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Breast-Density Legislation — Practical Considerations

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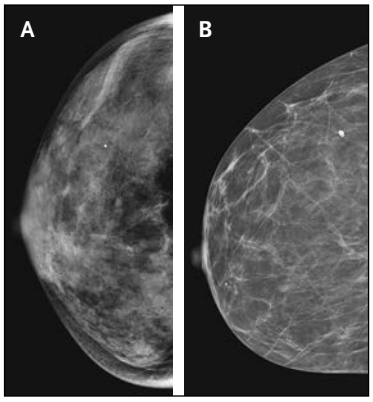
Ever since Nancy Cappello, a Connecticut woman who hadn't been told that her mammograms showed dense breast tissue, was diagnosed with stage 3 breast cancer in 2004 and advocated for a new state law, there's been a growing movement to educate women about breast density and the potential role of supplemental screening in early cancer detection. Cappello's state was the first to pass a law requiring physicians to offer supplemental whole-breast ultrasonography to women with dense breasts — defined as containing more than 50% fibroglandular tissue — and mandating that insurers cover the additional screening.

Since then, the number of breast-density laws in the United States has grown rapidly: as of January 2015, a total of 21 states had adopted such legislation. Laws vary considerably among states, with some requiring only that physicians notify women with dense breasts of their status and others stipulating that supplemental screening be offered to such women. Most state laws, however, do not mandate insurance coverage of additional screening, though the lack of such coverage could increase income-based health disparities.

In addition to legislation on the state level, the Breast Density and Mammography Reporting Act was introduced in Congress in October 2013. This legislation mandates that patients be sent a letter that not only informs them about their screening results but also includes information about their breast density and recommends supplemental screening for those with dense breasts.

The movement to inform women about their breast density has been driven primarily by grassroots organizations and laypeople. The medical community has been more cautious because the ability to detect breast cancer is affected by many factors beyond the limitations of screening mammography, and evidence supporting supplemental screening is lacking. First of all, dense breasts are normal and common; they are seen in approximately 40 to 50% of all women undergoing mammography (see figure). Since dense tissue can mask cancer, the sensitivity of film mammography is 62 to 68% in women with dense breast tissue, as compared with more than 85% in women with fatty breast tissue. Digital mammography, which has higher-contrast resolution and a better signal-to-noise ratio than film mammography, somewhat ameliorates the masking phenomenon, with sensitivity above 82% in women with dense breast



Mammographic Images of an Extremely Dense Breast (Panel A) and a Fatty Breast (Panel B).

tissue.[1] Nevertheless, assessment of breast density is subjective, since the radiologist estimates the amount of fibroglandular tissue visually.

A recent change in the radiologic reporting system will probably result in classification of an even greater percentage of women as having dense breast tissue, because instead of considering a woman's average breast density, the system will categorize any breast with a dense area as a dense breast. Given the subjective mode of assessment, it's quite possible that the same woman's breasts may be classified as dense one year and not dense the following year. Computer algorithms that calculate breast density are now available but have not been widely adopted. It's unclear whether these tools will facilitate more accurate determination of breast density. In reality, despite its limitations, mammography remains the only imaging method that has been shown to reduce the rate of death due to breast cancer — by 15 to 30%, according to multiple large, prospective, randomized, controlled studies.[2]

Proponents of supplemental screening argue that women with dense breast tissue are at increased risk for breast cancer. On the basis of available evidence, the breast-cancer risk in these women is believed to be 1.2 to 2.1 times that in women with average breast density. In comparison, the risk of breast cancer is doubled in a woman with a first-degree relative with breast cancer and increased by a factor of 8 in a woman known to carry a *BRCA1* or *BRCA2* mutation, regardless of breast density. Assessing a woman's risk for breast cancer is complicated, since there's no ideal model that considers all risk factors, and none of the available risk models include breast density. Currently, only women who are deemed to be at high risk — those with a lifetime breast-cancer risk of more than 20% — undergo supplemental screening with magnetic resonance imaging. Supplemental screening has been shown to be cost-effective in these women, with an additional 8.5 cancers identified per 1000 women screened.[3] There are no data to support this approach in women at average or intermediate risk for breast cancer.

