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The Divide Between Breast Density Notification Laws and Evidence-Based Guidelines for Breast Cancer Screening: Legislating Practice

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In 2003, Dr Nancy Cappello was stunned by her diagnosis of breast cancer just 6 weeks after normal findings on mammography.¹ She subsequently discovered medical literature documenting the lower sensitivity of mammography in women with dense breast tissue, as well as the association between greater breast density and increased cancer risk. Frustrated by the reluctance of her physicians to discuss the potential role of breast density in her diagnosis, Cappello pursued legislation in Connecticut, where she lived. The legislation was enacted, requiring insurers to cover breast ultrasonography as an adjunctive screening test to mammography for women with dense breast tissue and to notify women of their breast density results and the potential effect on the sensitivity of screening. As of April 2015, breast density notification laws had been enacted in 22 states and are advancing in an additional 13 states, and federal legislation has been introduced.² Modeling suggests that at least 28 million women in the United States between the ages of 40 and 74 years (43% of women in this age group) could be affected by such legislation.³

Breast density notification laws have the well-intentioned goals of improving individual decision making and the quality of breast cancer screening. However, there are few data that the laws actually improve the understanding of breast cancer risk, the limitations of mammography as a screening test, and the diagnosis or patient outcomes. Moreover, the laws create the unsubstantiated anticipation that additional testing is better for women. A recent survey found that Connecticut women were more likely than women from other states to have discussed their breast density with a clinician (67% vs 43%) despite similar knowledge of the effect of breast density on cancer risk.⁴ Women with extremely dense breast tissue have 2 times the relative risk of developing breast cancer than women with average breast density. However, the difference in absolute risk is small. The absolute 5-year risk of breast cancer for a 45-year-old woman with average breast density, no family history of breast cancer, and no history of prior breast biopsy is 0.7% and that of a similar

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woman with extremely dense breast tissue is 1.3%.⁵ Such laws also do not address other important risk factors for breast cancer such as age, family history of breast or ovarian cancer, *BRCA* (OMIM 113705 and 600185) and other genetic mutations, or prior breast biopsy. Breast density notification laws may limit a broader understanding and discussion of personal risk, as well as the benefits and harms of different screening approaches. For some women, other risk factors may be more relevant but not highlighted.

The legislation brings the probability of greater clinical uncertainty and increased liability for radiologists and primary care physicians, for whom failure to diagnose breast cancer is an important source of malpractice liability. For women, there are the likelihoods of false-positive results, unnecessary biopsies, and overdiagnosis that lead to the morbidity of unneeded treatment. Some states also require that a woman must be told that she may benefit from additional screening tests (eg, breast ultrasonography), and a few states (eg, Connecticut) mandate that insurance companies must cover additional testing for women with dense breast tissue. Such legislation goes beyond the evidence that supports additional testing for women who are at high risk for breast cancer on the basis of other established risk factors.⁶ Modeling suggests that supplemental ultrasonography after normal findings on screening mammography for women between the ages of 50 and 74 years with heterogeneously or extremely dense breast tissue may avert only 0.4 breast cancer deaths but result in 354 additional biopsy recommendations per 1000 women screened compared with biennial screening mammography alone, with a cost-effectiveness ratio of \$325 000 per quality-adjusted life-year gained.⁷ Women with lower breast density but with other risk factors for breast cancer may be falsely reassured that their low breast density confers some protection and may defer or postpone screening.

The laws raise additional issues. For example, interpretation of breast density is subjective. Wary of the additional complexity introduced by breast density legislation, radiologists may downgrade their assessment of density to avoid requirements for reporting, or they may upgrade their reporting so that supplemental screening can be ordered to minimize liability, thus limiting the validity of a breast density assessment. When pressed for time during office visits, primary care clinicians may reflexively order supplemental screening without assessing the benefits and harms or reaching informed decisions with their patients. The focus on breast cancer screening may divert attention from discussion of other health risks, such as risk factors for heart disease, which is the leading cause of death for women. Women who live in states where notification laws do not mandate insurance coverage may be responsible for paying for supplemental screening. Finally, a legislated approach to medical care is cumbersome as new evidence becomes available. Digital mammography and digital breast tomosynthesis, which creates a series of reconstructed images with a 3-dimensional format that minimizes the effect of overlapping and obscuring breast structures, are being broadly disseminated into clinical practice. Both technologies may be superior to the film mammography that was commonly used a decade ago, when the advocacy began for breast density notification laws.⁸ Overtime, advances in imaging, new screening modalities, and improved understanding of breast cancer risk related to density and other factors are likely to decrease the salience of this legislation.

The weaknesses of breast density notification laws are accentuated by the guidance from the US Preventive Services Task Force (USPSTF), which in April 2015 released for public comment a draft of updated recommendations for breast cancer screening.⁹ Specifically addressing the situation of women identified with dense breast tissue on an otherwise negative screening mammogram, the draft recommendations conclude that current evidence is insufficient to assess the balance of the benefits and harms of adjunctive screening with ultrasonography or magnetic resonance imaging. This draft further solidifies the task force's 2009 recommendations, particularly that the decision to start screening mammography in women before age 50 years should be individualized (grade C recommendation, which reflects an assessment that there is at least moderate certainty that the net benefit is small). The draft also reaffirms that the frequency of screening for average-risk women between the ages of 50 and 74 years should be biennial and not annual (grade B recommendation, which reflects an assessment that there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial).¹⁰

The Patient Care and Affordable Care Act requires that Medicare and other health plans must cover screening and preventive services in those with a USPSTF grade A or B recommendation, without patient cost sharing. Because of the controversy that surrounded the release of the task force's 2009 guidelines, the Patient Care and Affordable Care Act specified that the most current USPSTF recommendations for breast cancer screening other than those issued in 2009 would be considered the most current, therefore allowing insurance coverage of mammography for women between the ages of 40 and 49 years. When the final 2015 USPSTF recommendations are issued, the rules for coverage of breast cancer screening and other screening and preventive services may finally be the same. Between 2009 and 2015, little has changed in the USPSTF recommendations, reflecting the unfortunate reality that meaningful medical evidence often takes years to develop.

It is not surprising that patients and advocates are using legislation to address the limits of our knowledge about breast cancer screening. However, breast density notification laws are unlikely to improve our understanding of breast cancer risk, screening, and diagnosis or to save lives. Instead, the laws may result in substantial personal harms and societal costs. The 2015 update of the USPSTF recommendations provides an opportunity for states and the federal government to reconsider a legislative approach to breast cancer screening and to instead endorse care that is based on evidence.

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