AJR FOCUS ON:

Breast Density Legislation: Mandatory Disclosure to Patients, Alternative Screening, Billing, Reimbursement

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OBJECTIVE. The purpose of this article is describe the origins and provisions of breast density legislation and to evaluate these mandates with regard to the balance between the potential benefit of supplementary screening and the substantial risk of false-positive findings and the adjunctive tests they necessitate.

CONCLUSION. Many states have passed breast density notification legislation, and federal legislation is pending. These mandates present a number of challenges for patients and physicians. There is no consensus regarding the need for supplementary testing solely because a woman has dense breasts. The failure of density legislation to require insurance coverage in many states further complicates implementation of the mandates.

Origins of Breast Density Legislation

In 2003, Nancy Cappello, PhD, received a diagnosis of stage IIIC breast cancer metastatic to 13 axillary lymph nodes. The cancer was detected at clinical examination within weeks of a normal screening mammogram. Surprised by her late-stage diagnosis because she had consistently undergone annual mammography, Cappello learned for the first time that she had extremely dense breast tissue, which masked her cancer at mammography. She recounted [1] that even though her physician and her radiologist knew she had dense breasts, she had not been given this information.

Cappello concluded that the cancer could have been diagnosed earlier had she been informed of her breast density and undergone additional screening with ultrasound. On learning from her doctors that it was not standard practice either to discuss breast density with their patients or to recommend supplementary screening, Cappello was determined to inform and educate other women with dense breasts. Formerly the chief of special education for the state of Connecticut, Cappello successfully lobbied her state senators to introduce legislation requiring insurance coverage for whole-breast ultrasound screening as an adjunct to mammography for women with dense breast tissue. The bill passed in 2005 [2]. In 2009, the first breast density notification law passed in Connecticut [3]. The law requires direct communication of the finding of dense breast tissue to the patient so that the patient herself can seek additional screening.

In 2008, Cappello founded a nonprofit organization, Are You Dense Advocacy, Inc., to advance the cause of breast density legislation in other states. Since then, 20 states in addition to Connecticut have enacted breast density notification laws: Alabama, Arizona, California, Hawaii, Illinois, Indiana, Maryland, Massachusetts, Minnesota, Nevada, North Carolina, Pennsylvania, New Jersey, New York, Oregon, Rhode Island, Tennessee, Texas, Utah, and Virginia.

A federal breast density notification bill, the Breast Density and Mammography Reporting Act of 2013, was introduced by Representatives Rosa DeLauro (D-CT) and Steve Israel (D-NY) in October 2013 [4]. Senators Dianne Feinstein (D-CA) and Kelly Ayotte (R-NH) introduced a companion bill in the Senate. However, federal legislation has not been enacted as of this writing [5].

The federal Mammography Quality and Standards Act (MQSA) regulates radiologist communication of mammographic findings and currently requires that a patient's breast density be reported to the referring clinician in the final written report [6]. The Food and Drug Administration is proposing to add a breast density reporting amendment to the MQSA that requires inclusion of a patient's dense tissue composition in the plain-language summary given to the patient.

Keywords: breast density, legislation, mammography

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Provisions of Breast Density Legislation

The exact provisions of breast density notification laws vary by state [7]. Most require that patients be informed if they have dense breast tissue. All require a statement indicating that mammography may be more limited in dense breasts. In most cases, the laws also require a statement that dense breasts are associated with increased cancer risk. Finally, in some cases, a statement regarding the possible need for additional testing is also required.

In most of the states in which legislation has been enacted, the radiologist or imaging facility bears primary responsibility for communication to patients. The required form of communication may be written or oral or is unspecified. In most states, legislation also requires that a report of a patient's mammogram be sent to the referring physician, already a requirement under MQSA, and further discussion between the patient and her physician is generally encouraged.

Although most states require notification regarding the possible need for supplementary screening, only five states—Connecticut, Illinois, Indiana, New Jersey, and Texas—have accompanying legal provisions for insurance coverage. Thus, in most states, breast density notification legislation remains an unfunded mandate.

