

Recommended Talking Points for DENSE Legislative Initiatives

The American College of Radiology is supportive of patient empowerment and ensuring that all patients are provided with adequate information to make informed decisions about their medical care. However, the issue of breast density is a very complex and there is limited science to provide direction for patients, their primary care providers and breast imagers in what to do with information about density. The ACR believes that this is such a complex medical issue that it is not currently amenable to the development of governmental policy. Outlined below are some of the key points that we believe reinforce the ACR position not to support the Density Education National Survivor's Effort (DENSE) legislative proposal.

- There is significant observer variability in the assignment of a breast density category among radiologists. The categories are subjective and until a reliable, easily implemented method for objectively determining the amount of breast tissue is developed, the notification of breast density could lead to more confusion than clarification. For example, a woman could be assigned a “not dense” category 2 one year and a “dense” category 3 the next, even though the appearance of her breasts has not changed.
- Low Positive Predictive Value (PPV). PPV is the proportion of patients with positive test results who are diagnosed as having the disease. The Positive Predictive Value of abnormalities found on screening breast ultrasound from the American College of Radiology Imaging Network (ACRIN) trial that underwent biopsy was 8.8%. This is significantly lower than the PPV of 23.6% for screening mammography. This means that a substantial number of women will receive false positive results that will require additional work up. This means increased anxiety for these women as well as increased costs to the healthcare system.
- The ACRIN trial that is being used to justify screening breast ultrasound was done for high-risk women only. There are scant data available for average risk women.
- For high risk women there are several studies that show that breast MRI is superior to breast ultrasound for finding otherwise occult cancers.
- There is still debate within the scientific community as to the relationship between breast density and breast cancer risk. It seems that women with extremely dense breasts are at some increased risk compared to those with very fatty breasts but most women fall in between these two extremes. Furthermore, all women are at risk of developing breast cancer, regardless of their tissue patterns. Screening breast ultrasound has not been shown to be cost effective. It would lead to a very high “false positive” rate. In the one large blinded study of ultrasound screening, almost three times as many biopsies were recommended as a result of ultrasound screening as are recommended based on mammography screening.
- In all but one of the published studies concerning the use of screening ultrasound, the examinations were performed by the radiologist. There is not enough manpower to allow all women with dense breast to have a physician-performed screening ultrasound and we have little data that technologist-performed examinations will be as effective.
- In discussing direct patient notification of breast density with colleagues in Connecticut, who have been doing this for over a year now, it has been stated that women are, in general, confused and concerned about what exactly their breast density classification means and many of their health care providers are similarly uncertain.
- Notifying women directly of their breast density runs the risk of giving a false sense of security to women who are told their breast tissue is not dense.

The ACR Breast Imaging Reporting and Data System (BI-RADS®) recommends that all mammography reports to referring providers include a description of breast density. The patient's physician should use this information to discuss the appropriate options given her history and other circumstances.