Should Women Be Informed of Breast Density?

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Over the past 2 years, the breast advocacy group known as Are You Dense? has gained recognition through its quest to ensure that women with dense breast tissue have access to early breast cancer diagnosis. Their stated mission is to ensure that women are informed of their breast density, the limitations of mammography in detecting breast cancer in dense breast tissue, and the added risk that dense breast tissue confers to an individual woman. The organization advocates for and supports state and federal legislative actions requiring the communication of breast density information and access to reliable screening tools for women with dense breast tissue [1].

Although the goals of Are You Dense? are laudable and the ACR has stated that it supports an FDA mandate that breast density be included in mammography reports, Mammography Quality Standards Act regulations do not require that breast density be reported in either the mammography reports sent to referring physicians or the lay reports sent to women. Advocates claim that the primary benefit to women derived from receiving breast density information is a better understanding of cancer risk and the awareness that supplemental imaging be-
screening in the United States, the trade-offs between increased detection and less desirable outcomes will invoke controversy when new approaches to screening women with dense breast tissue are reviewed by organizations that recommend national health guidelines (for example, the US Preventive Services Task Force). Nonetheless, a strong sense of urgency and frustration is voiced by Are You Dense? advocates that national regulatory, medical, and scientific communities are responding too slowly to the mandate that women be informed of their breast density. The group’s legislative advocacy and lobbying efforts achieved new laws in Connecticut, Texas, and New York. Meanwhile, California, Kansas, Maine, Missouri, Nebraska, New Hampshire, Tennessee and Utah have endorsed patient notification bills, while Delaware, Michigan, Ohio and Oregon have pending legislation. Virginia requiring physicians to inform patients if they have dense breast tissue and discuss supplemental screening tests such as breast ultrasound or MRI. The bill enacted in Virginia contained the following language:

The guidelines shall also require all mammogram reports to include information on breast density. Such information shall inform patients with dense breast tissue, as determined by the physician, that supplementary screening tests may be beneficial, depending on individual risk factors.

With these enactments in place, it would behoove radiology organizations to review the experience in these states and evaluate their outcomes and effects. In addition, radiologists and other medical providers should prepare to do the following:

- Develop “best practices” for high-quality breast cancer screening paradigms of the future, including appropriate discussions and advice to women who may have questions or concerns about their breast density. The widespread availability of consumers’ access to their electronic medical records enables apt retrieval of a variety of medical information that was not readily accessible in the past; thus, breast density information will be available from a variety of sources. Health care systems and physicians should leverage this inevitability to better partner with consumers in health care decisions and strategies.
- Validate whether Breast Imaging Reporting and Data System® breast density determinations are the most accurate and reproducible that can be derived and provided to patients.
- Derive more concise estimations of the breast cancer risk attributable to parenchymal density so that informed discussions can be carried out between women and their medical providers regarding supplemental screening and risk reduction.
- Determine what appropriate additional screening examinations, if any, are appropriate for women with intermediate or moderate breast cancer risk, as is likely to be the case for a high percentage of women with moderate or extremely dense breast tissue. Currently, there are few data to support any screening guideline changes for this group until further analyses of available data are conducted to demonstrate the trade-offs between the advantages and disadvantage of additional testing.
- If supplemental ultrasound is a valid recommendation, the professional breast imaging community should standardize approaches to screening ultrasound, including appropriate training in the performance, interpretation, and reporting of such studies. Similar considerations would be needed for other modalities such as molecular breast imaging.

Finally, there are cost considerations and reimbursement concerns that will likely be raised by a number of different stakeholders. The cost of screening breast MRI is a drawback to its widespread use, and the cost of screening ultrasound is largely unknown. Currently, there is no Current Procedural Terminology® code for whole-breast screening ultrasound, digital breast tomosynthesis, or screening molecular breast imaging. Radiologists cite the additional time required to perform these examinations over their conventional counterparts as a disincentive to widespread adoption unless appropriate increases in reimbursement are provided.

In the near term, two outcomes can be predicted: (1) advocacy groups will continue their lobbying work with earnestness at the state level and nationally with the FDA, and (2) the scientific and professional breast imaging community will likely proceed with caution on this issue to arrive at effective, evidence-based imaging policies that appropriately balance the benefits and possible harms of new mandates regarding the widespread reporting of breast tissue density—which is rapidly becoming mandatory.

REFERENCES


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