patterns. In California, a working group of breast imagers and breast cancer risk specialists was formed soon after the passage of the law in an attempt to provide a common response framework. The California Breast Density Information Group (CBDIG) was composed of academic and community-based specialists and began a series of weekly conference calls aiming to produce accessible and valuable materials. We recognized that many institutions would also respond individually, based on local concerns, preferences, and available resources. The purpose of the coalition was to leverage the expertise of practitioners at multiple California institutions to develop an evidence-based consensus. This deliberative process could also provide a model that physicians in other states could use to develop their own response to pending or already enacted legislation.

The key issues involved in breast density notification involve *(a)* the relative risk of breast cancer associated with dense breasts, *(b)* masking of cancers by overlying breast tissue at mammography, and *(c)* the efficacy, benefits, and harms of supplementary screening tests. We sought to provide a balanced viewpoint on the available scientific data, independent of positions advanced by the manufacturing sector, radiology practices with existing scientific or financial investments in specific supplementary screening technology, and patient advocacy groups. Our goal was to construct an online resource of user-friendly, evidence-based information for patients, referring clinicians, and radiologists.

Our work led us to the development of a document suitable for Internet access, entitled "Frequently Asked Questions About Breast Density, Breast Cancer Risk, and the Breast Density Notification Law in California: A Consensus Document." We concluded that an online working document, although easily accessible and navigated, would also allow us to promptly update information as new scientific data become available. The document is available free online at *www.breastdensity.info* and included in Appendix E1 (online). The legislated notification statements are in Appendix E2 (online).

The remainder of this special report is a summary of our discussions, the issues practitioners are likely to encounter, and a brief review of the most pertinent literature that supports our frequently asked questions document.

## Advances in Knowledge

- Approximately 50% of women have breast tissue that is classified by the interpreting physician as either heterogeneously dense or extremely dense, translating into approximately 2 million women in the state of California receiving a density notification letter annually.
- Primary issues relating to breast density include the cancer risk imparted by dense tissue and the masking effect.
- For patients who are interested in additional screening options, a breast cancer risk assessment may be appropriate.

## CBDIG Position on Breast Density and Its Implications

Breast density is currently classified by the subjective visual assessment of the interpreting physician into one of four categories, as defined by the American College of Radiology's Breast Imaging Reporting and Data System (BI-RADS) (1) (Figure). Although new technologies provide quantitative density assessment, these are not part of common practice. On the basis of large-scale population-based data from a representative sample of mammography practices in the United States, the frequency distribution of the BI-RADS density categories is approximately as follows: almost entirely fatty, 10%; scattered areas of fibroglandular density, 40%; heterogeneously dense, 40%; and extremely dense, 10% (2). All women who fall into the heterogeneously dense and extremely dense categories—approximately 50% of women who undergo screening mammography—must be informed that they have dense breasts under the California law. Approximately 4 million screening mammography examinations are performed annually in California (3–6). Therefore, taking into consideration both screening and diagnostic mammographic examinations, more than 2 million women will receive a density notification letter each year in this state alone.

One important effect of increased breast density is a decrease in mammographic sensitivity (masking). It has been demonstrated that mammographic sensitivity is diminished in dense breasts (7–12). The magnitude of this decrease varies depending on patient age, the density categories that

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**Abbreviations:**
BI-RADS = Breast Imaging Reporting and Data System
CBDIG = California Breast Density Information Group
FDA = Food and Drug Administration
3D = three-dimensional

