Wisconsin Radiological Society

Wisconsin Medical Society

Breast Density Notification in Wisconsin

On April 3, 2018, Wisconsin Governor Scott Walker signed the state's Breast Density Notification Law, 2017 Wisconsin Act 201 (Assembly Bill 653). The law requires facilities that perform mammograms to notify women categorized as having heterogeneously dense or extremely dense breast tissue about their condition.

Frequently Asked Questions About Breast Density and the Notification Law

How is this different from the past?

Radiologists have routinely reported the breast density in the image interpretation, which is in the report sent to the patient's provider. According to the new law, women with dense breasts will be informed regarding their breast density as part of the standard lay letter that women receive after a screening mammogram.

What categories of women need to be informed of breast density under this new law?

Those with heterogeneously dense and extremely dense breasts (BI-RADS density categories C and D) as seen on the mammogram.

Is this unique to Wisconsin?

No. Wisconsin is the 35th state to pass legislation regarding breast density. Connecticut was the first in 2009.

What should the notification text include?

The notification to patients should be substantially similar to the language that is in the bill:

> *Your mammogram shows that your breast tissue is dense. Dense breast tissue is found in almost 40 percent of women and is a normal finding. However, studies show that dense breast tissue can make it harder to find cancer on a mammogram and is associated with a slightly increased risk of breast cancer. Regular screening mammograms are still recommended for you. This information is provided to raise your awareness about the result of your mammogram. You can use this information to talk with your health care professional about your own risks for breast cancer. Together, you can decide which screening options are right for you. The results of your mammogram were sent to your doctor. Please note that breast density is affected by several factors and may change over time.*

What are the clinical implications of increased mammographic breast density?

There are two primary implications of mammographic breast density. One implication is the effect on mammographic sensitivity (i.e., the test's ability to identify a clinically occult malignancy). This concept is known as masking. The second implication is the increase in breast cancer risk imparted by dense breasts.

How much does the cancer risk change with breast density?

In women with extremely dense breasts (~10% of the population) the relative risk is a 2-fold increase and in women with heterogeneously dense breasts (~40% of the population) it is a 1.2-fold increase.

Should my patients who receive this letter continue to get mammograms?

Yes. Mammography is the only screening tool that has been demonstrated through large randomized trials to lower breast cancer mortality. Those trials included all breast densities. While mammography's sensitivity is somewhat lower in women with extremely dense breasts, it is still the best modality for population-based screening. Also, mammography is the only test that can reliably detect suspicious calcifications. Such calcifications are often the first sign of in-situ cancers, which in 20 percent of cases, coexist with otherwise invisible invasive cancers.

I have a patient with dense breasts who desires supplemental screening. She is not at very high breast cancer risk and/or has no major risk factors. What should I recommend?

Digital breast tomosynthesis (DBT), screening MRI, and whole breast screening ultrasound (WBUS) are the most common supplemental screening options. There is insufficient evidence to favor one over the others at this point and not enough evidence to define if there is any long-term benefit. As with any screening test, there are potential harms, including false-positive exams and cost. Whichever supplemental screening test is being considered, it is important to keep in mind that for patients who are not high risk, the a priori probability of breast cancer is low. Therefore, the benefit of additional screening is diminished, whereas the potential harms remain the same.

Digital breast tomosynthesis (DBT) has been shown by many research studies to improve the results of mammography when compared to standard 2D digital mammography. DBT reduces the recall rate (false positives) by up to 40 percent. The cancer detection rate is improved by 20 percent to 40 percent. DBT is available at many breast imaging facilities. Positioning and breast compression are identical to the standard digital mammogram and DBT adds just a few seconds on to the exam time of a standard digital mammogram.

Investigation of screening MRI in average-risk women is ongoing. There is currently no data to support its use in an average-risk population. However, if a patient expresses a desire to be screened with MRI, then a full risk assessment would be helpful. Even if a patient does not have strong risk factors for breast cancer, there are a number of minor risk factors, including breast density, which together may raise her to intermediate risk (15% to 20% lifetime risk). The American Cancer Society states that for intermediate risk women, the decision to have a screening MRI should be made on a case-by-case basis using a shared decision-making approach.