Definition and Significance of Breast Density

Breast density is currently assigned by the interpreting radiologist's qualitative visual assessment into one of four categories defined in BI-RADS: a, almost entirely fatty; b, scattered areas of fibroglandular density; c, heterogeneously dense, which may obscure detection of small masses; and d, extremely dense, which lowers the sensitivity of mammography [8]. In the fourth edition of the BI-RADS atlas [9], these categories were also assigned percentage density ranges divided into quartiles. The fifth edition of the atlas [8] abandons quartile assessment and recommends that radiologists determine density on the basis of the potential of confluent dense tissue to mask breast cancer. Although various tools exist to provide quantitative estimates of breast density, these have not been widely incorporated into clinical practice, and none of these tools address the masking effect of dense tissue. Population-based data from a representative sample of mammography practices in the United States indicate the frequency distribution of the BI-RADS density categories is approximately as follows: fatty, 10%; scattered, 40%; heterogeneously dense, 40%; and extremely dense, 10% [8]. Breast density notification legislation would apply to all women who have heterogeneously and extremely dense breasts, which together constitute approximately 50% of all women undergoing screening in the United States.

The importance of breast density is twofold. First, dense tissue can mask existing cancers on mammograms, and second, the presence of dense tissue has been identified as an independent risk factor for the development of breast cancer. Of these two effects, the potential for dense breast tissue to mask cancer, thereby reducing mammographic sensitivity, is of greater concern [10].

Population-based data indicate that compared with women with average breast density (approximately halfway between scattered areas of fibroglandular density and heterogeneously dense), the reduction in mammographic sensitivity is approximately 7 percentage points for women with heterogeneously dense breasts and approximately 13 percentage points for women with extremely dense breasts [11]. This decrease in mammographic sensitivity underlies the call for supplementary screening of women with dense breasts. The importance of density as a risk factor for breast cancer tends to be overestimated in studies that compare women with the highest density to those with the lowest density, resulting in an estimated fourfold to sixfold difference in relative risk [12–17]. It is more meaningful to use average breast density as a reference point. The risk among women with heterogeneously dense breasts is approximately 1.2 times as great as average, and the risk for women with extremely dense breasts is approximately 2.1 times as great [18]. According to this more clinically relevant analysis, breast density is not a major risk factor. For example, the risk associated with extremely dense breasts is similar to that associated with having a first-degree relative with unilateral postmenopausal breast cancer [10].

Role of Mammography and Supplementary Screening Tools for Dense Breasts

In spite of its limitations in dense breasts, mammography is the only screening tool that has been found through large randomized controlled trials to reduce breast cancer mortality [19–21]. Because these trials included women with all breast densities, screening mammography remains the primary recommendation for all women, including those with dense breasts. Screening with other modalities should be considered only to supplement and not to replace mammography.

Candidate technologies for supplementary screening include breast MRI, screening whole-breast sonography, and digital breast tomosynthesis (DBT). In the American College of Radiology Imaging Network (ACRIN) 6666 multicenter prospective trial, 4.2 additional cancers per 1000 examinations were identified at prevalence screening with physician-performed handheld ultrasound (HHUS) that were not identified with mammography alone. In two subsequent incidence screening rounds, the average incremental cancer yield of HHUS was similar to that of the prevalence screen, 3.7 cancers per 1000 examinations [22, 23]. The ultrasound-detected cancers were predominantly invasive and early stage. By showing the potential for early invasive breast cancer detection in women with dense breasts through supplementary ultrasound screening, the ACRIN 6666 trial helped advocates to gain support for breast density notification legislation.

Women in the ACRIN trial were at elevated risk of breast cancer, more than one half having a personal history of breast cancer. Three small studies of HHUS were performed in the general population of Connecticut women after density legislation passed in that state. The results of these studies may better reflect screening outcomes among women at average risk. In these studies 1.8–3.2 mammographically occult cancers were identified for every 1000 women undergoing prevalence ultrasound screening [24–26]. As in the ACRIN 6666 trial, most of these cancers were invasive and early stage. However, in none of these trials was the incidence cancer detection rate reported. Furthermore, in the absence of randomized controlled trials of screening ultrasound, fundamental questions regarding lead time bias and mortality benefit remain unanswered.

A major drawback of HHUS is the high false-positive recall and biopsy rate, which has been found across all the screening studies. According to BI-RADS, 5th edition, auditing rules, the positive predictive value 1 (abnormal interpretation) and positive predictive value 3 (biopsy performed) for HHUS in a population at average risk are 1.3% and 6.5%, compared with 4–9% and 39.5% for mammography [27]. Thus, any potential benefit of screening HHUS must be carefully weighed against

the substantial risk of false-positive findings, which far exceeds that for mammography.