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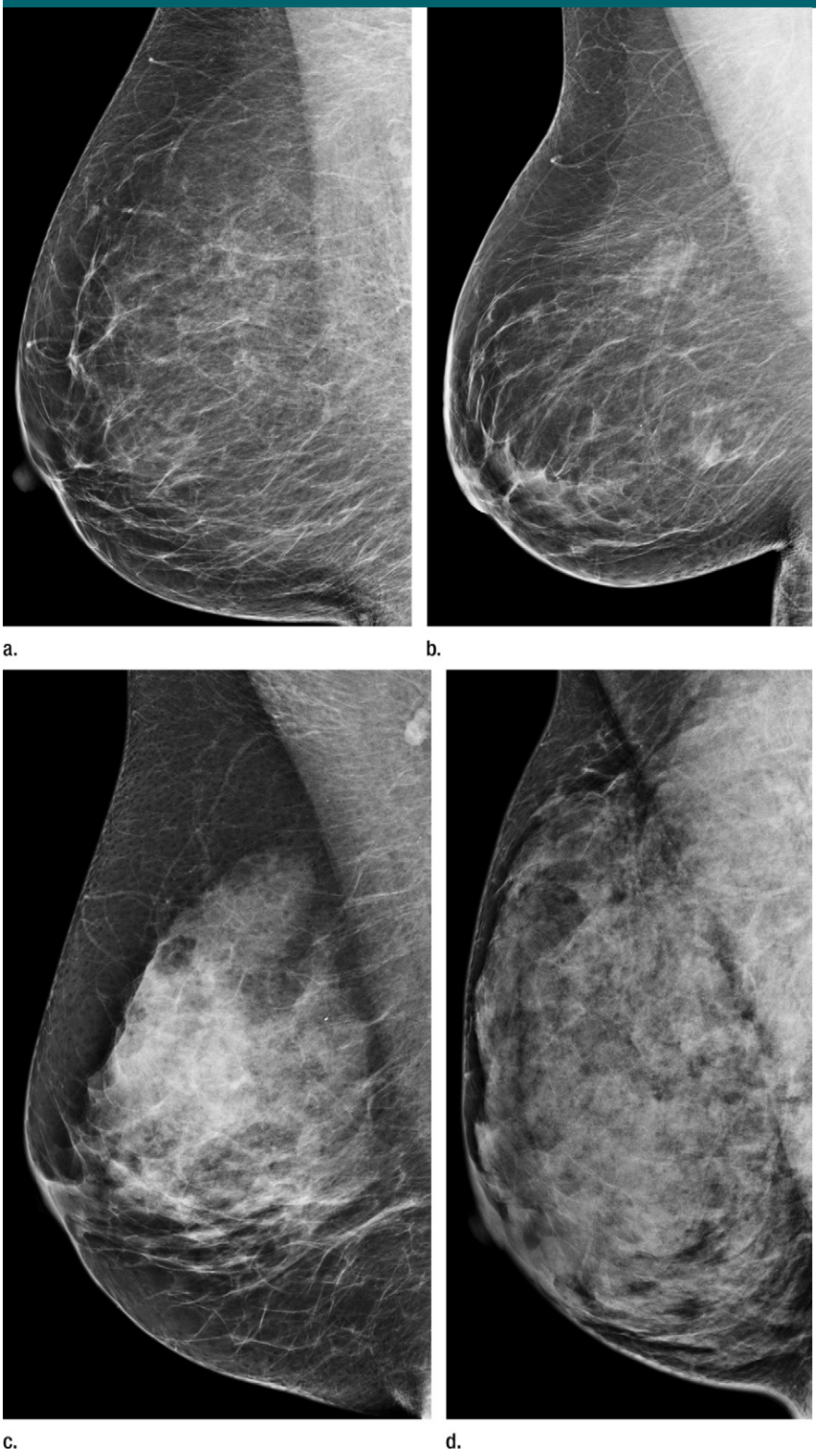
Conflicts of interest are listed at the end of this article.

See also the editorial by D'Orsi in this issue.




Mediolateral oblique mammographic views demonstrate the four BI-RADS breast density categories. **(a)** Almost entirely fatty. **(b)** Scattered fibroglandular density. **(c)** Heterogeneously dense, which may obscure detection of small masses. **(d)** Extremely dense, which lowers the sensitivity of mammography.

are compared (13,14), and the number of modalities used to identify a cancer (15,16). Population-based density data for more than 300 000 American women have demonstrated that, compared with women of "average" breast density (approximately halfway between scattered areas of fibroglandular density and heterogeneously dense [2], which represents the most clinically relevant approach), the reduction in sensitivity is approximately 7 percentage points for the 40% of women with heterogeneously dense breasts and approximately 13 percentage points for the 10% of women with extremely dense breasts (13). This reduction in mammographic sensitivity is a major contributor to the impetus for supplementary screening modalities.

An additional effect of increased mammographic breast density is an increase in breast cancer risk. The impact of density on breast cancer risk may be misinterpreted as overly important when reviewing studies that describe the risk by comparing the 10% of women with extremely dense breasts to the 10% of women with almost entirely fatty breasts (17–23). This is less meaningful to the overwhelming majority of women because the risk comparison is based on such a small population subset at the two extremes of the density spectrum. When risk is expressed relative to average breast density, the risk for the 40% of women with heterogeneously dense breasts is about 1.2 times greater than average and the risk for the 10% of women with extremely dense breasts is about 2.1 times greater (17). Therefore, breast density is a risk factor, but not a strong one. For example, the risk for a woman

with extremely dense breasts is similar to that for a woman with one first-degree relative with unilateral postmenopausal breast cancer. Furthermore, it makes little sense to consider half of the population undergoing screening mammography at high risk for breast cancer. Overall, CBDIG believes the masking effect of breast density is likely of greater import than the increase in breast cancer risk associated with density alone.

## CBDIG Position on Supplementary Screening Modalities and a Risk-based Approach

Mammography is the best single modality for population-based screening (24). It is the only modality proved to significantly reduce mortality from breast cancer in large randomized controlled trials (25–27). Those trials included women of all breast densities and were randomized independent of breast density. Thus, any supplementary screening should be obtained in addition to (not instead of) screening mammography, in accordance with nationally recognized guidelines (28–30).

