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## The cart's before the horse: Breast density legislation

Ellen Shaw de Paredes, MD

**B**reast cancer deaths are significantly reduced through early detection with screening mammography. Unlike most other areas of radiology, and medicine, breast cancer screening is heavily legislated. The Mammography Quality Standards Act of 1996 and its subsequent revisions in 1998 and 2004 established minimum standards for mammography facilities, and this act requires accreditation, certification, and annual inspection of each facility.

Four states — Connecticut, Virginia, New York, and Texas — now have legislation mandating disclosure of breast density directly to the patient by the facility. Numerous other states and the federal government are considering similar legislation. In Virginia, the law states that the following statement be placed on the letter of results sent to a patient whose breasts are heterogeneously or extremely dense: “Your mammogram demonstrates that you may have dense breast tissue, which can hide cancer or other abnormalities. A report of your mammography results, which contains information about your breast density, has been sent to your referring physician’s office, and you should contact your physician if you have any questions or concerns about this report.”

I believe that patients should be informed and educated about health-related issues. Breast density is now considered an independent risk factor for the development of breast cancer. Breast density also has been known to be a cause of missed breast cancers because of obscuration of a mass by the radiopaque glandular tissue. Many women whose breasts are dense are not aware of that fact, nor are they aware of the associated risks of increased density.

How do we screen those women with dense breasts for breast cancer? Additional screening with breast magnetic resonance imaging (MRI) is recommended by the American Cancer Society for women who are at high risk, whether their breasts are dense or not, and as many as 14.7 additional cancers per 1000 women per year are found in this way. Screening ultrasound is also a tool that may be used for women with dense tissue and can detect 4 additional cancers per 1000 women per year over screening mammography alone. However, no formal recommendation exists yet for or against screening ultrasound in women with dense breasts. Along with the benefit of detection of additional mammographically occult cancers, comes the risk of a high number of false positives on screening ultrasound.

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The problem with the current legislative mandate in Virginia, and I suspect in other states, is that we are not well prepared for the consequences of the information given to the patients. Referring physicians may not be prepared to discuss breast density with their patients. Mammography facilities may not be prepared for performing screening ultrasounds based on available equipment, technologists, and radiologists. We have no CPT code for screening breast ultrasound. The code for breast ultrasound (76645), which has been used until recently for a targeted exam, is not really appropriate for a full screening of both breasts with ultrasound. The skill and time for performance and interpretation of a bilateral screening ultrasound is significantly greater than that of a targeted study and should be coded differently and reimbursed at a higher level. Most insurance companies do not yet recognize a screening breast ultrasound, and therefore the patient may be left to pay out of pocket for this study.

In Connecticut, legislation mandating coverage for screening breast ultrasound preceded the mandate regarding informing patients about breast den-

sity. This seems to be a far more logical order of events than the reverse, which is what we now face elsewhere.

Clinical trials to show the effect on breast cancer mortality by ultrasound screening of women with dense breasts would be ideal, but may not be feasible given the urgency of the situation. As clinicians, we need to act upon the information from ACRIN and other studies to help to inform our patients about the potential role of additional screening. We also need to be prepared to discuss the downside of screening ultrasound, which is additional false positive results. In our practice, we recommend screening MRI and mammography for women at high risk, screening ultrasound and mammography for women with dense breasts and intermediate risk, and screening mammography only for women at low risk with or without dense breasts. This seems logical, yet should we be prepared to offer screening ultrasound to all women with dense breasts? Since > 40% of our patients are in the dense breasts category, this measure does not seem feasible.

The question remains, who should be offered screening ultrasound? If

the answer is "any woman with dense breasts," we need to rapidly expand our expertise in this area with additional technologists certified in breast ultrasound and radiologists prepared to interpret these studies. Perhaps with the new automated breast ultrasound (ABUS) units available, we may have a more consistent method of performing screening ultrasounds and following nonsuspicious findings.

Hopefully, as this issue spreads nationwide, we will be able to track some of the key questions, such as:

- 1) To whom should we offer screening ultrasound?
- 2) What is the benefit of additional screening in women with dense breasts?
- 3) How do we code screening ultrasound?
- 4) Do third party carriers recognize the complexity of this procedure?

Until then we are attempting to deal with the deluge of questions from patients and clinicians about these perplexing issues, and we are trying our best to make appropriate screening recommendations based on risk and density.

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