The data on screening ultrasound is limited at this point. The results of studies are variable based on whether the exam was performed with automated whole breast ultrasound or hand-held ultrasound.

Supplemental ultrasound adds substantially to the cancer yield in some studies. The majority of cancers found on ultrasound are smaller than 1 cm and are invasive. However, there are two major drawbacks to the currently available data. The first is that no studies have been performed with control groups and long-term follow-up. We do not know what the clinical impact of finding these additional small cancers is—specifically whether the cancers would otherwise be detected at the next mammography screen while still small, node-negative, and at early stage, and whether there is any impact on mortality. The second drawback is that many more biopsies are generated by screening ultrasound than screening mammography, and most of these additional biopsy recommendations ultimately end up being false positives. The positive biopsy rate for lesions detected on screening mammography is 25 percent to 40 percent, while the positive biopsy rate for lesions found on screening ultrasound is 5 percent to 10 percent. This means that 90 percent to 95 percent of biopsies initiated by the screening ultrasound in women with negative mammograms end up showing no cancer. Due to these concerns, there is no formal recommendation from the radiology community at this point regarding screening ultrasound.

Screening Test	ICDR	Positive Predictive Value	Sensitivity	Specificity	Pros	Cons
DBT	2.7/1000	24	89%	69%	Available in many breast imaging facilities in Wisconsin Reduces call-backs	Radiation (if using DBT with a synthesized mammogram, radiation is equivalent to a 2D mammogram) Variable insurance coverage
WBUS	2 – 3/1000	11	67% – 83%	90%	Hand-held WBUS is widely available No radiation	Automated WBUS has very limited availability in Wisconsin in 2018 Low specificity (++ false positives) Variable insurance coverage
MRI	8 – 18.2/1000	50	91%	97%	Most sensitive No radiation	Variable insurance coverage Gadolinium contrast needed

Abbreviations: ICDR, incremental cancer detection rate; DBT, digital breast tomosynthesis; WBUS, whole breast ultrasound; MRI, magnetic resonance imaging.

Are any supplemental screening tests recommended by radiologists for high-risk women?

In high-risk women, supplemental screening tests are recommended in addition to mammography. Studies support the use of annual screening MRI in women who are known to have a very high-risk (>20% lifetime or >5% 10-year) of breast cancer, regardless of their breast density. This examination is widely recommended by radiologists.

Approximately 50 percent of women who have a screening mammogram will be receiving letters including a statement suggesting consideration of other screening options. It is impossible for me to do a risk assessment on all of them. What do you suggest?

If a woman requests supplemental breast screening, it may be possible to rapidly triage the need for a risk assessment. The strongest risk factors for breast cancer, other than age and sex, are a personal or family history (especially a first degree relative with premenopausal breast or ovarian cancer), and a personal history of atypia on prior biopsy (atypical ductal hyperplasia [ADH], atypical lobular hyperplasia [ALH], lobular carcinoma in situ [LCIS]). Individually, these risks do not place a woman in the very high-risk category, but they do identify those who would likely benefit from a full risk assessment, using mathematical models such as Claus, BRCAPRO, Tyrer-Cuzick (IBIS Breast Cancer Risk Evaluation Tool), BOADICEA and others. The process of risk assessment is a very detailed process, and having a good understanding of the variables included in each of the freely available calculators is important. For some women, formal risk assessment with a genetic counselor may be the best option.

If your health care system does not have a risk assessment model built in to the electronic health record, some free online options include:

- Tyrer-Cuzick Model: http://ibis.ikonopedia.com
- Gail Risk Model: https://www.cancer.gov/bcrisktool/
- Bright Pink, Breast and Ovarian Health Organization: https://www.brightpink.org (patient-facing risk calculator)

If a woman is at very high risk (>20% lifetime or >5% 10-year), screening MRI is the appropriate supplemental screening tool. For patients who have had mantle radiation therapy at age <30, or who have previously tested positive for the BRCA1 or BRCA2 gene mutations or other genetic syndromes, screening breast MRI is recommended annually in addition to mammography. Of note, gene mutation testing is not a requirement to be considered an appropriate candidate for MRI screening. If a woman tests negative for BRCA gene mutation but has strong family history, she may still need MRI screening.

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