The literature on ultrasound screening is predominantly based on physician-performed examinations. The average performance time documented in the ACRIN 6666 trial was 19 minutes per examination [22]. Therefore, if widely used, physician-performed HHUS would likely adversely affect the radiologist workforce. Studies reveal a lower overall cancer detection rate (2.5 cancers per 1000 examinations) for technologist-performed HHUS than for physician-performed HHUS (4.3 cancers per 1000 examinations), although this result may in part reflect differences in the risk profiles of the patient populations studied [22, 24–26, 28, 29]. Technologist-performed HHUS suffers from a similarly low biopsy positive predictive value (5.8%) compared with physician-performed examinations (5.3%) [22, 24–26, 28, 29]. Having challenges similar to those for physician-performed ultrasound, technologist-performed ultrasound would also likely adversely affect the technologist workforce. Data on automated breast ultrasound are limited and preclude meaningful comparison with HHUS data.

MRI has not been well studied in populations at average risk. Among women at elevated risk, MRI depicts more cancers than does HHUS. In the ACRIN 6666 multicenter trial, the supplemental yield of HHUS was 3.7/1000 versus 14.7/1000 for MRI [23]. Thus, MRI is the superior screening modality for women at elevated risk. Furthermore, performing HHUS after MRI would be counterproductive because it would lead to more biopsies with false-positive results without any increase in cancer detection rate.

Although DBT has been less widely studied than ultrasound and MRI, population-based screening studies in Europe have shown that DBT may have higher breast cancer detection rates, similar to those of ultrasound (1.9–2.7 cancers per 1000 examinations). Like those detected with ultrasound, cancers detected with DBT are almost exclusively invasive and early stage. A major advantage of DBT compared with ultrasound is the simultaneous reduction in false-positive recall and biopsy rates when DBT is used in conjunction with conventional mammography, owing to its ability to resolve summation artifacts related to overlapping tissue [30, 31]. Similar outcomes have been found in several retrospective observational studies in the United States [32–35]. The Food and Drug Administration–approved synthesized 2D mammographic images created from 3D data address concerns about radiation dose. Additional studies are needed to determine the incremental benefit of DBT to women with dense breasts and to compare outcomes with ultrasound and MRI. Because tomosynthesis is performed with a digital mammography platform, it remains to be seen whether it will become part of the standard screening protocol rather than remaining a supplemental tool.

Problems and Challenges of Density Legislation

Although the forces behind breast density legislation may have been well intentioned, the benefit of these mandates remains uncertain. In addition, there are several potential harms. Women receiving information about their dense breasts may experience anxiety about their cancer risk and fear that mammography may have missed a breast cancer. Yet there is no consensus that supplementary screening is warranted simply because the breasts are dense. For most women with dense breasts who are at average risk, the potential benefits of supplementary screening must be carefully weighed against the substantial risk of false-positive findings.

Creating a demand for supplementary screening without addressing insurance coverage and reimbursement issues raises other problems. At present, there are no Current Procedural Terminology (CPT) codes for screening breast ultrasound. The American Medical Association CPT Editorial Panel approved category 1 CPT codes for tomosynthesis in February 2014, and these codes will be available for use by the 2015 CPT code cycle. However, the Centers for Medicare and Medical Services declared that tomosynthesis was considered an integral part of digital mammography and therefore could not be billed separately. Some centers have therefore elected to charge patients out-of-pocket fees for these tests. This has resulted in a disparity between women who can afford to pay for additional testing and those who cannot.

Conclusion

Twenty-one states have passed breast density notification legislation, and federal legislation is pending. These mandates raise a host of challenges for patients and physicians. There is no expert consensus on the need for supplementary screening of women solely because they have dense breasts [36]. Furthermore, most women with dense breasts are at average risk of development of breast cancer. As such, they must carefully weigh the potential benefit of supplementary screening against the substantial risk of false-positive findings and the associated adjunctive tests. The failure of breast density legislation to address insurance coverage and reimbursement issues further complicates the practical implementation of these mandates. Among women with dense breasts, mammography remains the primary recommended screening modality because it is the only modality proven to reduce breast cancer mortality in large randomized controlled trials. Additional screening tests should therefore supplement but not replace mammography.

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