There is currently little evidence to support widespread supplemental screening ultrasonography, although several state laws suggest offering whole-breast ultrasonography to all women with dense breasts or to some women at high risk for cancer. Automated ultrasound systems are now available and make implementation more feasible. Supplemental screening ultrasonography in women with dense breasts and above-average risk for breast cancer has resulted in the detection of an additional 3.2 cancers per 1000 women screened, but the benefit is probably lower among women with dense breasts and otherwise average risk. In addition, even among women with above-average risk, such screening has extremely high false positive rates; in several studies, only 6% of follow-up biopsies were positive,[3,4] which suggests that supplemental screening unnecessarily increases rates of biopsy, costs, and patients' anxiety. False positive rates are markedly lower for screening mammography, which detects 4 to 5 cancers per 1000 women and is associated with positive biopsy rates of 25 to 35%. The rates of callbacks and follow-up studies after supplemental screening ultrasonography also greatly surpass those for screening mammography. What's more, there are no long-term data showing reduced mortality among women who are screened with supplemental ultrasonography.

Given recent concerns raised by the U.S. Preventive Services Task Force about false positives and increased patient anxiety with routine mammography screening, it would be unwise to adopt supplemental ultrasound screening without careful consideration of the risks and benefits. In addition, there is growing concern about overdiagnosis and subsequent overtreatment of breast cancer related to the increased sensitivity of newer imaging techniques. It is well known that not all detected cancers — especially ductal carcinoma in situ — will become clinically significant during a woman's lifetime. There is a great need for tools that can differentiate between clinically significant and insignificant tumors, which remains a challenge.

Implementation of breast-density legislation has been inconsistent. In Connecticut, clinicians

variably refer patients with dense breasts for whole-breast ultrasound screening, with some practices referring 100% of such women and others referring none. Furthermore, only 45% of Connecticut women who were referred for follow-up ultrasonography actually received it.[5] Still, breast-density legislation provides an opportunity to strengthen patient–provider relationships by encouraging physicians to engage women in a conversation about the risks and benefits of screening, regardless of breast density.

In this era of cost containment, and given the limited data supporting screening ultrasonography, a rational and cost-effective approach to screening is needed. So how should the medical community address the growing concern over breast density and breast-cancer detection? It is critical that radiologists work with other specialists and primary care physicians to develop evidence-based recommendations regarding situations in which supplemental screening is advisable and which method is most efficacious. For example, some practices now use digital breast tomosynthesis, which leads to increased cancer detection while limiting the need for additional imaging in women with dense breast tissue, according to preliminary data.

An audio interview with Dr. Slanetz is available at NEJM.org

Having dense breast tissue does increase a woman's lifetime risk of breast cancer, but it's important for providers to place this risk in perspective for each patient. Risk stratification will be an essential tool in determining the best screening plan for each woman. It would be helpful if the medical community could reach a consensus on how best to advise women with dense breasts with regard to the limitations of various screening tests and the role of any supplemental screening. Then, practitioners could base patient care on existing evidence and each woman's individual risk. Such an approach might well maximize cancer detection and minimize the downsides of screening — especially false positives and the risks of overdiagnosis and overtreatment.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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Should We Practice What We Profess? Care near the End of Life

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Physicians should be in a better position than people without medical training to judge the likely value of health care services available near the end of life. Yet several studies have revealed a disconnect between the way physicians themselves wish to die and the way the patients they care for do in fact die.

A 1998 survey of participants in the Precursors Study, which enrolled 999 physicians who graduated from Johns Hopkins School of Medicine between 1948 and 1964, revealed that 70% had not had a conversation with their own personal physician about end-of-life care. But 64% had an advance directive that they'd discussed with their spouse or family, and more than 80% indicated that they would choose to receive pain medication but would refuse life-sustaining medical treatments at the end of life.[1] Similar preferences were expressed in a 2013 survey of 1147 younger academic physicians (a group that was more diverse and included more women): 88.3% indicated that they would forgo high-intensity end-of-life treatment.[2]

Although physicians ought not assume that their views about dying should apply to others, public surveys and research studies have shown that 80% of Americans, like the large majority