

Breast Density Notification Law Requires New Patients Notifications

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Wisconsin's new Breast Density Notification Law, 2017 Wisconsin Act 201 (Assembly Bill 653), requires facilities that perform mammograms to notify women categorized as having heterogeneously dense or extremely dense breast tissue (BI-RADS density categories C and D) about their condition.

Signed in April, the law makes Wisconsin the 35th state to pass breast density legislation. Representative Mike Rohrkaste authored the bill at the request of a constituent who was diagnosed with advanced breast cancer after dense tissue masked the tumor on her mammogram.

Facilities that perform mammograms are now required to include language that is substantially similar to the following sample language in, or along with, their required patient results letters:

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 recom-

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mended 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.

Patients who receive these notices most likely will seek guidance and ask questions, eg, whether any supplemental screening is recommended. There is currently insufficient evidence to support the routine use of additional screening tests beyond mammography in women whose only risk factor is dense breast tissue. However, for patients who have dense breast tissue, it may be useful to conduct a risk assessment to determine if additional screening is recommended. Many health systems' electronic medical records have a built-in assessment tool, or there are several online screening tools, including the following:

- Tyrer-Cuzick model, version 8 (includes breast density): <http://ibis.ikonopedia.com>
- Bright Pink: <https://www.brightpink.org>
- Gail risk model: <https://www.cancer.gov/bcrisktool/>

To further assist clinicians and their patients, the Wisconsin Radiological Society, with support from the Wisconsin Medical Society, has developed a set of FAQs and compiled a number of resources (Boxes 1 and 2). One particularly useful tool for physicians may be clinical scenarios, which address a variety of patient situations and the recommended actions in flow chart format.

While these resources are hopefully useful in assisting clinicians and patients in understanding the new law and notifications, each situation is unique and will require assessment as well as individual patient and physician discussion to determine the correct course of action.

Box 1. Patient Resources

- ACR Breast Density brochure: https://www.acr.org/-/media/ACR/Files/Breast-Imaging-Resources/Breast-Density-bro_ACR_SBI.pdf
- Website: <https://www.areyoudense.org>
- Mayo consumer site: <https://www.mayoclinic.org/tests-procedures/mammogram/in-depth/dense-breast-tissue/art-20123968>
- Website: <http://densebreast-info.org>

Abbreviation: ACR, American College of Radiology.

Box 2. Clinician Resources

- Clinical Scenarios: https://www.wisconsinmedicalsociety.org/_WMS/publications/wmj/pdf/117/2/Breast_density_scenarios-2018.pdf
- Frequently Asked Questions: https://www.wisconsinmedicalsociety.org/_WMS/publications/wmj/pdf/117/2/Breast_density_FAQs.pdf
- ACR position Statement on Breast Density: <https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Reporting-Breast-Density>
- ACR Position Statement on Higher-risk Women: <https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Breast-Cancer-Screening-in-Women-at-Higher-Than-Average-Risk>
- Supplemental Screening for Breast Cancer in Women with Dense Breasts: A Systematic Review for the U.S. Preventive Services Task Force: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5100826/pdf/nihms826317.pdf>

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Breast Density, Breast Cancer Risk and Wisconsin
Breast Density Notification Law (2017 Wisconsin Act 201)

Scenarios for Clinicians

Content adapted from the California Breast Density Information Group, March 2013



Scenario 1

My patient received the letter stating she has dense breasts.
Now she is wondering whether she should continue to get mammograms at all.



She should continue to get screening mammograms. The breast density law does not reflect any change in the current mammography screening recommendations by professional medical societies.

Mammograms have been shown to be effective in lowering breast cancer mortality for all breast densities. Mammography is the only screening modality that has undergone randomized controlled trials demonstrating a reduction in breast cancer mortality. There is no recommendation that it be replaced with another test in any subset of the population.

Scenario 2

My patient received the new breast density letter.
She is concerned because she now thinks she is at high risk for breast cancer.



Reassure the patient that breast density alone has only a small impact on breast cancer risk.



She wants to know specifically how it changes her risk.



Refer to her mammogram report (different from the patient letter).

1. If her density is BI-RADS category C: Heterogeneously dense, this is associated with a minimal risk above average (RR=1.2 compared to average breast density).
2. If her density is BI-RADS category D: Extremely dense, this double her risk of breast cancer compared to a woman with average density breasts and is has a relative risk of 4-6 compared to women with BI-RADS category A: almost entirely fat. This is a risk similar to having two first degree relatives with breast cancer.

Scenario 3

My patient received the new breast density letter.
She wants to be screened with another modality instead of mammograms.



Explain that at this point in time, there is **no** other method that is recommended to replace the mammogram. There are certain manifestations of cancer (for example, calcifications) that are only seen on mammography. The other “screening options” referred to in the letter are in addition to, and not instead of, a routine screening mammogram.

Scenario 4

My patient has “heterogeneously dense” or “extremely dense” breasts and she also has other risk factors. She has completed a risk assessment showing her overall risk to be high (e.g., calculated >20% lifetime risk or >5% 10-year risk), or has a BRCA mutation or history of mantle radiation.



Recommend annual breast MRI and annual mammogram for screening.
Screening breast MRI is typically covered by insurance for high-risk women.
If a woman is being screened annually with MRI and mammogram,
no additional screening tests (such as ultrasound) are needed.

Scenario 5

My patient has “heterogeneously dense” or “extremely dense” breasts and she also has other risk factors. She has completed a risk assessment showing her overall risk to be high (e.g., calculated >20% lifetime risk or >5% 10-year risk).



MRI was recommended but the patient is unable or unwilling to have the exam.



Recommend screening ultrasound as the second-best supplementary screening test for high-risk women. Studies have shown some utility for ultrasound in high-risk women if screening MRI is not performed.

Scenario 6

My patient received the new breast density letter. She wants to get additional tests to be screened for breast cancer.



Does she have a first degree relative (mother, sister, daughter) who had premenopausal breast or ovarian cancer, or a male relative with breast cancer?

or

Does she have a history of atypia (ADH, ALH) or LCIS on a previous breast biopsy?

YES



She would likely benefit from a breast cancer risk assessment.

This could be performed by a physician with experience in breast cancer risk model selection and interpretation, or by a cancer risk assessment program.

NO



If the patient does not have other breast cancer risk factors, **reassure** her that her risk remains low. **Educate** the patient about the risks and benefits of screening MRI and ultrasound (higher cancer detection, but also higher false positive biopsy rates and short-term follow-up recommendations). Many health centers have chosen not to offer screening breast ultrasound, in part because ultrasound depicts many fewer mammographically invisible cancers than does screening MRI.

If available, digital breast tomosynthesis (DBT) is a screening test with increased cancer detection and decreased false positives compared to 2D traditional mammography. However, DBT, breast ultrasound, and screening MRI all have variable insurance coverage based on the patient's risk and insurance plan. Assist the patient in making the best personal choice for her needs based on these factors.

Editor's Note: This content was adapted from California Breast Density Information Group (DBDIG). Breast Density, Breast Cancer Risk, and California Breast Density Notification Law SB 1538: Scenarios for Clinicians. March 2013. <http://www.breastdensity.info/docs/DENSITY-SCENARIOS-FOR-CLINICIANS.pdf>. Accessed May 26, 2018.

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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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