Supplementary screening tests under consideration for widespread use include breast magnetic resonance (MR) imaging, screening breast ultrasonography (US), and tomosynthesis. In the general population, both US and, to a greater extent, MR imaging provide increased cancer detection over that with mammography alone (31). However, compared with mammography, screening US is associated with a much higher rate of benign biopsies (31–34) and both MR imaging and US result in a much higher rate of recommendation for short-interval follow-up (17,34,35). Although not as widely studied, tomosynthesis is currently being introduced into many radiology practices and preliminary data are encouraging. Population-based screening trials suggest that tomosynthesis may increase breast cancer detection similar to US (albeit not as much as MR imaging) and that tomosynthesis decreases the rate of false-positive findings, even below that seen in screening mammography (36,37). The radiation dose of the combined two-dimensional plus three-dimensional (3D) mammography examination (as is required for all tomosynthesis examinations) is approximately double that of two-dimensional mammography alone. However, this dose still falls below U.S. Food and Drug Administration (FDA) limits and dose reduction strategies are being actively developed. In particular, the use of synthesized two-dimensional mammographic images created from 3D data has received recent FDA approval, resulting in substantial dose reduction. Thus, the dose-related risk implications for women are considered acceptable.

The California breast density law seeks to promote discussion between women with dense breasts and their physicians regarding the advisability of supplemental screening. In making this decision, the benefit of early cancer detection versus the drawback of increased false-positive findings should be considered. The higher the cancer risk, the more likely there will be benefit from supplemental screening. The benefit-versus-drawback assessment will be more favorable for women who are at high risk on the basis of multiple factors than it will be for average-risk women who only have dense breasts. Thus, CBDIG recommends an individualized risk-based approach for guiding the decision-making process with regard to supplementary screening.

In agreement with the American Cancer Society and National Comprehensive Cancer Network, CBDIG supports the use of validated mathematic models to determine a patient's breast cancer risk (28,30). Proper use of these models requires that the health care provider be fully informed of their merits and weaknesses. Providers can perform a risk assessment or refer the patient to a specialized program. However, given the estimated millions of women who will receive density notification letters, the time demands for detailed risk assessment are likely to be unmanageable. Therefore, it may be valuable for clinicians to elicit "red flag" risk factors to rapidly triage patients. Most important are the known high-risk factors (eg, *BRCA* genetic mutation). Apart from these, the strongest risk factors for breast cancer are personal or family history (especially at least one first-degree relative with premenopausal breast or ovarian cancer) and personal history of atypia at previous biopsy. Although none of these risk factors, including dense breasts, individually place a woman in the high-risk category, they may identify those who would benefit from a more complete risk assessment.

For the small number of asymptomatic patients who are identified as high risk on the basis of complete risk assessment, supplementary screening is recommended. The American Cancer Society, American College of Radiology, and National Comprehensive Cancer Network recommend screening breast MR imaging annually in addition to yearly mammography for these patients (28,29,38). Although the California legislature did not mandate insurance coverage for any supplementary breast cancer screening tests, screening MR imaging is generally reimbursed for women who are at a lifetime risk of greater than 20%. Some studies have provided support for screening US for high-risk women, but only for those who have no access to or cannot undergo MR imaging (29,31). If a woman undergoes screening MR imaging, screening US will provide no additional benefit (39–43). In addition, many facilities either do not offer screening US or offer it with out-of-pocket charges to the patient.

For patients who are not at high risk, including women with no risk factors other than dense breasts, the pretest probability of breast cancer is low. Therefore, the benefit of supplementary screening is diminished, whereas the potential drawbacks remain the same.

Supplementary screening of the general population of women with heterogeneously dense and extremely dense breasts remains controversial. Among Connecticut women who received a density notification letter, three small studies have shown that screening US helped identify 3.2, 3.2, and 1.8 mammographically occult

cancers for every 1000 women undergoing prevalence (first-time) US screening (35,44,45). Most cancers found with screening US are invasive and at an early stage. This suggests a benefit to screening US. However, there are several major limitations to the currently available data. First, no studies were performed with control groups and no study has provided long-term follow-up. Thus, we do not know the clinical impact of finding these additional small cancers in an average-risk population—specifically whether the cancers would otherwise be detected at the next mammography screening examination while still small, node-negative, and at an early stage and whether there is any associated mortality reduction. A second limitation, as noted previously, is the higher false-positive biopsy rates for lesions identified at US compared with those identified at mammography. Third, no studies in this general patient population have reported outcomes for incidence (subsequent) screening US, although a reduction in the cancer detection rate would be expected (31). This is an important consideration because most breast cancer screening examinations involve incidence rather than prevalence screening. Finally, the outcomes for screening US will likely be more favorable in centers with a dedicated program. Although future large-scale studies will likely address a number of these concerns, they remain pertinent based on currently published literature.

## Summary

Breast density notification legislation is becoming increasingly prevalent. The impact of these laws is far reaching, and radiologists should take a proactive role in assessing the need for potential change in their practices and in translating currently available outcomes data into information for referring clinicians and patients that can be easily understood and accessed. In our era of patient-centered care and personalized medicine, breast density notification legislation provides an opportunity for radiologists to engage with referring clinicians and patients. Statewide collaborations like CBDIG can assist in developing broad-scope guidelines and educational materials, which may minimize the burden for individual breast imaging facilities. The multi-institutional, multidisciplinary CBDIG approach may be a method for organizations to frame responses to individual state laws as similar legislation is passed across the United States.

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